ClinicalTrials.gov Study Document

Study Protocol and Statistical Analysis Plan

Official Title

The Effectiveness of Passive Physiological Intervertebral Movements in Patients With Cervicogenic Headache: A Randomized Clinical Trial

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Public posting note: This document was prepared for ClinicalTrials.gov public posting. It does not include participant names or individual participant identifiers.

1. Protocol Synopsis

Condition	Cervicogenic headache
Study Design	Assessor-blinded, parallel-group randomized clinical trial
Allocation	Randomized allocation to two intervention arms
Intervention Model	Parallel assignment
Planned/Actual Enrollment	64 participants, 32 per arm
Setting	Outpatient physiotherapy departments of Jordan University of Science and Technology and King Abdullah University Hospital
Study Period	May 2022 to August 2025
Treatment Duration	Eight supervised sessions over four weeks
Assessment Time Points	Baseline, immediately after the four-week intervention, and three-month follow-up
Experimental Arm	Passive Physiological Intervertebral Movements plus therapeutic exercise
Comparator Arm	Therapeutic exercise alone

2. Background and Rationale

Cervicogenic headache is a secondary headache disorder associated with dysfunction in the cervical spine, particularly the upper cervical segments. Patients may experience headache, neck pain, restricted cervical movement, disability, psychological symptoms, and reduced quality of life. Therapeutic exercise and manual therapy are commonly used in physiotherapy management. Passive Physiological Intervertebral Movements are manual therapy techniques used to assess and improve segmental mobility. The study evaluated whether adding these movements to a standardized exercise program provides additional benefit compared with exercise alone.

3. Objectives

The primary objective was to determine the effect of adding Passive Physiological Intervertebral Movements to therapeutic exercise on headache pain intensity among participants with cervicogenic headache.

Secondary objectives were to evaluate between-group differences in headache frequency, neck pain intensity, neck-related disability, depression, anxiety, stress, and health-related quality of life at the post-intervention and follow-up assessments.

4. Study Design and Setting

This was a randomized clinical trial with two parallel groups. Participants were assigned to either Passive Physiological Intervertebral Movements plus therapeutic exercise or therapeutic exercise alone. The study was conducted in outpatient physiotherapy settings at Jordan University of Science and Technology and King Abdullah University Hospital. Outcome assessments were collected at baseline, four weeks, and three months.

5. Participant Identification and Eligibility Overview

Participants were screened using a standardized diagnostic process for cervicogenic headache based on clinical history and physical examination. Diagnostic confirmation included assessment of upper cervical dysfunction and symptom behavior consistent with cervicogenic headache. Individuals with contraindications to cervical mobilization or conditions that could confound assessment or treatment were excluded. Full eligibility criteria are entered separately in the ClinicalTrials.gov record.

6. Recruitment

Participants were recruited from physical therapy and rehabilitation services at King Abdullah University Hospital, university students, Ministry of Health hospitals, private physiotherapy centers, and the community. Recruitment approaches included social media advertisements, word of mouth, posters at Jordan University of Science and Technology, and private sector flyers.

7. Randomization and Allocation Concealment

After eligibility confirmation and baseline assessment, participants were randomly assigned to study groups using a random number generator. The randomization process was overseen by an independent researcher who was not involved in diagnosis, treatment, or outcome assessment. Sequentially numbered, opaque, sealed envelopes were prepared before recruitment and used to maintain allocation concealment.

8. Blinding

Outcome assessments were conducted by an assessor who was blinded to group allocation and was not involved in treatment delivery. Due to the nature of the manual therapy intervention, treatment providers were not blinded.

9. Interventions

9.1 Common Therapeutic Exercise Program

Both groups received the same standardized therapeutic exercise program. The program included deep cervical flexor activation using a chin-tuck exercise, scapular retraction, passive static self-stretching for the upper trapezius, levator scapulae, and sternocleidomastoid muscles, and active neck mobility exercises in flexion, extension, side flexion, and rotation. Participants were encouraged to continue the exercises at home.

9.2 Experimental Intervention

Participants in the experimental arm received Passive Physiological Intervertebral Movements in addition to the exercise program. The manual therapy intervention was individualized according to clinical findings and targeted the upper cervical joints, including C0-C1, C1-C2, and C2-C3, with the aim of restoring upper cervical mobility.

9.3 Comparator Intervention

Participants in the comparator arm received the same structured therapeutic exercise program without Passive Physiological Intervertebral Movements.

9.4 Treatment Schedule

Each participant received eight supervised treatment sessions over four weeks, with two sessions per week. Each session lasted approximately 15 to 20 minutes.

10. Outcomes and Assessment Schedule

Outcomes were assessed at baseline, immediately after the four-week intervention, and at three-month follow-up. The primary outcome was headache pain intensity measured using the Numeric Pain Rating Scale. Secondary outcomes were headache frequency per week, neck pain intensity, Neck Disability Index score, Depression Anxiety Stress Scale-21 stress, anxiety and depression scores, and Short Form-12

physical and mental component scores. Detailed outcome measure definitions are entered separately in the ClinicalTrials.gov record.

11. Sample Size

The sample size was calculated using power analysis based on headache pain intensity as the primary outcome. Using an effect size derived from a similar study, with power of 0.90 and alpha of 0.05, the required sample size was 64 participants, with 32 participants per group.

12. Data Collection and Management

Baseline demographic and clinical data were collected using a structured questionnaire. Clinical outcomes were collected using validated self-administered questionnaires and scales at the pre-specified assessment time points. Data were treated confidentially and stored securely. Hard-copy data were kept in a locked file cabinet, and electronic data were kept on a password-protected computer according to institutional procedures.

13. Safety Monitoring

Participants were screened for contraindications to cervical mobilization before enrolment. Participants were informed that participation was voluntary and that they could withdraw at any time without penalty. Any unexpected symptoms or adverse responses during treatment were to be managed by the study team according to clinical judgment and institutional procedures.

14. Statistical Analysis Plan

14.1 Analysis Population

Analyses were based on participants with available data at each assessment time point. The number of participants included in each outcome analysis was reported for each assessment point.

14.2 Descriptive Statistics

Continuous variables were summarized using means and standard deviations. Categorical variables were summarized using frequencies and percentages. Baseline characteristics and baseline clinical measures were compared between groups to assess group comparability after randomization.

14.3 Baseline Comparisons

Independent-samples t-tests were used to compare continuous baseline variables between groups. Chi-square tests were used to compare categorical baseline variables between groups.

14.4 Outcome Analysis

Multivariate analysis of variance was used to examine between-group differences in outcome measures at the assessment points. When multivariate tests were statistically significant, independent-samples t-tests were conducted for individual outcome variables. The significance level was set at $p < 0.05$, one-tailed. Analyses were performed using IBM SPSS Version 25.

14.5 Missing Data and Follow-up

Participant flow and available data were reported by group and time point. Participants who withdrew or were lost to follow-up were described in the participant flow and were not assumed to have outcome data beyond the last completed assessment unless such data were available.

15. Ethical Considerations

The study protocol and procedures were approved by the Institutional Review Board at Jordan University of Science and Technology, Approval No. 73/148/2022. Written informed consent was obtained from participants before study procedures. Participation was voluntary, and participants could withdraw at any time without negative consequences for their treatment or rights.

16. Public Posting and Retrospective Registration Note

This document was prepared to support ClinicalTrials.gov registration and/or results reporting for a completed randomized clinical trial. The record should transparently indicate that ClinicalTrials.gov registration occurred after trial completion, if applicable.