Research protocol

Exercise alone versus combined with transcranial or trans-spinal direct current stimulation for cervicogenic headache: a randomized controlled trial protocol

Meghna Wadhwa[1]
Arunmozhi Ranganathan[2]

[1]Corresponding contact. Sardar Bhagwan Singh University (Dehradun). Uttarakhand, India. sethimeghna@gmail.com
[2]Sardar Bhagwan Singh University (Dehradun). Uttarakhand, India.

ABSTRACT | BACKGROUND: Cervicogenic headaches (CGHs) are secondary headaches that result from dysfunction of the cervical spine and are frequently linked to musculoskeletal disorders. While traditional physiotherapy provides symptomatic alleviation, neuromodulation treatments such as Transcranial electrical stimulation (tDCS) and Spinal direct current stimulation (tsDCS) have demonstrated promising results in improving treatment outcomes and altering pain perception. To manage CGH, this study compares the efficacy of tDCS, tsDCS, and supervised exercise therapy. **METHODS:** International Headache Society's classification (ICHD-3) will be used to diagnose cervicogenic headache (CGH) in participants. Transcranial direct current stimulation (tDCS) along with exercise, transcutaneous spinal direct current stimulation (tsDCS) along with exercise, and exercise alone will be the three intervention groups to which ninety-nine patients will be randomly assigned. Treatment will be given for 5 consecutive days, and the exercise program will be supervised by a physiotherapist. Outcome measures will be the Headache Disability Index (HDI), Numeric Pain Rating Scale (NPRS), Cervical range of motion (CROM), pressure pain threshold (PPT) and the Headache Impact Test-6 (HIT-6). All the recordings will be done at baseline, after the five-day intervention period, and at a two-week follow-up. One-way ANOVA and repeated measures ANOVA will be used for statistical analysis to compare differences between groups and within-group changes over time. Calculations will be made for each outcome measure to get the 95% CI. **DISCUSSION:** With their potential to address processes of central sensitization and pain system malfunction at both the cortical and spinal levels, tDCS and tsDCS are stimulation techniques that show promise for neuromodulatory effects on the brain and spinal cord. They may also help treat cervicogenic headaches. **TRIAL REGISTRATION:** The registration process for the study with Clinical Trials Registry of India has been initiated (Ref. Number- REF/2023/08/071305) and has received ethical clearance from the Institutional Review Board (SBSU/PhD/2021/PT-IRB/201). **PROTOCOL VERSION:** Version 1.0; Dated: 21 July 2025.

KEYWORDS: Transcranial Direct Current Stimulation. Trans-Spinal Direct Current Stimulation. Physiotherapy Modalities. Cervicogenic Headache.

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1. Introduction

The secondary headache condition known as cervicogenic headache (CGH) is brought on by cervical spine dysfunction, particularly involving the upper cervical joints, muscles, and neural structures. Any structure innervated by the spinal nerves C1–C3 may be the cause of a cervicogenic headache, as CGH is believed to be referred pain resulting from irritation induced by cervical tissues innervated by these nerves[1]. According to recent studies, its prevalence among headache patients ranges from 0.4 to 4%. In contrast to primary headaches like tension-type headaches or migraines, CGH is characterized by pain that travels from the neck region to the head, commonly presenting with unilateral or sometimes bilateral symptoms such as pain, reduced cervical movement, and tenderness over the spine[2]. It is commonly associated with poor posture, musculoskeletal imbalances, or trauma such as whiplash injuries. The condition significantly affects an individual's daily activities, work productivity, and overall quality of life due to its long-term and repetitive nature. Current treatment strategies for CGH primarily focus on conservative management, including manual therapy, postural correction, strengthening exercises, and pharmacological interventions. While these approaches only provide symptomatic relief, they do not always give long-term improvements, and some patients experience persistent pain and disability. Furthermore, there is increased interest in non-invasive, drug-free alternatives for pain management and rehabilitation because pharmaceutical treatments like muscle relaxants and nonsteroidal anti-inflammatory medications (NSAIDs) have the potential to cause negative effects[3].

Recent evidence on the pathogenesis of CGH and advancement in brain and spinal stimulation techniques have led to the exploration of these non-invasive direct current stimulations as potential adjuncts to conventional therapy. TDCS is a non-invasive method of stimulating the brain that targets specific cortical areas with low-intensity direct electrical currents, modulating neuronal excitability[4]. Research has shown that TDCS can influence pain perception, enhance motor function, and promote neuroplasticity by altering cortical activity[5]. In the context of headache disorders, TDCS has demonstrated promising results in conditions such as migraines and chronic tension-type headaches[6], but its application in cervicogenic headache remains underexplored.

On the other hand, TSDCS is a novel neuromodulator that targets the spinal cord rather than the brain. By applying direct current stimulation over the spinal region, TSDCS aims to modulate spinal excitability, influence nociceptive pathways, and enhance motor function[7]. As the cervical spine is central to the development of cervicogenic headache, TSDCS may offer a more direct approach in addressing headache and dysfunction in these patients. However, limited studies have investigated its efficacy in managing cervicogenic headaches, and comparative research between TDCS and TSDCS in this population is lacking.

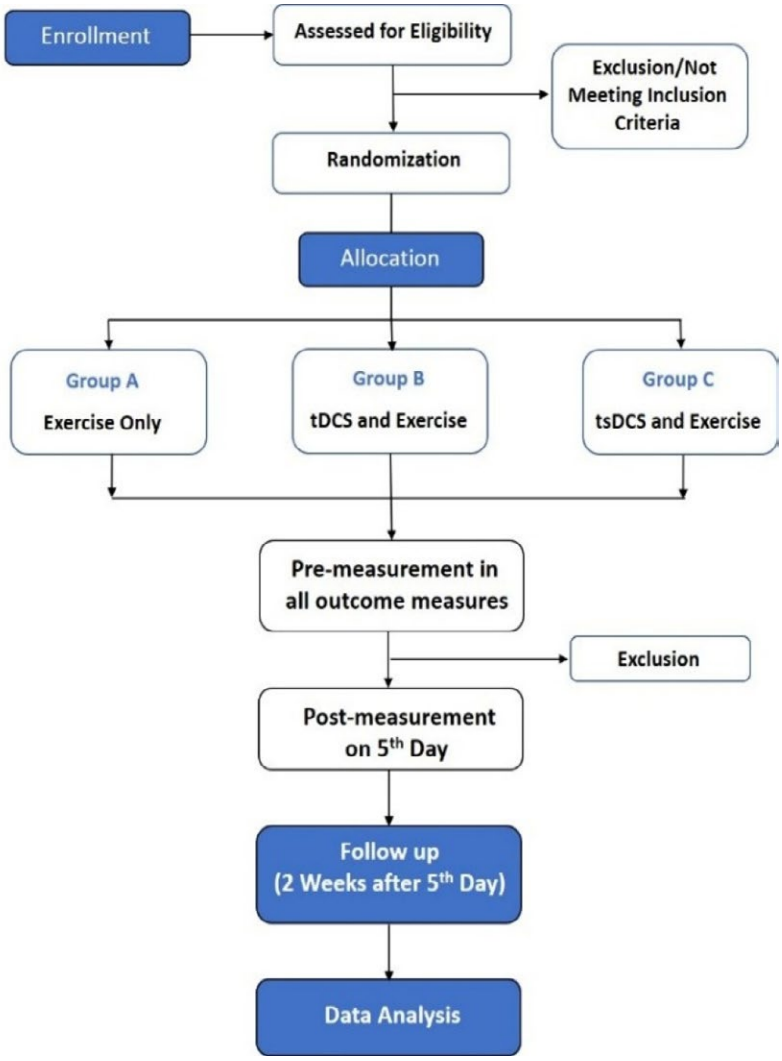
Given the potential of these stimulation-based intervention techniques, the purpose of this study is to evaluate how well TDCS and TSDCS work in individuals suffering from cervicogenic headaches as supplements to traditional exercise therapy. The research will assess their impact on pain levels, neck mobility, functional status, and disability scores. By evaluating whether TDCS or TSDCS provides superior benefits in conjunction with exercise, this research seeks to enhance current rehabilitation strategies for CGH. The findings may contribute to the growing body of evidence supporting the application of non-invasive neuromodulatory electrical techniques in musculoskeletal care and create a foundation for more targeted, alternatives for non-invasive treatment of cervicogenic headaches in people.

2. Method

2.1 Study design

This is a single-blind, randomized, multi-centre, parallel-group trial to compare three treatment protocols for the management of cervicogenic headache (CGH). Individuals will be randomly distributed across three different groups. Participants in group A will be administered supervised exercises for CGH. Group B will receive transcranial direct current stimulation (tDCS) in combination with exercises. Group C will receive transcutaneous spinal direct current stimulation (tsDCS) along with exercises. This clinical trial's design complies with the SPIRIT criteria (2013)[8]. A flowchart for the study process is shown in figure 1.

Figure 1. Flowchart illustrating the study process based on SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines[8]. The diagram outlines participant enrolment, randomization, intervention allocation, follow-up, and data analysis



Source: the authors (2025).

2.2 Setting

Ninety-nine participants with episodic CGH referred to various physiotherapy outpatient departments of Sardar Bhagwan Singh University will be recruited into this trial.

2.3 Inclusion and exclusion criteria

Participants must meet the updated diagnostic standards for cervicogenic headache (CGH) established by ICHD-3 to be eligible[9]. To be eligible for the trial, patients need to demonstrate: (1) cervicogenic headache with clinical or imaging evidence; (2) temporal headache that developed with the onset of a cervical disorder; (3) limited cervical range of motion (CROM); (4) aged between 18 and 44 years; (5) can be of any sex/gender; (6) must score at least 4 out of 10 on the average numeric pain rating scale (NPRS); (7) and a headache disability score of ≥ 40.

Patients were excluded from the study if they met any of the following criteria: (1) presence of other primary headaches such as migraines or tension-type headaches; (2) bilateral headache presentation; (3) red flag conditions including tumor, fracture, metabolic disorders, rheumatoid arthritis, osteoporosis, resting blood pressure greater

than 140/90 mmHg, or prolonged use of steroids; (4) two or more positive neurological signs indicative of nerve root compression; (5) diagnosis of cervical spinal stenosis; (6) bilateral symptoms in the upper limbs; (7) evidence of CNS involvement; (8) history of surgical procedures involving the head or neck; or (9) treatment received for head or neck pain within the past three months; (10) subjects who are pregnant (11) any skin condition. The calculated sample size was 96 subjects (i.e.32 subjects per group). It was increased to 99 in total (33 per group) to account for an overall dropout rate of 10–15%.

2.4 Consent process

An informational document detailing the study protocol will be given to participants, together with details about the type of the intervention, the duration of the study, potential risks and benefits, and assurances on voluntary involvement and the freedom to discontinue participation at any time. Privacy of all personal data will be maintained. It will clearly inform that, in case of any unfavourable results, there will be no compensation. Even though the results of the study may be made public, the participants' identities will be kept anonymous. After signing the informed consent, a research assistant will collect their demographic data and perform the initial screening after recruitment.

The study is conducted in accordance with the ethical guidelines of the Indian Council of Medical Research (2017) for biomedical and health research involving human participants; in accordance with the principles of good clinical practice; the medical research involving human subjects act; and the declaration of Helsinki (revised in 2013).

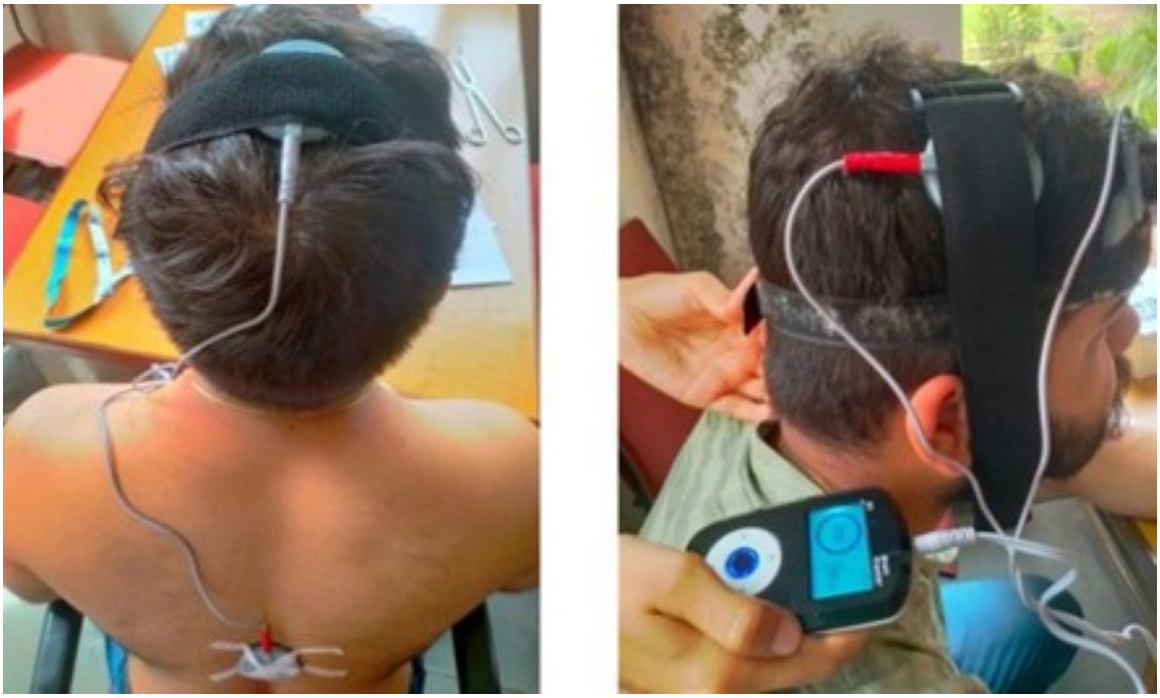
2.5 Intervention

Each subject will receive five treatment sessions per week, with each session lasting for about 30 minutes. All interventions will be given by the principal researcher to maintain consistency and protocol adherence. Treatment will be discontinued if a subject withdraws consent, experiences increased discomfort or agony brought on by the procedure or acquires any contraindication while the treatment is underway during course of treatment or receives any other form of physiotherapy during the study.

Group A will be given a supervised exercise program for five consecutive days, focusing on strengthening and mobilizing the scapulothoracic and neck muscles, along with posture correction exercises. All exercises will be performed within a pain-free range and gradually progressed based on the individual's tolerance and improvement. In addition to these supervised sessions, participants will receive an exercise regimen to follow at home consisting of the same exercises performed during treatment sessions.

Group B will receive transcranial direct current stimulation along with the supervised exercise program. TDCS will be administered with a battery-powered device (Brain Premier E1) for five days in a row using two circular saline-soaked electrodes, each 1.5 inches (≈ 3.8 cm) in diameter (area ≈ 11.4 cm^2). A constant current of 2 mA will be applied for 20 minutes per session, with a fade-in and fade-out time of 30 seconds each, corresponding to a current density of ≈ 0.175 mA/cm^2 [5]. Jobin et al. (2025) indicated that using smaller electrodes enhances the focality of stimulation while keeping current density within established safety limits in tDCS and tsDCS protocols, followed by exercises[10]. TDCS treatment session will include a safety questionnaire to gauge any negative effects. M1 will receive anodal stimulation, and the supraorbital region will receive cathode stimulation. M1 will be identified using the 10/20 EEG system. C3 (left hemisphere) and C4 (right hemisphere) are the coordinates for M1 and Fp2 for supraorbital area[11]. Placement of electrodes is selected based on previous studies on effects of tDCS on migraine and chronic pain. Previous research has demonstrated that M1 activation via the descending pain modulatory network decreases the connection between the prefrontal pain centres and the thalamus, resulting in pain reduction. Additionally, it stimulates the somatosensory cortex, which is implicated in pain perception and leads to enhanced motor learning and improved response to exercise therapy, both of which reduce pain[12].

Figure 2. Showing electrode placement for tsDCS and tDCS



(A) (B)

Source: the authors (2025).
(A) For tsDCS: The cathode will be positioned over the somatosensory cortex (2 cm from the CZ region of 10/20 EEG system), and anode will be placed over T10 with the main axis parallel to the spinal cord.
(B) For tDCS: The anodal electrode is placed over the M1 (primary motor cortex), and the cathodal electrode over the Fp2 for the supraorbital region.

Group C will receive tsDCS along with the supervised exercise program. tsDCS will also be administered using the same electrodes and device (Brain Premier E1) for five consecutive days (2 mA for twenty minutes with a thirty-second fade-in and fade-out time), followed by exercises. The cathode will be positioned over the somatosensory cortex (2 cm from the CZ region of the 10/20 EEG system), and the anode will be placed over T10 with the main axis parallel to the spinal cord[7]. A safety questionnaire will be filled after tsDCS session to measure adverse effects. In addition to receiving either tDCS, tsDCS, or the supervised exercise program, all three groups will be given an identical at-home workout regimen, with identical instructions and exercise repetition counts. Participants will also be provided with a log sheet to track their adherence to the home program. They will be instructed to continue their regular routines within pain-free limits and to avoid any movements or tasks that may aggravate their symptoms.

2.6 Randomization and blinding

This study follows a single-blind design. The therapist administering tDCS and tsDCS interventions will not be blinded due to the differences in electrode placement and stimulation parameters between the techniques. However, the outcome assessor will be independent and blinded to group allocation to ensure unbiased data collection. computer-generated number sequence will be used for randomization. Sequentially numbered, opaque, sealed envelopes will be used for allocation under the guidance of a research assistant. Each participant will be randomly allocated to one of three groups: First group will be given supervised exercise program; Group B will receive tDCS in addition to supervised exercise program and Group C will receive tsDCS in addition to supervised exercise program.

2.7 Outcome measures

The primary outcome measures include headache disability index (HDI), a 25-item validated questionnaire developed by Dr. Jacobson GP, Ramadan NM, et al. to assess the impact of headache and its treatment on daily living. It comprises functional and emotional subscales to measure disability associated with chronic headaches[13]. Numeric pain rating scale (NPRS), a widely used validated 11-point scale ranging from 0 (no pain) to 10 (worst imaginable pain). It will be administered in paper format. NPRS is a reliable tool for assessing pain intensity, with a minimal clinically important difference (MCID) of 2 points[14].

Secondary outcomes measures: the Pressure Pain Algometer (PPA) will be used to quantify pressure pain thresholds (PPT) in muscles. PPT is defined as the minimum pressure that elicits pain, providing an index of mechanical pain sensitivity. A handheld algometer with a 1 cm² probe will be applied perpendicularly to the skin until the participant reports the first sensation of pain. PPTs will be measured bilaterally at the following sites: (1) anterior temporalis muscle, (2) upper trapezius tender point, and (3) the area between C0 and C1. The Headache Impact Test (HIT-6) is a brief, validated tool for assessing the impact of headaches on daily functioning, including work, school, home, and social life[15]. It has strong psychometric properties for measuring headache-related disability. The minimal clinically important change (MCIC) is −8 points on a 42-point scale in patients with chronic tension-type headache (CTTH). Traditional pain measures like frequency, intensity, and duration may not fully reflect the disability caused by headaches, especially in chronic cases. Therefore, assessing the functional impact is essential[16].

Cervical spine range of motion (ROM)—including flexion and extension (sagittal plane), lateral flexion (frontal plane), and rotation (transverse plane)—will be measured pre- and post-intervention (Day 5) using an Android smartphone app. Cervical ROM assessment is a key component in physiotherapy for neck pain, helping quantify physical impairment and support diagnosis. Smartphone apps, using embedded accelerometers and magnetometers, offer valid and reliable measurements for cervical ROM and are cost-effective tools for clinical and research use[17]. Outcome measures will be documented at baseline (Pre-Intervention), after five days of intervention, and at two-week follow-up. Patients will be blinded to the intervention and group allocation.

2.8 Participant timeline

The schedule of enrolment, interventions, and assessments is shown in table 1, following SPIRIT recommendations. Outcome measures will be assessed at baseline (Pre-Intervention), after the 5-day intervention period, and at a 2-week follow-up.

Table 1. Enrolment, intervention and assessment

Study Period	Enrolment (Pre-Intervention)	Allocation	Intervention (Days 1–5)	Post-Intervention (Day 5)	Follow-up (2 Weeks)
Eligibility Screen	✓				
Informed Consent	✓				
Randomization		✓			
Intervention: tDCS / tsDCS / PT			✓		
NPRS	✓			✓	✓
HDI	✓			✓	✓
HIT-6	✓			✓	✓
PPT	✓			✓	✓
CROM	✓			✓	✓

Source: the authors (2025).

2.9 Sample size calculation

A sample size of 96 subjects will be required based on a prior sample size calculation using Andrew Fishers Formula for a one-way ANOVA with three independent groups (tDCS, tsDCS, and supervised exercise therapy). The primary outcome variable used for the calculation was the Numeric Pain Rating Scale (NPRS), based on prior clinical studies that reported moderate to large treatment effects using non-invasive stimulation techniques in chronic pain populations. A medium effect size (Cohen's f = 0.30) was assumed, with a significance level (alpha) of 0.05 and statistical power set at 80% to detect meaningful between-group differences. This yielded a minimum required sample size of 96 participants (32 per group). To account for an anticipated dropout rate of approximately 10%, the total sample size was increased to 99 participants, with 33 individuals allocated to each group.

2.10 Data collection and management

Competent research assistants will handle all data entry. The designated statistician will have access to the final trial dataset, and the chief investigator will oversee the maintenance of data confidentiality and storage.

2.11 Statistical analysis

All statistical analyses will be conducted using IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics will summarise demographic variables (age, gender, occupation) and baseline measures (CROM, HIT-6, HDI, NPRS, PPT). Data normality will be assessed using Kolmogorov–Smirnov and Shapiro–Wilk tests. For normally distributed data, one-way ANOVA will compare between-group differences, and repeated measures ANOVA will analyse within-group changes over time. A 95% confidence interval and a significance level of $p < 0.05$ will be applied. Post hoc tests will identify specific group or time-point differences where required.

3. Discussion

As far as we are aware, this will be the first trial to directly compare tDCS and tsDCS combined with exercise in CGH, while previous studies have investigated tDCS combined with exercise in this population[18–19]. When compared to traditional physiotherapy treatment, a pragmatic effectiveness research design will allow for a better understanding of the genuine impact of these neurostimulation techniques in lowering several headache parameters over a duration of two weeks. Exercise alone has been shown to reduce pain intensity, improve cervical range of motion, and enhance functional outcomes in patients with cervicogenic headache, supporting its inclusion as a standard intervention in all groups[20].

A homogeneous sample of headache sufferers with characteristics of upper cervical articular dysfunction who may respond to these treatments may be a strength of our study, but recruitment will be difficult because of the stringent inclusion criteria. There have been no documented adverse side effects from the use of tDCS or tsDCS that target the upper cervical spine in previous headache therapy trials other than mild tingling, itching, and headache. Consequently, it seems that this method is safe for clinical application[21].

Several RCTs and systematic reviews have studied the use of tDCS in chronic pain and migraine, but they have not particularly addressed its role in CGH. For example, DaSilva et al. demonstrated that anodal tDCS over the motor cortex reduced pain intensity and frequency in chronic migraine patients[22]. Similarly, a Cochrane review by O'Connell et al. concluded that tDCS may benefit some musculoskeletal pain conditions such as fibromyalgia and low back pain[23]. Furthermore, recent meta-analyses in migraine highlight the potential additive effect of non-invasive neuromodulation combined with exercise, emphasizing the relevance of examining combined interventions in headache populations[24–26].

The tsDCS, on the other hand, is an emerging technique with limited application in clinical conditions. Cogiamanian et al. showed that anodal tsDCS over the thoracic spine could modulate spinal excitability in healthy individuals[27]. Matsumoto et al. later applied tsDCS in patients with knee osteoarthritis and found increased pain thresholds and improved pain tolerance[28]. However, no RCT has studied the use of tsDCS over the cervical spine in patients with CGH, making this research an original contribution. In this study, tsDCS was selected because it can modulate spinal excitability and segmental nociceptive pathways, which are directly relevant to the pathophysiology of cervicogenic headache.

Evidence from studies in other musculoskeletal conditions, such as knee osteoarthritis, suggests that tsDCS can increase pain thresholds and reduce hypersensitivity, indicating potential benefits in cervical pain management[27,28]. To our knowledge, no previous studies have applied tsDCS in individuals with CGH using pressure pain thresholds as an outcome measure, emphasizing the originality of the current trial in assessing changes in both local and widespread mechanical pain sensitivity.

The study protocol's limitations need to be addressed. Effects of neuromodulation vary both intra-individually and inter-individually. Such findings have been reported for both tDCS and tsDCS techniques[29,30]. Factors like brain-derived neurotrophic factor (BDNF) polymorphisms present in the individuals to be treated may affect the neuroplasticity and clinical effects of tsDCS and other stimulation modalities[30]. Results could vary depending on how central nociceptive signal transmission is affected. Medication used by patients may have biochemical effects that may alter the outcome. A computational modeling study to optimize current delivery will not be conducted.

Effects of tsDCS and tDCS on hypersensitivity have been indirectly evaluated in various peripheral musculoskeletal conditions using Pressure Pain Threshold (PPT) as an objective measure. PPT is a reliable indicator of mechanical hyperalgesia and is frequently used to assess changes in pain sensitivity associated with central and peripheral sensitization. In patients with chronic musculoskeletal pain, including those with cervicogenic headache, hypersensitivity both at the site of pain and in remote areas is a well-documented feature, attributed in part to altered central pain processing mechanisms[31]. Previous studies have demonstrated that tDCS applied over the motor cortex can increase PPT values and reduce perceived pain by enhancing descending inhibitory pathways. Similarly, tsDCS has shown potential in modulating spinal excitability and reducing segmental hypersensitivity, as evidenced by increased PPT in treated regions[32]. These neuromodulators may be particularly beneficial in cervicogenic headache, where both peripheral nociceptive input from cervical structures and central sensitization play a role in symptom persistence. Incorporating PPT as an outcome measure in the present study will thus allow for indirect assessment of changes in local and widespread hypersensitivity, providing insight into the analgesic mechanisms of tsDCS and tDCS in CGH management. This study aims to add valuable insight to the existing research on tsDCS and tDCS as treatment options for headache management. By focusing on their role in the non-pharmacological care of cervicogenic headache, the findings may help guide more informed and effective clinical decisions for both healthcare providers and patients.

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Patient and public involvement

Patients and the public were not involved in the design, conduct, reporting, or dissemination plans of this research.

Trial status

This protocol is Version 1.0, finalized on 21 July 2025. Participant recruitment began on 15 August 2025 and is expected to continue through November 2025. Final follow-up assessments are planned to conclude by 15 February 2026. No participants have been recruited at the time of this submission.

Authors' contributions

The authors declared that they have made substantial contributions to the work in terms of the conception or design of the research; the acquisition, analysis or interpretation of data for the work; and the writing or critical review for relevant intellectual content. All authors approved the final version to be published and agreed to take public responsibility for all aspects of the study.

Competing interests

No financial, legal, or political conflicts involving third parties (government, private companies, and foundations, etc.) were declared for any aspect of the submitted work (including but not limited to grants and funding, advisory board participation, study design, manuscript preparation, statistical analysis, etc.).

Data availability statement

As this is a study protocol no data has been generated or analysed till now.

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