Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Effects of Cervical Stabilization Exercises Alone and in Combination with Ocular Exercises on Neck Pain, Function, and Quality of Life in Individuals with Cervicogenic Headache and Migraine Associated with Forward Head Posture

Protocol summary

Study aim

Determining the Effects of Six Weeks of Cervical Stabilization Exercises and Ocular Exercises on Neck Pain, Function, and Quality of Life in Individuals with Cervicogenic Headache and Migraine Associated with Forward Head Posture

Design

This is a randomized controlled clinical trial with two parallel groups and 60 participants. Participants will be randomly allocated to the control and intervention groups using block randomization. The random allocation sequence will be generated using the RAND function in Microsoft Excel, with a 1:1 allocation ratio.

Settings and conduct

This randomized trial will include 60 women recruited from Sina Hospital. Participants will be randomly assigned to two groups. Both groups will perform cervical stabilization exercises for six weeks; the intervention group will also perform ocular exercises. Outcomes will be assessed before and after treatment by a blinded assessor.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 18–65 with cervicogenic headache, migraine, FHP (CVA ≤53°), recent headache, and NDI 5–24. Exclusion criteria: Neck trauma/surgery, visual, vestibular or middle ear disorders, surgical cervical conditions, or medical/psychiatric conditions affecting participation.

Intervention groups

Control group: Cervical stabilization exercises, 30 minutes, three times weekly for six weeks. Intervention group: The same exercises plus ocular exercises, 20 minutes per session, three times weekly for six weeks. Both groups will continue prescribed migraine medication and record headache symptoms, medication use, and exercise adherence. Telephone follow-up will occur biweekly. Other non-pharmacological treatments are prohibited.

Main outcome variables

Neck pain (VAS); Neck disability (NDI); Quality of life (SF-36); Headache impact (HIT-6)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261011071378N1**
Registration date: **2026-10-27, 1405/08/05**
Registration timing: **prospective**

Last update: **2026-10-27, 1405/08/05**
Update count: **0**

Registration date

2026-10-27, 1405/08/05

Registrant information

Name
Shiva Ahmadi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 6653 6490
Email address
sh.ahmadi1219@gmail.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2027-04-21, 1406/02/01

Expected recruitment end date
2027-12-21, 1406/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effects of Cervical Stabilization Exercises Alone and in Combination with Ocular Exercises on Neck Pain, Function, and Quality of Life in Individuals with Cervicogenic Headache and Migraine Associated with Forward Head Posture

Public title
Comparing the Effects of Neck Exercises and Eye Exercises on Neck Pain, Function, and Quality of Life in People with Headache and Migraine Associated with Forward Head Posture
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 18–65 years diagnosed with cervicogenic headache–migraine according to the International Classification of Headache Disorders, 3rd edition (ICHD-3) Presence of forward head posture (FHP), defined as a craniovertebral angle (CVA) of ≤ 53° Experience of headache within the previous 6 weeks Neck Disability Index (NDI) score between 5 and 24 Willingness to participate in the study and adhere to the prescribed exercise program No history of neck trauma No history of neck surgery No visual disorders, history of retinal surgery, or elevated intraocular pressure No middle ear disorders or balance disorders, such as Ménière's disease No cervical orthopedic conditions requiring surgical intervention No mental disorders.
Exclusion criteria:
Diagnosis of other types of primary headache, including tension-type headache, cluster headache, exertional headache, and medication-overuse headache. Secondary headaches due to other causes, such as temporal arteritis, trigeminal neuralgia, or brain tumors. Receiving any other non-pharmacological interventions (e.g., physiotherapy, acupuncture, or massage therapy) during the study period. Pregnancy or breastfeeding. Changes in pharmacological treatment or initiation of new medications during the study period.
Age
From **18 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly allocated at the individual level to either the control group or the intervention group using block randomization to maintain a balanced number of participants in both groups. The random allocation sequence will be generated using statistical software. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes prepared by an independent researcher who is not involved in participant recruitment or outcome assessment. The group assignment will be revealed after participant enrollment and completion of baseline assessments.
Blinding (investigator's opinion)
Single blinded
Blinding description
The outcome assessor will be blinded to participants' group allocation to minimize potential assessment bias. Due to the nature of the interventions, participants and the treating therapist cannot be blinded to group allocation. The outcome assessor will not be involved in treatment delivery and will not have access to information regarding group assignments. The principal investigator and data analyst will be blinded to group allocation only if this can be ensured in practice. All participants will be informed about the study procedures and will provide informed consent before participation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Tehran University of Medical Sciences ,Sina Hospital
Street address
Bagher Khan St., corner of Farzin St., Tehran
City
Tehran
Province
Tehran
Postal code
1441633963
Approval date
2026-05-23, 1405/03/02
Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1405.031

Health conditions studied

1

Description of health condition studied
Cervicogenic Headache and Migraine Associated with Forward Head Posture
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Neck pain intensity score
Timepoint
At baseline, before the intervention, and after 6 weeks of intervention.
Method of measurement
Using the Visual Analogue Scale for pain, ranging from 0 (no pain) to 10 (worst pain).

2

Description
Neck Disability Index score
Timepoint
At baseline, before the intervention, and after 6 weeks of intervention.
Method of measurement
Using the Neck Disability Index, a 10-item questionnaire with a total score ranging from 0 to 50; higher scores indicate greater disability.

3

Description
Headache impact score
Timepoint
At baseline, before the intervention, and after 6 weeks of intervention.
Method of measurement
Using the Headache Impact Test, a 6-item questionnaire assessing the impact of headache on daily functioning and activities; higher scores indicate a greater impact.

4

Description
Health-related quality of life score
Timepoint
At baseline, before the intervention, and after 6 weeks of intervention.
Method of measurement
Using the 36-Item Short Form Health Survey, which assesses 8 health domains; each domain is scored from 0 to 100, with higher scores indicating better health status and quality of life.

5

Description
Craniovertebral angle
Timepoint
At baseline, before the intervention, and after 6 weeks of intervention.
Method of measurement
Using standardized lateral photography to measure the angle between the horizontal line and the line connecting the external ear tragus to the spinous process of the seventh cervical vertebra, using Kinovea software version 0.8.15.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants will perform the same cervical stabilization exercises as the control group for 30 minutes per session, three sessions per week, for six weeks. Additionally, they will perform ocular exercises for 20 minutes per session, three sessions per week, for six weeks. Participants will continue their prescribed migraine medications as before enrollment.
Category
Rehabilitation

2

Description
Control group: Participants will perform cervical stabilization exercises using a pressure biofeedback unit for 30 minutes per session, three sessions per week, for six weeks. Participants will continue their prescribed migraine medications as before enrollment.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Shiva Ahmadi
Street address
Sina Hospital, Imam Khomeini Street, Tehran
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8500
Email
sinahosp-ipd@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin kordi
Street address
Poursina St., Keshavarz Blvd., Tehran
City
Tehran
Province
Tehran
Postal code
1417653861
Phone
+98 21 8889 6692
Email
admission@tums.ac.ir
Web page address
https://tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Shiva Ahmadi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Sport Medicine
Street address
Bagher Khan Street, Corner of Farzin Street, Tehran
City
Tehran
Province
Tehran
Postal code
1441633963
Phone
+98 21 6653 6490
Email
sh.ahmadi1219@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shiva Ahmadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Sport Medicine
Street address
Bagher Khan Street, Corner of Farzin Street, Tehran
City
Tehran
Province
Tehran
Postal code
1441633963
Phone
+98 21 6653 6490
Fax
Email
sh.ahmadi1219@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shiva Ahmadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Sport Medicine
Street address
Bagher Khan Street, Corner of Farzin Street, Tehran
City
Tehran
Province
Tehran
Postal code
1441633963
Phone
+98 21 6653 6490
Fax
Email
sh.ahmadi1219@gmail.com
Web page address

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

To protect participants' confidentiality and privacy, there are no plans to share individual participant data. Study results will be reported in aggregate form.

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Study protocol, statistical analysis plan, and final clinical study report for the randomized controlled trial evaluating the effects of cervical stabilization exercises with and without ocular exercises in women with cervicogenic headache and migraine associated with forward head posture. The documents will describe the study design, interventions, outcome measures, statistical methods, and overall study findings. Individual participant data will not be included in the shared documents.

When the data will become available and for how long

The documents will be made available upon reasonable request after publication of the main study results. Access will remain available for at least five years after publication, subject to applicable institutional policies and the availability of the documents.

To whom data/document is available

Researchers affiliated with academic or scientific institutions may submit a request to access the documents. Requests from other qualified researchers may also be considered on a case-by-case basis

Under which criteria data/document could be used

The documents may be used for academic research, methodological evaluation, and scientific review. Users must use the documents responsibly, cite the original study appropriately, and must not misrepresent the study findings. Any use must comply with applicable ethical requirements and institutional policies.

From where data/document is obtainable

Requests should be directed to the principal investigator or corresponding researcher through the official institutional email address provided in the study registration. The request should include the applicant’s name, institutional affiliation, purpose of the request, and the specific documents required.

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

Requests will be reviewed by the principal investigator or an authorized research team member. The purpose of the request and its consistency with ethical and academic requirements will be assessed. If approved, the requested documents will be provided electronically, subject to applicable institutional policies. The applicant will be notified if the request is declined.

Comments