Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Added Value of Diaphragmatic Myofascial Release in the Management of Chronic Tension-Type Headache: A Randomized Controlled Trial

Protocol summary

Study aim
comparison of the effects of suboccipital myofascial release and diaphragm myofascial release on pain intensity and frequency and quality of life in patients with symptomatic tension-type headache aged 18-40 years.

Design
a controlled, double group, single blinded(assessor), randomized(randomizer site), phase 3 clinical trial on 22 patients.

Settings and conduct
The study is carried out at Shiraz's school of rehabilitation sciences, comparing the effects of added value of diaphragm myofascial release and sub-occipital release on tension type headache. Manual techniques are applied thrice a week for 2 weeks. blinding of evaluator is maintained by separating treatment and assessment roles.

Participants/Inclusion and exclusion criteria
Age range: 18 to 40 years, Headache lasting from 30 min to 7 days, At least two of the following pain characteristics: 1. Bilateral location 2. Pressing or tightening (non-pulsating) quality 3. Mild or moderate intensity 4. Not aggravated by routine physical activity, such as walking or climbing stairs Both of the following: 1. No nausea, vomiting (anorexia can occur) 2. No more than one of photophobia or phonophobia not attributed to another disorder People with CTTH who had headache for at least 3 days in a week for the past four Consecutive weeks (48). tenderness over the suboccipital region (88) and diaphragm

Intervention groups
one of the intervention groups will receive suboccipital muscle release and diaphragm, and the other group will receive sub-occipital release only.

Main outcome variables
pain intensity, pain frequency, quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250629066291N3**
Registration date: **2026-05-18, 1405/02/28**
Registration timing: **prospective**

Last update: **2026-05-18, 1405/02/28**
Update count: **0**

Registration date
2026-05-18, 1405/02/28

Registrant information

Name
Farzaneh Haghighat

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3230 5410

Email address
haghighat_fa@yahoo.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-06-06, 1405/03/16

Expected recruitment end date
2026-12-07, 1405/09/16

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Added Value of Diaphragmatic Myofascial Release in the Management of Chronic Tension-Type Headache: A Randomized Controlled Trial

Public title
Added Value of Diaphragmatic Myofascial Release in the Management of Chronic Tension-Type Headache
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age range: 18 to 40 years Headache lasting from 30 min to 7 days. 3. At least two of the following pain characteristics:1. Bilateral location2. Pressing or tightening (non-pulsating) quality 3. Mild or moderate intensity 4. Not aggravated by routine physical activity, such as walking or climbing stairs People with CTTH who had headache for at least 3 days in a week for the past four Consecutive weeks No nausea, vomiting (anorexia can occur) No more than one of photophobia or phonophobia not attributed to another disorder
Exclusion criteria:
Visual or hearing impairment Nervous system disorders Balance disorders cervical disk herniation History of surgery in the neck and spine area A history of additional migraine headache or secondary headaches History of any trauma to the cervical spine, such as whiplash injury Cognitive disorders Inflammatory diseases such as rheumatoid arthritis History of any fracture in the neck area Congenital neck abnormalities (torticollis) Respiratory diseases and shingles Professional athletes Cervical spinal canal stenosis Radicular pain related to the neck area Malignancy Fibromyalgia pregnant or breastfeeding Undergoing physiotherapy treatment within the last six months Use of painkillers, anti-inflammatory drugs, or muscle relaxants within the past 72 hours
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider

Sample size
Target sample size: **22**
Randomization (investigator's opinion)
Randomized
Randomization description
The random assignment method in this study will be the blocked permutation method (number of blocks 8 and block size 4) which will be generated using randomizer site The samples will be assigned in a 1:1 ratio. Opaque, sealed envelopes will be used to conceal the assignment.
Blinding (investigator's opinion)
Single blinded
Blinding description
The individual who performs the assessments is separate from the one who administers the treatments, and neither is aware of the other's work. The person responsible for randomization is also independent from both of the aforementioned individuals.
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
Ethics committee, Research and Technology Vice-Chancellor, 7th floor, Central building of Shiraz University of Medical Sciences, Zand Street
City
Shiraz
Province
Fars
Postal code
7198754361
Approval date
2026-01-10, 1404/10/20
Ethics committee reference number
IR.SUMS.REC.1404.581

Health conditions studied

1

Description of health condition studied
tension-type headache
ICD-10 code
G44.2
ICD-10 code description
Tension-type headache

Primary outcomes

1

Description
pain intensity
Timepoint
before intervention, after intervention period.
Method of measurement
numerical pain rating scale

2

Description
headache frequency
Timepoint

4 weeks before intervention, 1 week after intervention period

Method of measurement

interview and headache records

3

Description

quality of life

Timepoint

before intervention, 1 week after intervention

Method of measurement

headache disability index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: diaphragm release and suboccipital release: To release the diaphragm, the patient is positioned in the supine position. The therapist stands at the head of the patient. The therapist makes manual contact bilaterally under the costal cartilages of the lower ribs (7th to 10th) with hypothenar regions of the hands and last three fingers. During the patient’s inspiration, the therapist is gently pulling the points of hands contacts toward the head and slightly laterally, while elevating the ribs simultaneously. During exhalation, the therapist deepens hand contacts towards the inner costal margins. The release technique is performed thrice a week for two weeks; each technique lasts for 5 to 7 minutes. All release techniques will be done by the same physiotherapist. For suboccipital release technique, the patient is asked to lie down in a relaxed supine position on the treatment table while the therapist sits on a chair at the head of the patient. The therapist's elbows are supported by the table, and their forearms are positioned in supination. The patient is then instructed to rest their head on the therapist's palms. Next, the therapist places the pads of four fingers of both hands on either side of the C2 vertebra, just below the occipital region, and applies pressure until a melting sensation is felt. The intervention lasts four minutes. During this technique, the patient is asked to close both eyes to prevent eye movements, which could affect the tone of the sub occipital muscles. This technique is performed three times a week for two weeks for each patient in this group.

Category

Treatment - Other

2

Description

Intervention group: For suboccipital release technique, the patient is asked to lie down in a relaxed supine position on the treatment table while the therapist sits on a chair at the head of the patient. The therapist's elbows are supported by the table, and their forearms are positioned in supination. The patient is then instructed to rest their head on the therapist's palms. Next, the therapist places the pads of four fingers of both hands on either side of the C2 vertebra, just below the occipital region, and applies pressure until a melting sensation is felt. The intervention lasts four minutes. During this technique, the patient is asked to close both eyes to prevent eye movements, which could affect the tone of the sub occipital muscles. This technique is performed three times a week for two weeks for each patient in this group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of rehabilitation school, Shiraz university of medical sciences

Full name of responsible person

Farzaneh Haghighat

Street address

Mehr building, Shahid chamran hospital, Shahid chamran boulevard, Shiraz

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7194815644

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rehabdep@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hamid Mohammadi

Street address

Research and Technology vice-chancellor, 7th floor, Central building of Shiraz University of Medical Sciences, Zand street, Shiraz

City

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7134814336

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+98 71 3212 2430

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vcrdep@sums.ac.ir

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

Farzaneh Haghighat

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

information collection form including primary and secondary outcomes, informed consent form and SSPS file.

When the data will become available and for how

long

After publication of the results of the study

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Only for recording information in scientific databases

From where data/document is obtainable

correspondence with the project manager by email. Haghighat_fa@yahoo.com

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

Maximum one month after sending the request by email.

Comments