Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of active and positional release technique on pain, range of motion and functional disability in cervicogenic headache patients.

Protocol summary

Study aim
To compare the effects of active and positional release technique on pain, range of motion and functional disability in cervicogenic headache patient.

Design
Two arm parallel group randomized trial with blinded 4th week follow up and outcome assessment with sample size of 68

Settings and conduct
Tehsil Head Quarter hospital Shakargarh

Participants/Inclusion and exclusion criteria
Inclusion Criteria: • Aged between 20-50 years • Both Male and females • Individuals diagnosed with neck pain accompanied by cervicogenic headaches • Patients experiencing unilateral pain due to cervicogenic headaches • Individuals suffering from cervicogenic headaches characterized by restricted cervical range of motion Exclusion Criteria: • History of tension type headache • History of trauma to the cervical • History of Vertebrobasilar insufficiency • History of Malignancy in the cervical area • History of operative procedure done in the cervical region

Intervention groups
Participants will be randomly allocated into two groups (Group A: Active Release Technique, Group B: Positional release technique). The participants of group A will be given instructions on how to carry out each exercise properly, by the Kibler squeeze to perform active release technique. The participants randomly allocated in Group B will be received the Positional release technique. in side-lying position on unaffected side. Create a score of 10 by lightly pinching or squeezing the point. Then, try changing the subject's arm posture by raising it over their heads to relax the Sternocleidomastoid muscle that are tracing, or by bending their necks so they are facing the uncomfortable side while lying on a thick cushion. For 90 seconds, this position will be retained. The subject will be returned to its original position after being released.

Main outcome variables
Pain; Function; Range of Motion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240724062528N1**
Registration date: **2024-09-22, 1403/07/01**
Registration timing: **registered_while_recruiting**

Last update: **2024-09-22, 1403/07/01**
Update count: **0**

Registration date
2024-09-22, 1403/07/01

Registrant information

Name
Hafiza Saira Rasheed

Name of organization / entity
The University of Lahore

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Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-03, 1403/02/14

Expected recruitment end date
2024-11-06, 1403/08/16

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of active and positional release technique on pain, range of motion and functional disability in cervicogenic headache patients.

Public title

Effects of active and positional release technique in cervicogenic headache patients.

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Aged between 20-50 years Both Male and females Individuals diagnosed with neck pain accompanied by cervicogenic headaches Patients experiencing unilateral pain due to cervicogenic headaches Individuals suffering from cervicogenic headaches characterized by restricted cervical range of motion

Exclusion criteria:

History of tension type headache History of trauma to the cervical History of Vertebrobasilar insufficiency History of Malignancy in the cervical area History of operative procedure done in the cervical region

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

A randomized clinical trail will be conducted using purposive samlping technique to collect the data. Participants will be randomly allocated into two groups by lottery method where Group A will receive active release technique and Group B positional release technique for 4th weeks. Neck disability index , headache disability index and goniometer used to measure outcome variables.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will be a single blinded study in which assessor will be kept blinded. Outcome assessors are blinded to the treatment assignments of the participants to prevent bias in evaluating the results. This is often done by having assessors work with coded data or by separating the outcome assessment process from the treatment administration and assignment process.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of University of Lahore

Street address

University of Lahore Teaching Hospital Lahore , Punjab , Pakistan

City

Lahore

Postal code

55150

Approval date

2024-05-22, 1403/03/02

Ethics committee reference number

REC-UOL-/201/08/24

Health conditions studied

1

Description of health condition studied

Cervicogenic headache is characterized by persistent unilateral head pain originating from the structures of the neck, including both bony components and soft tissues.It is classified as a secondary headache, with its origins traced back to the upper cervical spine and the atlanto-occipital joint.

ICD-10 code

G44.86

ICD-10 code description

Cervicogenic Headache

Primary outcomes

1

Description

The Numeric Pain Rating Scale is a segmented numeric version of the visual analog scale in which a respondent selects a whole number (0–10 integers) that best reflects the intensity of his/her pain. It takes <1 minute to complete Scores range from 0-10 points, with higher scores indicating greater pain intensity.

Timepoint

4th weeks

Method of measurement

The NPRS is a segmented numeric version of the visual analog scale (VAS) in which a respondent selects a whole number (0–10 integers) that best reflects the intensity of his/her pain. The common format is a horizontal bar or line. The NPRS takes <1 minute to complete Scores range from 0-10 points, with higher scores indicating

greater pain intensity. The NPRS can be administered verbally (therefore also by telephone) or graphically for self-completion.

2

Description

The term 'goniometry refers to the measurement of angles, which in rehabilitation settings refers to the measurement of angles in each plane at the joints of the body. The neutral zero method (0 to 180- degree system) is the most widely used method. The range of motion of each joint should be measured in isolation, to avoid trick movement (simultaneous movement of another joint) and muscle insufficiency which may alter the reading.

Timepoint

4th weeks

Method of measurement

The measurement of angles, which in rehabilitation settings refers to the measurement of angles in each plane at the joints of the body. The neutral zero method (0 to 180- degree system) is the most widely used method. The range of motion of each joint should be measured in isolation, to avoid trick movement (simultaneous movement of another joint) and muscle insufficiency which may alter the reading.

3

Description

The Henry Ford Hospital Headache Disability Inventory/Index (HDI) was developed to quantify the impact of headache on daily living. A 25-item headache questionnaire derived from case history responses of subjects with headache, and it sub grouped into functional and emotional subscales to assess the impact of headache, and its treatment on daily living. The Headache Disability Inventory/Index designed by Dr. Jacobson GP, Ramadan NM, et al. (Kılınç et al., 2023)

Timepoint

4th weeks

Method of measurement

A 25-item headache questionnaire with headache, and it sub grouped into functional and emotional subscales to assess the impact of headache, and its treatment on daily living. Using this system, a total score of 10-28 is considered to indicate mild disability; 30-48 is moderate disability; 50-68 is severe disability; 72 or more is complete disability.

Secondary outcomes

1

Description

Neck disability Index(NDI) questionnaire has been designed to give us information as to how your neck pain has affected your ability to manage in everyday life.

Timepoint

4th weeks

Method of measurement

Neck disability Index consist of 10 sections; Each section is scored on a 0 to 5 rating scale, in which zero means 'No pain' and 5 means 'Worst imaginable pain'. Points summed to a total score where 0 means: no activity limitations, 50 points or 100% means complete activity limitation.

Intervention groups

1

Description

Experimental Group A: Active release technique(ART) and Routine Physical Therapy:The participants randomly allocated in Group A will be received the Active release technique. Before this technique routine physical therapy consist of heat therapy for 10 minutes will be applied. Tightness in the Sternocleidomastoid is common in patients with Cervical headache. Reduced tightness and trigger point discomfort can be achieved with the aid of the post-isometric relaxation (PIR) approach. To do PIR, first extend the muscle passively. Next, have the patient mildly contract (10–20% of maximum) counter to resistance for 5 seconds passively. Finally, exhale & relax the muscle, and repeat. Five repetitions of PIR exercises will be done. Two sets with a minute rest in between, performed three times per week for four weeks. After this they will receive Active Release Technique. The subjects will be given instructions on how to carry out each exercise properly, including: a. Sitting chair stretch, b. Brugger’s stretch c. Wall angles and doorway stretches will be used to target the pectoralis major, upper trapezius, and levator scapulae, respectively. d. The pushup plus e. Head and neck retractions f. The rhomboids, deep neck flexors, and serratus anterior are strengthened by the Kibler squeeze.

Category

Other

2

Description

Experimental Group B: Positional release technique and Routine Physical Therapy :The participants randomly allocated in Group B will be received the Positional release technique. Before this technique routine physical therapy consist of heat therapy for 10 minutes will be applied. They will receive positional release technique. And then to perform PIR same process followed in group A will be used. Then patient will be instructed to side-lying position on unaffected side. Create a score of 10 by lightly pinching or squeezing the point. Then, try changing the subject's arm posture by raising it over their heads to relax the Sternocleidomastoid muscle that are tracing, or by bending their necks so they are facing the uncomfortable side while lying on a thick cushion. For 90 seconds, this position will be retained. The subject will be returned to its original position after being released. Additionally, this will be carried out for 4 weeks in 3 sessions per week with 2 repeats.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
THQ hospital Shakargarh
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
The University of Lahore
Proportion provided by this source
100
Public or private sector
Private
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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Position
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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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Demographic data and data related to final outcome will be shared by maintaining the confidentionally

When the data will become available and for how long

Data will be available after the publication of findings till six months

To whom data/document is available

Saira Rasheed

Under which criteria data/document could be used

For research purpose

From where data/document is obtainable

To the corresponding author of the study , Saira Rasheed and can contact on 0308-0777993, sairach171783@gmail.com

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

Open access and there is the traditional public data release where anyone can get access to the data

Comments