# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## The effectiveness of deep neck flexor exercises in comparison with myofascial release of suboccipital muscle on pain and forward head posture in people with chronic tension type headache and forward head posture

## Protocol summary

**Study aim**
Comparison of the effectiveness of deep neck flexor exercises with suboccipital muscle myofascial release on headache parameters, forward head posture, disability, quality of life, and pressure pain threshold of sub-occipital muscles in patients with chronic tension-type headache and forward head posture

**Design**
A double-blind (patients and assessor), randomized by block balanced randomization method and the generatorslist.com system, double-dummy design controlled clinical trial of 44 patients.

**Settings and conduct**
Patients are referred by a neurologist to a physiotherapy clinic under the auspices of the Iran University of Medical Sciences in Tehran. The treatment is applied in 12 sessions in two groups. outcomes assessment will be performed before and after the sessions and again 6 weeks later. The blinding method is double-blind (patients and evaluators).

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: 18 to 55 years; Diagnosis of chronic tension headache according to the International Headache Committee; No change in dose and type of prophylactic medication 3 months before the start and during the study; Craniovertebral angle less than 49 degrees Exclusion criteria: History of cervical trauma; Severe pain or severely limited range of motion of the neck; History of injection, surgery, severe disc herniation or neck/shoulder fracture; Joint stiffness or advanced osteoarthritis of the neck; Neurological or vascular disorders; Consumption of strong analgesics more than 200 per month; Pregnancy; Score more than 85 in Spielberger Anxiety Questionnaire

**Intervention groups**
One group: deep neck flexor exercises with pressure biofeedback combined with placebo suboccipital myofascial release another group: suboccipital myofascial release combined with placebo deep neck flexor exercises.

**Main outcome variables**
headache intensity; severity of the forward head posture

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20220219054060N1**
Registration date: **2022-04-21, 1401/02/01**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-21, 1401/02/01**
Update count: **0**

**Registration date**
2022-04-21, 1401/02/01

**Registrant information**

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Mobina Ahmadi

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-04-21, 1401/02/01

**Expected recruitment end date**

2023-02-20, 1401/12/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effectiveness of deep neck flexor exercises in comparison with myofascial release of suboccipital muscle on pain and forward head posture in people with chronic tension type headache and forward head posture

**Public title**

The effectiveness of exercises in comparison with manual treatments in chronic tension type headache

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

People with at least 2 of the 4 characteristics of bilateral headache, Non-pulsatile pain pressure, mild to moderate severity and no aggravation of pain by daily activities such as walking People who have experienced the headache for at least 3 months People who have the headache more than 15 days per month People who have only one of the symptoms of photophobia, phonophobia or mild nausea People with a craniovertebral angle less than 49 degrees The dose and type of prophylactic medication have not changed in the last 3 months People who do not intend to change the dose and type of prophylactic medication during the study period Participants have completed at least the elementary level of education and have the ability to understand and read Persian to complete the questionnaire. The headache can be accompanied by muscles tenderness around the head and neck

**Exclusion criteria:**

People with dizziness, severe nausea or vomiting due to the headache People with episodic tension type headache or other primary and secondary headaches Pain aggravated by movement of the head Abnormal changes in the radiographic image of cervical spine Previous trauma to the cervical spine Severe pain or significant limitation of the normal range of motion of the cervical spine History of injection, surgery, severe disc protrusion, or neck or shoulder fracture that affects treatment Joint stiffness, atherosclerosis or advanced osteoarthritis of the cervical spine Neurological or vascular disorders such as epilepsy or Bow hunter’s syndrome Absence of two consecutive sessions and more than treatment sessions Consume more than 200 pieces of morphine or other strong analgesics per month Pregnancy Receive physiotherapy treatment for headache within 6 months before starting treatment People who drink alcohol or have drug abuse For whatever reason, the participant is reluctant to be touched by the therapist Symptoms are severe and irritating Underlying diseases (such as rheumatoid arthritis) or metabolic disorders (such as osteoporosis or soft tissue laxity in the treatment area) for which manual therapies are contraindacated Score is more than 85 in the Spielberger Anxiety Trait Questionnaire

**Age**

From **18 years** old to **55 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **44**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

All eligible patients with chronic tension-type headache are randomly divided into two groups of treatment: deep neck flexor exercise and myofascial release groups with a 1: 1 ratio. Generatorslist.com is used to determine random allocation; This method is done with the help of four-digit blocks including even and odd numbers. For this purpose, 4-digit numbers are selected that have 2 even digits and 2 odd digits; Each digit represents each participant in the study. The random allocation process will be performed by someone outside the research team before the study begins. At the end of the random allocation, the numbers will be placed inside the numbered envelopes separately and after the initial evaluation by the examiner, the numbered envelopes will be given according to the ordinal number of each person entered in the study. Finally, after each participant enters the treatment sessions, the therapist opens the envelope of the participants and applies therapeutic interventions based on the number in the envelope. Patients are told not to provide information about their group to the assessor to prevent data contamination.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, participants, the outcome assessor, and, the statistician will be blinded. Method of blindness: a) Participants: In each of the treatment groups, a real treatment was used with the placebo form of treatment of another group (the first group includes deep neck flexor exercise with placebo myofascial release, and the second group includes suboccipital myofascial release with placebo deep neck flexor exercise) so that the participants could not guess which treatment group they had entered; also, the participants will not be aware of how the other group will be treated. B) Outcome Assessor: Outcome assessment will be performed by a person who has no knowledge of the grouping of individuals and the treatments performed in each treatment group. C) Statistician: Data analysis will be performed by a person who does not know the grouping of people and the treatments performed in each treatment group.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

This randomized clinical trial is of the double-dummy type. in this way, one group will receive deep neck flexor exercises with placebo treatment of myofascial release of suboccipital muscles and the other group will receive myofascial release of suboccipital muscles with placebo treatment of deep neck flexor exercises.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Research Ethics Committees of Iran University of Medical Sciences

**Street address**

Unit 2,First Floor,Golestan Dormitory, Iran School of Rehabilitation, Maddakaran St., Shah Nazari St., Madar Sq., Mirdamad Blvd.

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Tehran

**Province**

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**Postal code**

1545913487

**Approval date**

2022-03-16, 1400/12/25

**Ethics committee reference number**

IR.IUMS.REC.1400.1239

## Health conditions studied

### 1

**Description of health condition studied**

chronic tension-type headache

**ICD-10 code**

G44.221

**ICD-10 code description**

Chronic tension-type headache, intractable

## Primary outcomes

### 1

**Description**

The average severity of headache during the last 1 month

**Timepoint**

Pain intensity will be measured at the beginning of the study (before the intervention), after the end of 12 sessions of treatment and 6 weeks after the end of the intervention.

**Method of measurement**

Visual Analogue Scale

### 2

**Description**

the severity of forward head posture

**Timepoint**

Measurement of the forward head posture will be performed at the beginning of the study (before the start of the intervention), after the end of 12 sessions of treatment and 6 weeks after the end of the intervention.

**Method of measurement**

Craniovertebral angle: The angle between the horizon line and the line connecting the tragus of the ear to the spinous process of the seventh cervical vertebra

## Secondary outcomes

### 1

**Description**

Duration of the headache

**Timepoint**

The duration of headache will be measured at the beginning of the study (before the intervention), after the end of 12 sessions of treatment, and 6 weeks after the end of the intervention.

**Method of measurement**

The average number of hours that a person has the headache in a month.

### 2

**Description**

Frequency of the headache

**Timepoint**

The frequency of headaches will be measured at the beginning of the study (before the intervention), after the end of 12 sessions of treatment and 6 weeks after the end of the intervention.

**Method of measurement**

The number of days in the month when a person has a headache.

### 3

**Description**

Disability

**Timepoint**

Disability will be assessed at the beginning of the study (before the intervention), after the end of 12 sessions of treatment, and 6 weeks after the end of the intervention.

**Method of measurement**

Persian version of the Henry Ford Hospital Headache Disability Inventory questionnaire

### 4

**Description**

Quality of life

**Timepoint**

Quality of life will be assessed at the beginning of the study (before the intervention), after the end of 12

sessions of treatment, and 6 weeks after the end of the intervention.

**Method of measurement**

Persian version of Headache Impact Test questionnaire -6

**5**

**Description**

Pressure Pain Threshold of suboccipital muscles

**Timepoint**

The pressure Pain Threshold of suboccipital muscles will be assessed at the beginning of the study (before the intervention), after the end of 12 sessions of treatment, and 6 weeks after the end of the intervention.

**Method of measurement**

Algometer device in the lower part of the occipital bone and outside the upper head of the upper trapezius muscle on both sides

## Intervention groups

**1**

**Description**

Intervention group 1: deep neck flexor exercises with pressure biofeedback combined with placebo myofascial release of suboccipital muscles

**Category**

Rehabilitation

**2**

**Description**

Intervention group 2:sub-occipital myofascial release combined with placebo deep neck flexor exercises with pressure biofeedback.

**Category**

Rehabilitation

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Sina hospital

**Full name of responsible person**

Mansoureh Togha

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**2**

**Recruitment center**

**Name of recruitment center**

Physiotherapy Clinic, School of Rehabilitation, Iran University of Medical Sciences

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## Sponsors / Funding sources

**1**

**Sponsor**

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**Full name of responsible person**

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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**

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**
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Iran University of Medical Sciences
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## 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**
Yes - There is a plan to make this available
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
Data collected after unidentifiable individuals are collected for primary and secondary outcomes and shared as needed.
**When the data will become available and for how long**
The access period starts 6 months after the results are published
**To whom data/document is available**
The data will be available to physiotherapists working in scientific institutions as well as clinicians working in the field of musculoskeletal disorders, especially in the head and cervical regions.
**Under which criteria data/document could be used**
The raw data and results of this study may be used in systematic studies. Hence, the raw data and results of

this study will be available to researchers working in the field of headache.

**From where data/document is obtainable**

Applicants can contact Mobina Ahmadi (Physiotherapist) by e-mail. Email address: m.oahmadi@ymail.com

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

Applicants must explain in detail about their project and how to use the data/documentation of this study in their project. Then, the data/documentation files will be sent to the applicants through e-mail following the request. This process may take 10-12 business days.

**Comments**