Research Article

Neck exercises Versus Myofascial Release for Chronic Tension-Type Headache and Posture: A Randomized Controlled Trial Protocol

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Running title: Neck Exercise vs. Myofascial Release for Headache & Posture

Abstract:
Background: Tension-Type Headache (TTH) is recognized as the most common type of headache worldwide causing significant psychological, physical, financial, and societal consequences. One of the activating factors of Chronic Tension-Type Headache (CTTH) is cervical dysfunction such as Forward Head Posture (FHP) leading to suboccipital muscle tenderness and Deep Neck Flexor (DNF) muscles weakness. Physiotherapy affect these patients through two mechanisms: top-down (e.g., DNF exercises) and bottom-up (e.g., suboccipital Myofascial Release (MFR)), but their relative effectiveness in reducing headache-related parameters remains unclear.

Methods: This randomized, parallel-group, assessor blind, double-dummy clinical trial includes 44 participants divided into two groups: one receiving MFR with sham exercise and the other DNF exercises with sham MFR. Interventions will be carried out over four weeks, followed by a six-week follow-up. Primary outcomes include headache intensity and craniovertebral angle (CVA), while secondary outcomes assess headache frequency, duration, pressure pain threshold, disability and quality of life.
Conclusion: This study aims to compare the effectiveness of a top-down versus a bottom-up physiotherapy approache in CTTH patients with FHP. If a significant difference is found, the study will identify the superior approach for short- and medium-term outcomes, providing valuable insights for clinicians and health managers.
Keywords: Tension-Type Headache, Posture; Myofascial Release Therapy; Exercise

1. Introduction

1.1. Background and rationale:

Tension-Type Headache (TTH) is recognized as the most common type of headache worldwide. Epidemiological studies in developed nations estimate that the prevalence of TTH ranges from 35% to 78% among adults (1, 2). This condition imposes a significant burden of disability, reduces quality of life, and leads to substantial medical expenditures (3, 4). According to the 2018 Global Burden of Disease study, TTH ranked as the third most prevalent condition out of 328 diseases and injuries analyzed across 195 countries from 1990 to 2016, affecting approximately 1.89 billion people (5). Experiencing this condition, particularly Chronic Tension-Type Headache (CTTH), significantly diminishes quality of life (6). This neurological disorder exhibits a higher prevalence in women (5:4) and reaches its peak occurrence between the ages of 30 and 39 (5).

According the International Headache Association classification "CTTH is bilateral pressure type pain with mild to moderate intensity that occurring on ≥15 days/month on average for >3 months, lasting for hours to days. This is not aggravated by routine physical activity; Only one symptom (photophobia, phonophobia, or mild nausea) is allowed; no moderate or severe nausea/vomiting" **(7)**

According to the International Association for the Study of Pain (IASP), CTTH is classified as nociplastic pain resulting from altered nociceptive processing in the nervous system without obvious tissue damage or a specific neurological disease. This type of pain involves changes in sensory processing, increased activity in central pain pathways, and reduced inhibitory pain control, causing central sensitization(8).

Although the precise cause of this type of headache is not yet known, there are activating factors (e.g. stress or hormonal disorders)(9, 10); another factor is musculoskeletal disorders of the cervical spine. Marcus et al. classified these disorders into three categories: mechanical, musculoskeletal(muscle tenderness), and postural disorders (11). The Forward Head Posture (FHP) as most common postural disorder of the cervical spine which has increased in prevalence with lifestyle changes (12). Continuous activity of the extension in the upper cervical region may be a reason for activation of the Trigger Points(TrPs) and increase the suboccipital muscle tension (13).

Fernández et al. found a strong link between suboccipital active TrPs, FHP, and CTTH (14). Patients with active TrPs experienced more headache intensity and frequency than those with latent TrPs (14). Additionally, greater FHP intensity correlated with higher headache duration and frequency, as well as the occurrence of active TrPs in the suboccipital region (14). This

suggests that increased suboccipital muscle tension may amplify nociceptive signaling to the trigeminal nucleus caudalis, lowering the Pressure Pain Threshold (PPT) and contributing to central sensitization (14).
TTH is treated symptomatically and to prevent recurrence (15). The most common treatment for TTH is pharmacotherapy; however, due to the side effects of medications and the possibility of Medication-Overuse Headache (MOH), non-pharmacological treatments such as physiotherapy are recommended (16). Most physiotherapy treatments focus on reducing muscle tension such as exercises, manual therapy and dry needling (17).
Fernández et al. emphasized that effective headache management should go beyond addressing tissue-based impairments (bottom-up approaches) and incorporate strategies that normalize the Central Nervous System (CNS) sensitization (top-down approaches)(18). Among various bottom-up interventions, soft tissue therapies are effective in treating this type of headache (18). All soft tissue-based interventions designed for reduction of muscle tension by delivering appropriate proprioceptive input to the CNS (19). Otherwise, exercise including aerobic and Localized exercises is among the key top-down approaches for managing chronic pain (20). The localized exercises may be a more effective choice for managing TTH than aerobic exercises (18, 21). The MFR engages bottom-up mechanisms by stimulating fascial mechanoreceptors, optimizing suboccipital muscle and fascia alignment, increasing local blood flow, and reducing hypoxia, ultimately normalizing input to the Trigemino-cervical Nucleus Complex (TNC) (22-24).The Deep Neck Flexors (DNF) exercises utilize top-down mechanisms by activating descending inhibitory pathways, enhancing motor unit recruitment, and improving motor control to reduce pain through normalization of CNS sensitization (24, 25).
Previous studies have examined the effect of exercise and suboccipital MFR separately in these patients, and the effect of combining these therapies, with limitations such as the lack of sham treatment and defective blinding and partial reporting of outcomes (26-29). Owing to the limited methodological quality of the studies, the level of evidence for these types of treatments is low (30); In addition, DNF exercises as an active treatment are more effective than inactive treatments for chronic neck pain and Cervicogenic headache, but studies on their effect in CTTH patients are limited (31-33). Also, the DNF exercises is the most effective treatment in the top-down interventions group, and the MFR is one of the effective treatments in the bottom-up interventions group and to the best of the authors' knowledge, studies have not published to compare this two isolated treatments from this perspective (18).

1.2. Objectives:

The main objectives are to evaluate the effectiveness of 12-session DNF exercise in comparison with suboccipital MFR on the headache intensity and Craniovertebral Angle (CVA) in adults with CTTH and FHP in the short and medium term. The secondary objectives are to assess the changes in the aforementioned treatment in outcomes such as headache duration and frequency, disability, quality of life, and PPT.

2. Materials and Methods

2.1. Trial design:

The present study will be a randomized, parallel-group, single-blind and assessor blinding, double-dummy (a group receives one active and one placebo treatment and the other group in reversed), and controlled trial with superiority framework that has a 1:1 allocation ratio: Group A (MFR plus sham DNF exercise) and group B (DNF exercise plus sham MFR). The treatment will

last 4 weeks, with assessments conducted pre- and post-treatment, followed by a 6-week follow-up. The overall study structure is exhibited in Figure 1. The projecting of this study adhered to the guidelines of the Consolidated Standards of Reporting Trials (CONSORT) and Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (Supplementary File S1).

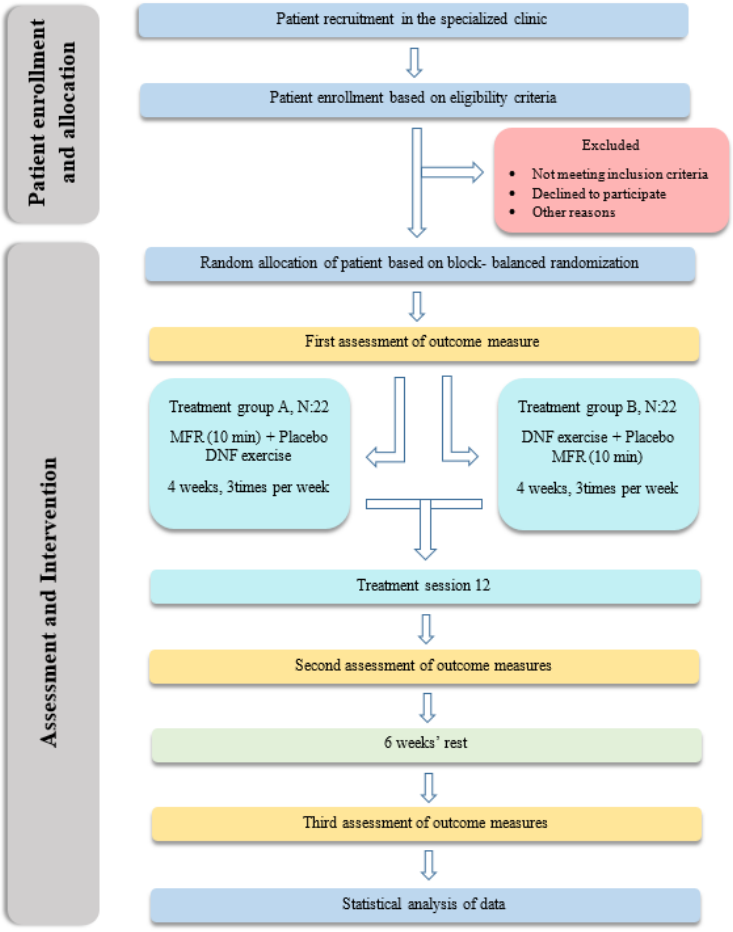

Figure 1: Patient Timeline Flowchart (MFR:myofascial Release; DNF:Deep Neck Flexor)

2.2. Study setting:

The trial will be carried out in the Physiotherapy Department of the School of Rehabilitation Sciences of Iran University of Medical Sciences in Tehran, Iran. Participants will be recruited through social media, neurology clinics, and leaflets distributed. Then a face-to-face meeting will be scheduled with eligible volunteers to confirm their diagnosis.

2.3. Eligibility criteria:

The inclusion and exclusion criteria have been noted in Table 1.

The assessor will provide all eligible participants with information about the study, and take the signed written Informed Consent (IC) under the Ethics Committee of Iran University of Medical Science's guidelines (Supplementary File S2). Additionally, the assessor will provide the participants with a background information form will characterize the demographic data and

anthropometric data and also, the clinical history of the headache. The lateral view photos of the participants taken after measuring the CVA will be deleted in the presence of the participants.

Table 1: Eligibility Criteria (ICDH: International Classification of Headache Disorders)

Inclusion Criteria	**Exclusion Criteria**
1- Age between 18 and 55 years **2- Confirmed diagnosis of Chronic Tension-Type Headache Based on ICHD-3** **3- Craniovertebral angle ≤ 49 degrees** **4- Suboccipital muscles trigger points** **5- ability to understand and read Persian language**	1- Participants with other type of headache 2- Pain provocations with head movement or routine physical activity 3- Severe pain or significant limitation in cervical spine range of motion 4- History of cervical spine trauma 5- Prior interventions, including injections, surgery, severe disc protrusion, or cervical/shoulder fractures impacting treatment 6- Metabolic or Neurological disorders (e.g. Bow hunter's syndrome or epilepsy) 7- Laxity of cervical soft tissues 8- Use of Narcotic analgesics or participants with the medical overuse headache 9- Receiving physiotherapy interventions for headache within 6 months preceding treatment initiation 10- Contraindications to manual therapy include: (a) Presence of substance or alcohol abuse; (b) Haphephobia (c) Symptoms become more bothersome with palpation 11- Pregnancy 12- Severe anxiety according to the Spielberger State-Trait Anxiety Inventory 13- Failure to attend two or more consecutive treatment sessions 14- Alter the type and dosage of prophylactic medication throughout the trial

2.4. Interventions:

Due to the present study being a double-dummy clinical trial; Group A (MFR and sham DNF exercise) and group B (DNF exercise and sham MFR). The intervention will be administered over four weeks, thrice weekly, for a total of 12 sessions. If participants will be unable to attend a scheduled session, the "Compensatory session" for maintain the study's integrity.

2.4.1. Interventions description:

Group A (suboccipital MFR and sham DNF exercise):

These participants will receive the suboccipital MFR that was performed according to the previous literatures (34, 35). While the participant rests in a supine position with eyes closed, the therapist will position their hands under the participant's head, with the tip of fingers placed in the space between the occipital condyles and the second cervical vertebra. The therapist's fingers will be stabilized at a 45° flexion at the MP and IP joints, while the thenar eminences support the head. Treatment begins with soft tissue responses, such as localized softening and increased head weight. The therapist will then apply gentle traction to the suboccipital soft tissues through forearm supination, followed by cranial-oriented traction (Figure 2). Pressure will be adjusted to reduce muscle tension and achieve balance on both sides. The procedure will last 10 minutes, with pain levels monitored to ensure they do not increase by more than 2 points on the Visual Analog Scale (VAS).

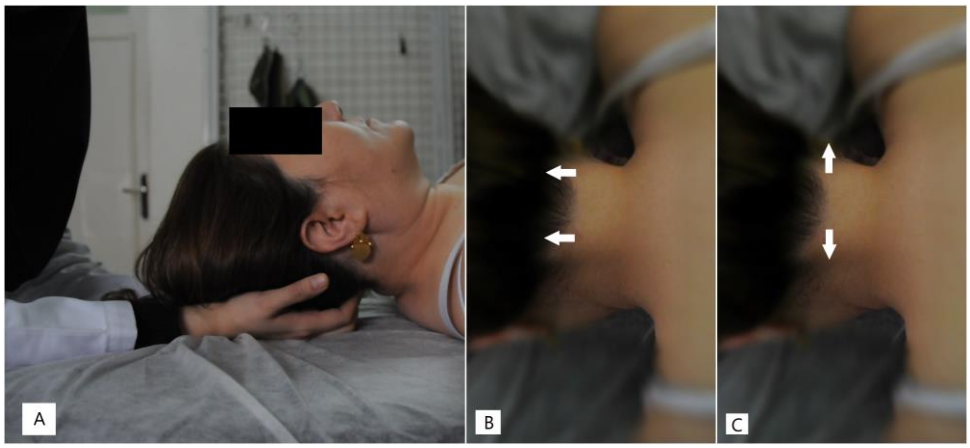

Figure 2: Suboccipital Myofascial Release (A: Position of patient and therapist, B: Caudocephalic direction of pressure, C: Horizontal direction of pressure)

This group also receives a sham DNF exercise by using Pressure Biofeedback Unit (PBU) (Stabilizer, Chattanooga, DJO Global, USA). Given that the minimum detectable change with PBU is 15 mmHg (36); after lying in supine position, placing the airbag under the occipital and inflating it to about 11 mm Hg, the participant will be asked to raise the sphygmomanometer scale to about 12 mm Hg by nodding the head.

Group B (DNF exercise and sham suboccipital MFR):

These Participants will execute the DNF exercise using a PBU in the supine position, with the airbag positioned beneath the occipital bone and inflated to 20 mmHg. The participant will be asked to do the chin-tuck, aiming to maintain a steady target pressure on the PBU (Figure 3). The exercise will be repeated for 3 sets, with the target pressure increasing by 2 mm Hg per set. The pressure increases from 20 to 32 mm Hg over the 4-week treatment period (exercise schedule in supplementary File S3). Each target will be maintained for 10 seconds and repeated 10 times, with a 5-second rest between repetitions and a 2-minute rest between sets.

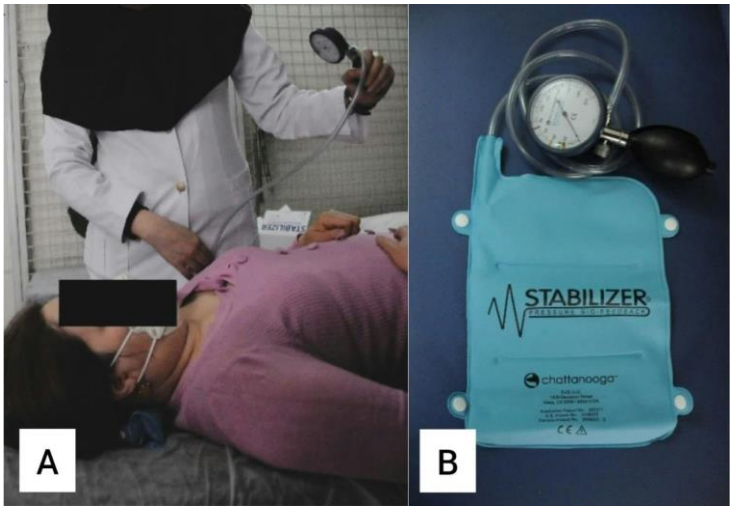

Figure 3: Deep neck flexor exercise procedure (A: Position of patient and therapist, B: Pressure Biofeedback Unit)

The other intervention in the second group is the sham MFR. The therapist's fingers are placed only between the occipital bone and the second cervical vertebra and a superficial touch without any pressure will be applied. Similar to the opposite group, the sham treatment in this group will last 10 minutes.

Participants may can leave the study at any time and for any reason without consequences. They are asked to avoid physiotherapy for headaches at other centers, not miss more than two consecutive sessions, and refrain from performing exercises at home between sessions. The dosage and type of prophylactic medication should remain unchanged throughout the trial. Increasing pain by more than 2 VAS scores post-intervention is another criterion for discontinuing interventions.

To enhance motivation, treatments are free, and participants can receive the real form of sham treatment after the study. Equal-value gifts are provided after the first session and follow-up. Regular researcher contact ensures participants can report any issues.

2.5. Outcomes:

2.5.1. Primary outcomes:

Headache Intensity: The mean average headache intensity will be measured based on the VAS (0-10 cm). In the initial evaluation, Participants will be asked to record intensity during the past month in the Headache Questionnaire and this outcome will be assessed using a daily basis headache diary at post-treatment and 6 weeks' follow-up.

Craniovertebral Angle: Another primary outcome is FHP based on the CVA will be assessed Utilizing the photographic assessment of body posture from a lateral view, captured with a camera (smartphone iPhone 13 pro, Apple Inc.) at a 1.0x magnification ratio. The CVA less than 49 degrees are known as FHP .This method has high reliability for the assessment of CVA (ICC = 0.93) (37). In this approach, light-reflective markers are placed on the spinous process of the C7 vertebra and the auricular tragus. The participant sits on a chair, aligned with their shoulder, positioned 100 centimeters from a fixed camera mounted on a tripod at a height of 120 centimeters. The angle formed between the line from the ear tragus to the C7 spinous process and a horizontal reference line is measured using Kinovea software as CVA. Kinovea is a motion

analysis software that after importing pictures, zooming and adjusting points can export angles (ICC=.99) (Figure 4) (38).

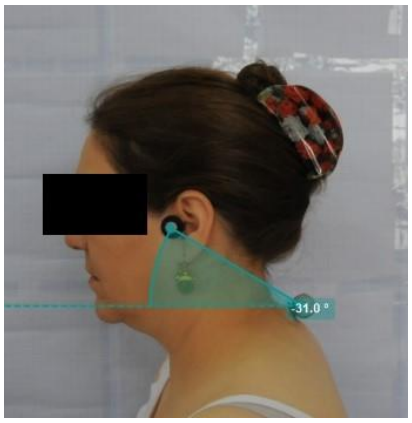

Figure 4: Craniovertebral Angle assessment by using Kinovea software)

2.5.2. Secondary outcomes:

Headache Duration: The pain duration will be measured according to duration of headache episodes (hours/day). This outcome will be assessed, like headache intensity, by the headache questionnaire in the baseline and the headache diary in the next assessments.

Headache Frequency: The headache frequency will be determined according to the number of headache episodes (days/week). This outcome will be assessed like two aforementioned headache parameters.

Disability: This outcome will be assessed using the Persian version of the Henry Ford Hospital Headache Disability Inventory (HDI) questionnaire (Supplementary file S4) (39). This questionnaire consists of 25 questions, covering both functional and emotional aspects. The internal consistency of this for the whole questionnaire with Cronbach's alpha is 0.91 (ICC = 0.97)

Quality of life: Quality of life will be subjectively assessed by the Persian version of Headache Impact Test-6 (HIT-6) questionnaire (ICC= .77) (Supplementary file S5) (40). This brief questionnaire contains 6 questions that reflect the last 4 weeks. Scores range from 36 to 78, with higher scores denoting a more profound effect on quality of life. The reliability of the questionnaire has been reported as 0.8 (retesting), 0.9 (peer forms), and 0.89 (internal consistency).

Pressure Pain Threshold: The suboccipital muscles PPT will measure in the prone position on a Manual Physical Therapy Table and pressure will be exerted by an SF-500 diagram pressure dynamometer (SUNDOO Inc, Zhejiang, China) vertically with a 1 cm^2 cross-sectional area and at a rate of approximately 1 kg / cm^2, applied below the occipital bone and lateral to the upper trapezius muscle bilaterally (Figure 5). Pressure will be measured when the sensation changes from pressure to pain. The assessment will be repeated three times with 30-second intervals to prevent habituation, and the mean will be calculated (41).

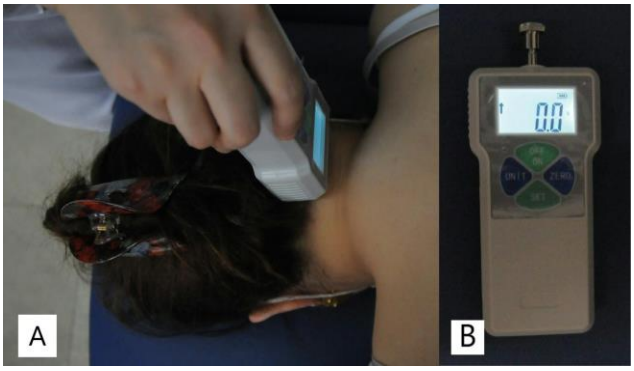

Figure 5: Pressure Pain Threshold assessment (A: Position of patient and therapist, B: Pressure dynamometer tool)

In general, both groups will be treated for 12 sessions over 4 weeks (3×/week) and study outcomes including pain parameters, FHP, disability, quality of life and PPT. The headache parameters will be evaluated at the baseline session by headache questionnaire and these will be evaluated at post-treatment assessments using a headache diary. Other primary and secondary outcomes will be measured as like as baseline assessment.
Furthermore, anxiety status will be determined with the Persian version of the Spielberger State-Trait Anxiety Inventory (STAI) questionnaire in the baseline assessment session.
Study's SPIRIT schedule of enrolment, interventions, and assessments checklist is presented in Table A1(Appendix file).

2.6. Sample size:
Sampling for this study will be simple, continuous, and from the available samples. The samples will be referred by a neurologist. Because already no established Minimal Clinical Important Difference (MCID) for CVA exists in CTTH patients; Therefore, in this trial MCID is considered equivalent to 0.5 pooled SD to determine the sample size. This was measured using the data of the CVA outcome of a study conducted by Eunsang Lee in 2019 (26).
The sample size was determined using the Sampsi command in Stata 16.0 software (Figure B1(Appendix file)). This estimate necessitates 30 patients (15 per group) to achieve 80% statistical power at a 5% significance level for an independent samples t-test with an effect size of 0.25. We will aim to enroll 44 participants to compensate for an estimated 30% of dropouts.

2.7. Recruitment and allocation:
Participants will be recruited via social media, neurology clinics, and bulletin board leaflets. The voluntary patients will be referred to the physical therapy clinic of the School of Rehabilitation Sciences of Iran University of Medical Sciences for further evaluation and enrollment. Finally, those who are compatible with the inclusion criteria of the study can be enrolled in the trial.
After enrollment, participants will be randomly assigned to two treatment groups: the DNF exercise group and the MFR group in a 1:1 ratio using block balanced randomization method.
The randomization process was conducted according to computer-generated randomization, using block sizes of four-digit including even and odd numbers that have 2 even digits and 2 odd digits; Each digit represents a participant, with even numbers assigned to the DNF exercise group and odd numbers to the MFR group. A third party outside the research team will conduct random assignment before the trial begins. The allocation sequence, concealed from the

outcome-assessor, will be stored in sequentially numbered opaque, sealed, and stapled envelopes that will be disclosed by the therapist.
Intervention will be exerted by a physical therapist with over five years of clinical experience who has passed the training course of MFR techniques.

2.8. Blinding:
In this study, participants and outcome evaluators will remain blinded to group allocation. Due to the intervention's nature, blinding the administering investigator will not be feasible. Participants will be unaware of the study hypothesis and their group allocation. They will not be informed regarding the specific treatments exerted on another group or the distinctions between the groups. Participants will be instructed not to reveal their treatments to the assessor or other participants until the trial concludes.
Each participant will be given an identification code and all data will be numbered with the coded ID number and stored in a drawer. Also, the data that links the patient code to other patient data, such as patients' written consent, is stored in a separate drawer that will only be accessible to the primary investigator. To enhance data management and confidentiality, all data will be digitized and securely stored in a locked file by the therapist and lateral view photos will be deleted in the same session after measuring the CVA.
Blinding was ensured through similar tactile sensations, identical clinical settings, active exercises without therapeutic effects, and assessor blinding. Participants reported their perceived treatment (MFR/Exercise/Unsure) with a confidence rating (0-10), and the results will be reported.

2.9. Statistical methods
The data analysis will be accomplished with the IBM-SPSS Statistics 27. Descriptive data will be shown as mean, median, or count (percent) depending on the data type. Normality will be verified by a Shapiro-Wilk test. Mauchly's Test will assess sphericity and Levene's test will assess variance homogeneity; Then violations will be addressed. The effects of interventions on outcomes in each group will be examined by use of a repeated measures analysis of variance (ANOVA)for between and within group comparison, with the treatment group (MFR versus exercise) as the between-participant variable and time (baseline, post, and 6-week follow-up) as the within participant variable. A 95% confidence level ($\alpha = 0.05$) and 80% study power will be used. Due to the presence of two primary outcomes in the study and three levels of comparison—pre-post, post-follow-up, and pre-follow-up—Bonferroni correction will be applied manually using the formula 0.05/ (number of comparison levels), resulting in the statistical significance level adjusted to P=0.017. Effect sizes for group differences will be determined th2rough Cohen's d, categorized as: trivial (0.01–0.2), small (0.2–0.5), large (0.5–0.8), very large (1.2–2), and huge (more than 2).(42).
The Per-Protocol analysis was chosen to address missing data and ensure a precise evaluation of treatment effectiveness.

2.10. Oversight and monitoring:
The study is a single-center trial. All activities will be performed and coordinated within the Faculty of Rehabilitation Sciences of Iran University of Medical Sciences. The conductor, the corresponding author, and other authors of this study will organize the trial's project oversight group. This team will maintain daily communication and oversee study progress and data

collection. The steering committee of the trial includes two physiotherapist authors, a headache specialist neurologist, and a statistician who will double-check and analyze data repeatedly after entering them into the software. This committee will meet monthly to discuss study procedures and the data collection process. The opinions and suggestions of the participants or members of the research team are collected and implemented in a feasibility study, and any necessary study modifications will be documented and reported.
So far, no adverse events have been reported for this type of treatment. However, if unwanted side effects are observed and reported during or after the trial, they will be mentioned in the final paper.

2.11. Protocol amendments:

Any modifications will be discussed in the monitoring committee and justified in ClinicalTials.gov and IRCT.ir after being approved by the ethics committee and will be mentioned in a separate section titled "amendments" in the final paper.
Upon trial completion, the collected data will be analyzed and published in international journals. The findings will also be presented at neurology or physiotherapy conferences.

3. Discussion

FHP may exacerbate pain following sustained upper cervical extension or a pain-avoidance posture of suboccipital muscles TrPs (26). However, this posture appears to be a common finding of chronic primary headaches (supported by moderate to strong evidence) but the association between FHP and headache parameters is debated yet (30). On the other hand, based on clinical and neurophysiological data, muscle referred pain from TrPs in the upper cervical segment, innervated by the trigeminal nerve, may contribute to widespread pain hypersensitivity and central sensitization in CTTH patients (43).
Additionally, based on the results of systematic reviews, have shown that physical therapy employing both types of top-down and bottom-up treatments has been effective in reducing the symptoms of CTTH patients by decreasing hypersensitivity of active TrPs or postural re-education programs (18, 44). This study proposes to investigate the effect of DNF exercises as a top-down intervention compared to suboccipital MFR as a bottom-up intervention on the parameters of headache, CVA, disability, quality of life, and PPT in these patients in short-term and medium-term.
So far, studies have not compared the two treatments separately in these patients from the perspective of two different mechanisms, and there is a lack of studies assessing which type of treatment affects faster and which one has a longer-lasting effect, and the low methodological quality of the conducted studies has created the need to conduct studies with a higher methodological quality.
A key strength of our study is the assessment of both dominant and non-dominant hand sides and justifying anxiety between two groups as an important trigger factor and methodological design for blinding the participants and the assessor. Another strength of this study is the comparison of the effectiveness of these interventions in the medium-term, while most previous studies examined outcomes in the short term. Also; the simultaneous use of clinical and self-report variables, allowing for broader applicability of treatment results across different target groups is another trial’s power points.

3.1. Delimitations and limitations

The study included participants aged 18 to 55 years, limiting applicability to younger populations. Due to low awareness of physiotherapy for CTTH in Iran and to minimize drop-out, headache parameters will be assessed using a questionnaire at baseline; Future studies could assess headache parameters four weeks before treatment for a more comprehensive baseline. Participants expectation bias will be reduced by reassuring participants to receive real treatment post-study, and objective measures like CVA and PPT will minimize bias. Additionally, multi-center studies with diverse populations and various headache types are recommended to improve generalizability. While key confounders like anxiety were adjusted and professional athletes excluded, future research should control for activity level and prior intervention and; also, use 3D analysis for a more accurate assessment of CVA. The hand-held dynamometer will be used to assess pressure pain threshold (PPT). While some studies support the reliability and validity of this method, there is currently no specific evidence regarding the SF-500 pressure dynamometer. Future research should evaluate its reliability and validity.

5. Conclusions

Tension-type headache is the most commonly occurring headache disorder (1, 2).This type of headache has many activating factors, one of the most important being cervical spine musculoskeletal disorders. These include mechanical, musculoskeletal (e.g. suboccipital muscle tenderness), and postural dysfunctions (e.g. forward head posture) (11). Increased suboccipital muscle contraction associated with FHP amplifies nociceptive signaling to the trigeminal nucleus caudalis, contributing to central sensitization and the transition from episodic to chronic TTH (14).

Pharmacological treatments are the primary approach for TTH but have limitations, such as side effects and the risk of medication-overuse headache (16). Consequently, non-pharmacological interventions like physiotherapy are recommended (16). Physiotherapy treatments focus on two mechanisms: top-down (e.g. DNF exercises) to normalize central nervous system sensitization, and bottom-up (e.g. suboccipital myofascial release) to enhance proprioceptive input (18).

Although prior studies have individually assessed DNF exercises and suboccipital MFR in TTH, methodological limitations, including inadequate blinding, lack of sham treatments, and incomplete outcome reporting, have reduced the reliability of the findings (26-29). Furthermore, no published research directly compares these two distinct interventions in CTTH patients with FHP. However, studies have not yet compared DNF exercises, which are considered the most effective treatment in the top-down interventions group with MFR as one of the most effective treatments in the bottom-up interventions group from this perspective over short- and medium-term periods.

This study aims to address this gap by evaluating the efficacy of DNF exercises using a PBU versus suboccipital MFR on outcomes including pain intensity, duration, and frequency; craniovertebral angle; disability; quality of life; and pressure pain threshold in patients with chronic TTH and FHP over short- and medium-term periods. This research will provide critical insights into optimizing physiotherapy interventions for TTH management, potentially guiding evidence-based clinical practices.

Supplementary Materials:

Supplementary File S1: Protocol document aligned with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines. Supplementary File S2:

Informed Consent (IC) form. Supplementary File S3: schedule of DNF exercise. Supplementary File S4: HDI questionnaire. Supplementary File S5: HIT-6 questionnaire.

Author Contributions:
Vancouver guideline authorship eligibility; project conductor, data creation, and writing the original draft, M.A.; conceptualization, methodology, supervision, review, and editing, MR.P.; conceptualization, methodology, review, and editing, M.T.; methodology, review, and editing R.S. All authors have read and agreed to the published version of the manuscript.
Funding: This study did not receive external financial support

Institutional Review Board Statement:
Registered by ClinicalTrials.gov ID: NCT05383365; under the title "Deep Neck Flexor Exercise Versus Myofascial Release of Suboccipital Muscles in Chronic Tension-type Headache".
Registered by the Iranian Registry of Clinical Trials ID: IRCT20220219054060N1; under the title "The effectiveness of deep neck flexor exercise 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" dates 2022-04-21.
Ethical approval was granted by the Research Ethics Committee of Iran University of Medical Sciences, Tehran, Iran (IR.IUMS.REC.1400.1239) approval dates: 2022-03-16

Trial Status and Protocol Version:
The current protocol version is 1 from February 16, 2023. Expected recruitment end data is July 31, 2025.

Informed Consent Statement:
All eligible participants will receive details regarding the study, and then, the written Informed Consent (IC) f in accordance with the Ethics Committee of Iran University of Medical Science, will be signed.

Data Availability Statement:
Upon completion of the trial, any requests for the final trial dataset can be sent to the corresponding author.

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Conflicts of Interest:
The authors have no competing interests to declare. This study will be conducted under the oversight of the School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran; although the mentioned center will not participate in the study design, data collection, management, analysis, interpretation, manuscript preparation, or publication decision.

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Appendix A

Table A1. SPIRIT schedule of enrolment, interventions, and assessments checklist. (STAI: Spielberger State-Trait Anxiety Inventory MFR: Myofascial Release; DNF: Deep Neck Flexor;

	STUDY-PERIOD														
	Enrolment	**Allocation**	**Post- Allocation**												**Close-out**
TIMEPOINT**	***-w_1***	**0**	***w_1***			***w_2***			***w_3***			***w4***			***W_{10}***
			t1	***t 2***	***t 3***	***t 4***	***t 5***	***t 6***	***t 7***	***t 8***	***t 9***	***t 10***	***t 11***	***t 12***	
ENROLMENT:															
Eligibility screen	X														
Informed consent	X														
Background information form	X														
STAI questionnaire	X														
Allocation		X													
INTERVENTIONS:															
[MFR + placebo DNF exs]			←	—	—	—	—	—	—	—	—	—	—	→	
[DNF exs + placebo MFR]			←	—	—	—	—	—	—	—	—	—	—	→	
ASSESSMENTS:															
[Pain Parameters]	X													X	X
[CVA]	X													X	X
[PPT]	X													X	X
[HDI]	X													X	X
[HIT-6]	X													X	X

exs: exercise; CVA: Craniovertebral Angle; PPT: Pressure Pain Threshold; HDI: Headache Disability Index; HIT-6: Headache Impact Test-6)

Appendix B

```
sampsi 48.46 49.41, sd1(0.95) sd2(0.95) power (0.95) ratio (1) post (2) method (ancova) pre (1) r01(0.3) r1(0.3)
Estimated sample size for two samples with repeated measures Assumptions:
alpha = 0.0500 (two-sided)
power = 0.9500
m1 = 48.46
m2 = 49.41
sd1 = .95
sd2 = .95
n2/n1 = 1.00
number of follow-up measurements = 2
correlation between follow-up measurements = 0.300
number of baseline measurements = 1
correlation between baseline & follow-up = 0.300
Method: ANCOVA
relative efficiency = 1.786
adjustment to sd = 0.748
adjusted sd1 = 0.711
```

Figure B1. Sampsi command in Stata 16.0 software for sample size calculation.

Supplemetary File S3: Deep Neck Flexor Exercise schedule

Sets / Weeks	Set1	Set 2	Set3
First	20 to 22	22 to 24	24 to 26
Second	22 to 24	24 to 26	26 to 28
Third	24 to 26	26 to 28	28 to 30
Forth	26 to 28	28 to 30	30 to 32

Supplemetary File S4: Headache Disability Inventory Questionnaire

پرسشنامه ناتوانی ناشی از سردرد هنری فورد

مشخصات فردی

کد فرد شرکت کننده: جنس : مرد / زن سن: شغل:

تحصیلات: شدت سردرد :ضعیف / متوسط / شدید تاریخ:

روش کار :هدف از این پرسشنامه مشخص کردن مشکلاتی است که احتمالا شما به خاطر سردردهایتان تجربه می کنید. لطفا هر گزینه را با "بله" ، "خیر" یا "گاهی اوقات" پاسخ دهید. به موارد زیر فقط با در نظر گرفتن سردردتان پاسخ دهید.

موارد(۲۵) بلی گاهی اوقات خیر

(۱) به خاطرسردردهایم احساس ناتوانی می کنم.

(۲) به خاطر سردردهایم در انجام کارهای روزانه ام محدودیت دارم.

(۳) کسی درک نمیکند که سردردها چه تاثیری بر زندگی من دارد.

(۴) فعالیتهای تفریحی خود(مانند عادات ورزشی)را به دلیل سردردهایم محدود می کنم.

(۵) سردردهایم مرا عصبانی میکند.

(۶) گاهی اوقات احساس میکنم به دلیل سردردهایم، کنترلم را از دست می دهم.

(۷) به دلیل سردرد تمایل کمی به حضوردراجتماع دارم.

(۸) همسرم با خانواده و دوستانم نمی دانند من به خاطر سردردهایم در چه شرایط سختی قرار دارم.

(۹) سردردهایم آنقدر بد هستند که حس میکنم دارم دیوانه می شوم.

(۱۰) تصورم نسبت به دنیا بر اثر سردردهایم تغییر میکند.

(۱۱) زمانی که احساس می کنم سردردی در حال شروع شدن است از بیرون رفتن واهمه دارم

(۱۲) به خاطر سردردهایم احساس ناتوانی و درماندگی میکنم.

(۱۳) از تاثیری که سردرد روی کار روزانه در محل کار و منزل دارد، نگران هستم.

(۱۴) سردردهایم در روابطم با خانواده یا دوستان تنش ایجاد می کند.

(۱۵) زمانی که سردرد دارم از بودن کنار مردم اجتناب می کنم.

(۱۶) فکر میکنم سردردهایم باعث شده به اهدافم در زندگی نرسم.

(۱۷) به خاطر سردردهایم نمی توانم خوب فکر کنم.

(۱۸) به خاطر سردردهایم دچار سفتی بدن مثل گرفتگی عضلات میشوم.

(۱۹) به خاطر سردردهایم از دورهمی های دسته جمعی لذتی نمی برم.

(۲۰) به خاطر سردردهایم زودرنج شده ام.

(۲۱) به خاطر سردردهایم از مسافرت اجتناب میکنم.

(۲۲) سردردهایم مرا گیج میکند.

(۲۳) سردردهایم مرا سرخورده میکند.

(۲۴) به خاطر سردردهایم مطالعه برایم دشوار است.

(۲۵) به سختی می ت وانم توجه ام را از سردرد دور و به سایر چیزها معطوف کنم.

با تشکر از همکاری شما

Supplemetary File S5: Headache Impact Test-6

HIT-6™
(VERSION 1.1)

تست تأثیر سردرد

این پرسش‌نامه طراحی شده است تا به شما کمک کند تا احساس خود را بهتر توصیف کنید و نشان دهید به خاطر سردردهایتان چه کارهایی را نمی توانید انجام دهید.
برای کامل کردن پرسش‌نامه در مربع کنار گزینه ی موردنظرتان علامت بزنید.

۱ در زمان هایی که سردرد دارید، چه قدر از اوقات درد شما شدید است؟

هرگز ☐ به ندرت ☐ بعضی اوقات ☐ اغلب اوقات ☐ همیشه ☐

۲ چه قدر از اوقات سردرد هایتان توانایی شما را برای انجام فعالیت های معمول روزانه مثل کار در خانه، شغل، مدرسه، یا فعالیت های اجتماعی محدود می کند؟

هرگز ☐ به ندرت ☐ بعضی اوقات ☐ اغلب اوقات ☐ همیشه ☐

۳ وقتی سردرد دارید، چه قدر از اوقات دلتان می خواهد بتوانید دراز بکشید؟

هرگز ☐ به ندرت ☐ بعضی اوقات ☐ اغلب اوقات ☐ همیشه ☐

۴ در طول ۴ هفته ی گذشته، چه قدر از اوقات احساس کرده‌اید به خاطر سردرد هایتان آن قدر خسته هستید که نمی توانید به کار یا فعالیت های روزانه بپردازید؟

هرگز ☐ به ندرت ☐ بعضی اوقات ☐ اغلب اوقات ☐ همیشه ☐

۵ در طول ۴ هفته ی گذشته، چه قدر از اوقات احساس کرده‌اید به خاطر سردرد هایتان کم تحمل یا زود رنج شده‌اید؟

هرگز ☐ به ندرت ☐ بعضی اوقات ☐ اغلب اوقات ☐ همیشه ☐

۶ در طول ۴ هفته ی گذشته، چه قدر از اوقات سردرد هایتان توانایی شما را برای تمرکز بر روی کار یا فعالیت های روزانه محدود کرد؟

هرگز ☐ به ندرت ☐ بعضی اوقات ☐ اغلب اوقات ☐ همیشه ☐

ستون ۱ (هرکدام ۶ نمره) + ستون ۲ (هرکدام ۸ نمره) + ستون ۳ (هرکدام ۱۰ نمره) + ستون ۴ (هرکدام ۱۱ نمره) + ستون ۵ (هرکدام ۱۳ نمره)

برای نمره دادن، نمرات پاسخ های هر ستون را جمع نمایید.
لطفاً نتیجه ی تست تأثیر سردرد خود را به پزشکتان نشان دهید.

مجموع نمرات

نمرات بالاتر نشان دهنده ی تأثیر بیشتر سردرد بر زندگی شماست.
گستره ی نمره از ۳۶ تا ۷۸ می باشد.