Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Added-value of Myofascial Diaphragmatic Release to the Neck Muscles Trigger Points in the Management of Chronic Migraine a Randomized Clinical Trial

Protocol summary

Study aim
The Added Value of Myofascial Diaphragm Release to Cervical Trigger Point Release in the Management of Chronic Migraine in Patients Aged 25–55 Years

Design
Interventional, Randomized, Controlled Clinical Trial

Settings and conduct
This study will be conducted at the School of Rehabilitation Sciences, Shiraz, to evaluate the added value of myofascial diaphragmatic release to cervical trigger point release and muscle stretching. The intervention will be delivered over 2 weeks, with three sessions per week (six sessions in total).

Participants/Inclusion and exclusion criteria
Inclusion Criteria Age 25–55 years. Chronic migraine (>3 months) diagnosed according to the International Headache Society (IHS) criteria by a neurologist. At least one active trigger point in the sternocleidomastoid, upper trapezius, or suboccipital muscles that reproduces the participant's headache pain. An active trigger point is confirmed by the presence of tenderness, referred pain, and a local twitch response upon palpation. Exclusion Criteria History of neck trauma. Cervical radiculopathy. History of neck or shoulder surgery. Diagnosis of other headache disorders. Trigger point treatment in the cervical region within the previous 6 months. Rheumatologic disorders, dizziness, hypertension, psychological stress, psychological disorders, cardiopulmonary diseases, or pregnancy.

Intervention groups
In the intervention group, manual diaphragmatic release will be added to the treatment provided to the control group. The control group will receive myofascial release of trigger points and stretching of the sternocleidomastoid, upper trapezius, and suboccipital muscles. Both interventions will be performed in the supine position.

Main outcome variables
Headache intensity, Disability, Quality of life, Daily headache frequency, Total daily headache duration, Mean daily headache intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250629066291N6**
Registration date: **2026-09-17, 1405/06/26**
Registration timing: **prospective**

Last update: **2026-09-17, 1405/06/26**
Update count: **0**

Registration date
2026-09-17, 1405/06/26

Registrant information

Name
Farzaneh Haghighat

Name of organization / entity

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Iran (Islamic Republic of)

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haghighat_fa@yahoo.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-23, 1405/07/01

Expected recruitment end date
2027-05-05, 1406/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Added-value of Myofascial Diaphragmatic Release to the Neck Muscles Trigger Points in the Management of Chronic Migraine a Randomized Clinical Trial

Public title

Added-value of Myofascial Diaphragmatic Release to the Neck Muscles Trigger Points in the Management of Chronic Migraine a Randomized Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 25–55 years Chronic migraine (>3 months) diagnosed according to the International Headache Society (IHS) criteria by a neurologist. At least one active trigger point in the sternocleidomastoid, upper trapezius, or suboccipital muscles reproducing headache pain (active trigger points defined by tenderness, referred pain, and a local twitch response on palpation).

Exclusion criteria:

History of neck trauma Cervical radiculopathy History of neck or shoulder surgery Diagnosis of other headache disorders Trigger point treatment in the cervical region within the previous 6 months Rheumatologic disorders, dizziness, hypertension, psychological stress, psychological disorders, cardiopulmonary diseases, or pregnancy

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with a fixed block size of 4 and a 1:1 allocation ratio will be used. Thus, each block of 4 participants will contain 2 allocations to intervention A and 2 to intervention B, with the allocation sequence randomly determined within each block. However, as a total sample size of 50 participants cannot be evenly randomized using blocks of 4 alone, combined block sizes will be used (e.g., twelve blocks of 4 plus a final block of 2, or randomly varying block sizes of 4 and 6).

Blinding (investigator's opinion)

Single blinded

Blinding description

The assessors will be blinded to the randomization process, which will be performed by an independent researcher. Assessment and intervention procedures will be conducted by two separate physiotherapists to minimize the risk of bias.

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

2026-07-12, 1405/04/21

Ethics committee reference number

IR.SUMS.REHAB.REC.1405.007

Health conditions studied

1

Description of health condition studied

Chronic migraine headaches

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

Pain intensity

Timepoint

Mean over the week preceding and the week following the treatment period

Method of measurement

One week before treatment initiation, at the first visit of the participants for assessment of the inclusion and

exclusion criteria, they will be provided with a Daily Headache Diary containing a Visual Analog Scale (VAS). They will be asked to record their headache intensity each day for 1 week by marking a point on the 10-cm VAS line according to the intensity of their headache, ranging from 0 (indicating no pain) to 10 (indicating the maximum pain). The Daily Headache Diary will be collected one week later, at the first treatment session. After accurately measuring the distance from the zero point to the marked point for each day, the mean daily headache intensity over the 1-week period will be calculated. At the end of the final treatment session, another similar Daily Headache Diary will be provided to the participants, and they will again be asked to mark their headache intensity each day using the same method. This Daily Headache Diary will also be collected one week later, and the mean daily headache intensity will again be calculated using the method described above. Finally, two numerical values representing the mean headache intensity measured by the VAS will be obtained and statistically compared.

Secondary outcomes

1

Description

Disability

Timepoint

At baseline (before the first treatment session) and one day after the final treatment session

Method of measurement

Quality of life will be assessed using the Migraine-Specific Quality of Life Questionnaire (MSQ). This questionnaire is a well-established instrument that has been widely used in research and clinical practice to assess quality of life (QOL) (167). The MSQ version 2.1 consists of 14 questions, with each question having 6 response options, with a total score of 100. Higher scores on this questionnaire indicate better quality of life. The questionnaire will be completed by the participants and collected from them twice: first, at the first treatment session before the treatment begins, and second, one day after the final treatment session.

2

Description

Quality of life

Timepoint

At baseline (before the first treatment session) and one day after the final treatment session

Method of measurement

Quality of life will be assessed using the Migraine-Specific Quality of Life Questionnaire (MSQ). This questionnaire is a well-established instrument that has been widely used in research and clinical practice to assess quality of life (QOL) (167). The MSQ version 2.1 consists of 14 questions, with each question having 6 response options, with a total score of 100. Higher scores on this questionnaire indicate better quality of life. The questionnaire will be completed by the patients and collected from them twice: first, at the first treatment session before the treatment begins, and second, one day after the final treatment session.

3

Description

Mean headache duration

Timepoint

During the week before treatment initiation and the week following treatment

Method of measurement

One week before treatment initiation, that is, at the first visit of the patient for assessment of the inclusion and exclusion criteria, a Daily Headache Diary will be provided to the patients, and they will be asked to record the duration of their headache each day for 1 week in the column designated for daily headache duration. The Daily Headache Diary will be collected from the patients one week later, that is, at the first treatment session, and the mean daily headache duration over the 1-week period will be calculated. At the end of the final treatment session, another similar Daily Headache Diary will be provided to the patients, and they will again be asked to record their headache duration each day using the same method. This Daily Headache Diary will also be collected from the patients one week later, and the mean daily headache duration will be calculated.

4

Description

Daily headache frequency

Timepoint

During the week before treatment initiation and the week following treatment.

Method of measurement

One week before treatment initiation, that is, at the first visit of the patient for assessment of the inclusion and exclusion criteria, a Daily Headache Diary will be provided to the patients, and they will be asked to record the number of headache episodes occurring each day for 1 week in the column designated for the number of daily headache episodes. The Daily Headache Diary will be collected from the patients one week later, that is, at the first treatment session, and the mean daily headache frequency over the 1-week period will be calculated. At the end of the final treatment session, another similar Daily Headache Diary will be provided to the patients, and they will again be asked to record the number of headache episodes occurring each day using the same method. This Daily Headache Diary will also be collected from the patients one week later, and the mean number of daily headache episodes will be calculated.

5

Description

Type and dosage of the medication

Timepoint

During the week before treatment initiation and the week following treatment.

Method of measurement

The type of medication used by each patient and the dosage taken, according to the prescription of their treating physician, will be recorded and documented in the aforementioned Daily Headache Diary for review and, if necessary, statistical analysis.

Intervention groups

1

Description
Control group:
Category
Treatment - Other

2

Description
Intervention group:
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
کلینیک دانشکده علوم توانبخشی، دانشگاه علوم پزشکی شیراز
Full name of responsible person
فرزانه حقیقت
Street address
Mehr Building, Shahid Chamran Hospital, Shahid Chamran Boulevard
City
Shiraz
Province
Fars
Postal code
7194815644
Phone
+98 71 3624 0101
Email
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
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3212 2430
Email
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
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Person responsible for updating data

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Latest degree
Ph.D.
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7194815644
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haghighat_fa@yahoo.com
Web page address

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