Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 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

Name of organization / entity

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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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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

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
Name of organization / entity
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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