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

Mobina Ahmadi[1*], Mohammadreza Pourahmadi[1], Mansoureh Togha[2], Reza Salehi[1, 3, 4]

1. Department of Physiotherapy, Rehabilitation Research Center, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran.
2. Department of Headache, Iranian Center of Neurological Research, Neuroscience Institute, Tehran University of Medical Sciences, Tehran, Iran.
3. Department of Rehabilitation Management, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran.
4. Geriatric Mental Health Research Center, Iran University of Medical Sciences, Tehran, Iran.

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ABSTRACT

Introduction: Tension-type headache (TTH) is the most common type of headache worldwide, causing significant psychological, physical, financial, and societal consequences. One of the activating factors of chronic TTH (CTTH) is cervical dysfunction, such as forward head posture (FHP), leading to suboccipital muscle tenderness and deep neck flexor (DNF) muscle weakness. Physiotherapy affects 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.

Materials and Methods: This randomized, parallel-group, assessor-blind, double-dummy clinical trial included 44 participants divided into two groups: One receiving MFR with sham exercise and the other receiving DNF exercises with sham MFR. Interventions were performed over four weeks, followed by a six-week follow-up. The primary outcomes were headache intensity and craniovertebral angle (CVA), while the secondary outcomes were headache frequency, duration, pressure pain threshold (PPT), disability and quality of life.

Results: After the trial's completion, all collected data will undergo statistical analysis and subsequently be published in international, high-impact factor, related journals. In addition, the findings will be presented at neurology or physiotherapy conferences.

Conclusion: This study compares the effectiveness of a top-down versus a bottom-up physiotherapy approach 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 healthcare managers.

*** Corresponding Author:**
Mobina Ahmadi
Address: *Department of Physiotherapy, Rehabilitation Research Center, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran.*
Tel: *+98 (918) 8659057*
E-mail: *m.oahmadi@ymail.com*

Introduction

Tension-type headache (TTH) is 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 among 328 diseases and injuries analyzed across 195 countries from 1990 to 2016, affecting approximately 1.89 billion people [5]. Experiencing this condition, particularly chronic TTH (CTTH), significantly diminishes the quality of life [6]. This neurological disorder exhibits a higher prevalence in women (5:4) and peaks between the ages of 30 and 39 [5].

According to the International Headache Association classification, "CTTH is a bilateral pressure-type pain with mild to moderate intensity that occurs on ≥15 days/month on average for >3 months, lasting 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 neociplastic pain resulting from altered nociceptive processing in the nervous system without obvious tissue damage or 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 unknown, there are activating factors (e.g. stress or hormonal disorders) [9, 10] and musculoskeletal disorders of the cervical spine. Marcus et al. classified these disorders into mechanical, musculoskeletal (muscle tenderness), and postural disorders [11]. The forward head posture (FHP) is the most common postural disorder of the cervical spine, and its prevalence has increased with lifestyle changes [12]. Continuous extension activity in the upper cervical region may activate trigger points (TrPs) and increase suboccipital muscle tension [13].

Fernández et al. found a strong link between suboccipital active TrPs, FHP and CTTH [14]. Patients with active TrPs experience greater headache intensity and frequency than those with latent TrPs [14]. Additionally, greater FHP intensity is correlated with longer headache duration and frequency and 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 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 headaches, non-pharmacological treatments, such as physiotherapy, are recommended [16]. Most physiotherapy treatments focus on reducing muscle tension through 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 central nervous system (CNS) sensitization (top-down approaches) [18]. Among various bottom-up interventions, soft tissue therapies effectively treat this type of headache [18]. All soft tissue-based interventions are designed to reduce muscle tension by delivering appropriate proprioceptive input to the CNS [19]. Exercise, including aerobic and localized exercise, is a key top-down approach for managing chronic pain [20]. Localized exercises may be more effective for managing TTH than aerobic exercises [18, 21]. Myofascial release (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]. 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 effects of exercise and suboccipital MFR separately in these patients and the effects of combining these therapies with limitations, such as the lack of sham treatment, defective blinding, and partial reporting of outcomes [26-29]. Owing to the study's limited methodological quality, the evidence level for these 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, DNF exercises are the most effective treatment in the top-down intervention group, and MFR is an

effective treatment in the bottom-up intervention group. To our knowledge, no studies have compared these two isolated treatments from this perspective [18].

Objectives

The main objective is to evaluate the effectiveness of 12-session DNF exercises compared to suboccipital MFR on 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 outcomes of the treatment above, such as headache duration and frequency, disability, quality of life, and PPT.

Materials and Methods

Trial design

The present study was a randomized, parallel-group, single-blind, assessor-blinding, double-dummy (one active and one placebo treatment in each group is reversed), and controlled trial with a 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 lasted 4 weeks, with assessments conducted pre- and post-treatment and a 6-week follow-up. Figure 1 shows the overall study structure. The projection of this study adhered to the guidelines of the consolidated standards of reporting trials and standard protocol items: Recommendations for interventional trials (SPIRIT) guidelines (Supplementary 1).

Study setting

The trial was performed in the Physiotherapy Department of the School of Rehabilitation Sciences of Iran University of Medical Sciences in Tehran Province, Iran. Participants were recruited through social media, neurology clinics, and leaflets. A face-to-face meeting was scheduled with eligible volunteers to confirm their diagnosis.

Eligibility criteria

Table 1 presents the inclusion and exclusion criteria. The assessor informed all eligible participants about the study and obtained their signed written informed consent under the Ethics Committee of Iran University of Medical Sciences guidelines (Supplementary 2). Additionally, the assessor provided the participants with a background information form that characterized the demographic data and anthropometric and clinical history of the headache. The lateral view photos of the participants taken after measuring the CVA were deleted in the presence of participants.

Interventions

As the present study was a double-dummy clinical trial, group A (MFR and sham DNF exercise) and group B (DNF exercise and sham MFR) were created. The intervention was administered over four weeks, thrice weekly, for 12 sessions. If participants cannot attend a scheduled session, a "compensatory session" is held to maintain the study's integrity.

Intervention description

Group A (suboccipital MFR and sham DNF exercise)

These participants received suboccipital MFR, which was performed according to previous studies [34, 35]. While the participant rested supine with eyes closed, the therapist positioned their hands under the participant's head, with the tip of fingers placed between the occipital condyles and the second cervical vertebra. The therapist's fingers were 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 then applied gentle traction to the suboccipital soft tissues through forearm supination, followed by cranial-oriented traction (Figure 2). The pressure was adjusted to reduce muscle tension and achieve balance on both sides. The procedure lasted 10 minutes, with pain levels monitored to ensure they do not increase by more than 2 points on the visual analog scale (VAS).

This group also received a sham DNF exercise using a pressure biofeedback unit (PBU) (Stabilizer, Chattanooga, DJO Global, USA). Given that the minimum detectable change with PBU is 15 mm Hg [36], after lying in the supine position, placing the airbag under the occipital and inflating it to approximately 11 mm Hg, the participant was asked to raise the sphygmomanometer scale to approximately 12 mm Hg by nodding the head.

Group B (DNF exercise and sham suboccipital MFR)

The participants executed the DNF exercise using a PBU in the supine position, with the airbag positioned beneath the occipital bone and inflated to 20 mm Hg. The participant was asked to perform a chin-tuck to maintain a steady target pressure on the PBU (Figure 3).

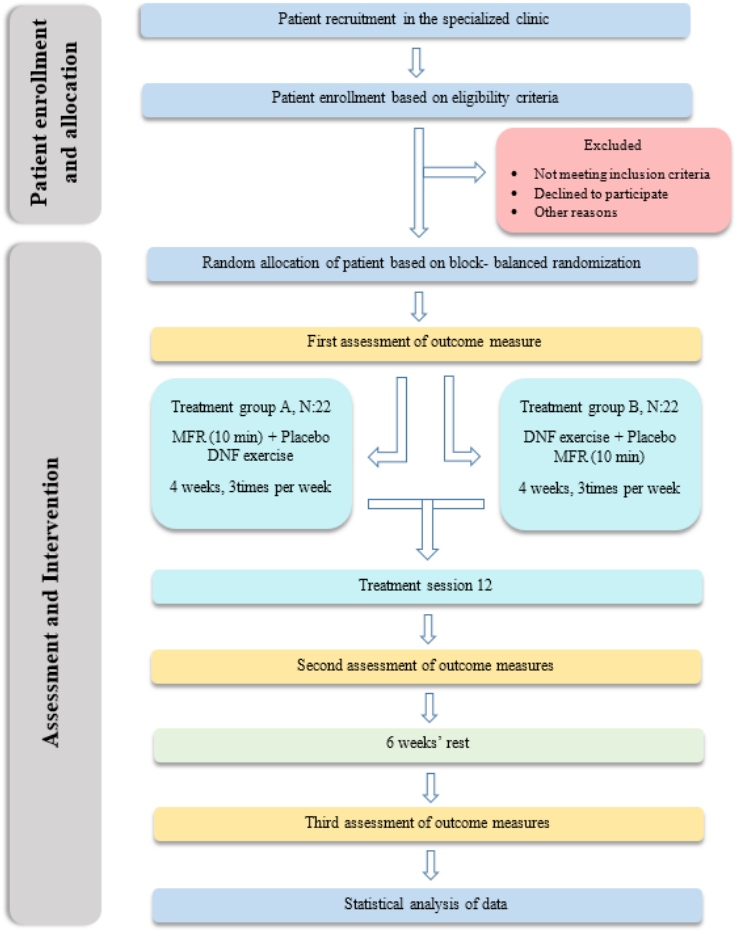

Figure 1. Patient timeline flowchart

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MFR: Myofascial release; DNF: Deep neck flexor.

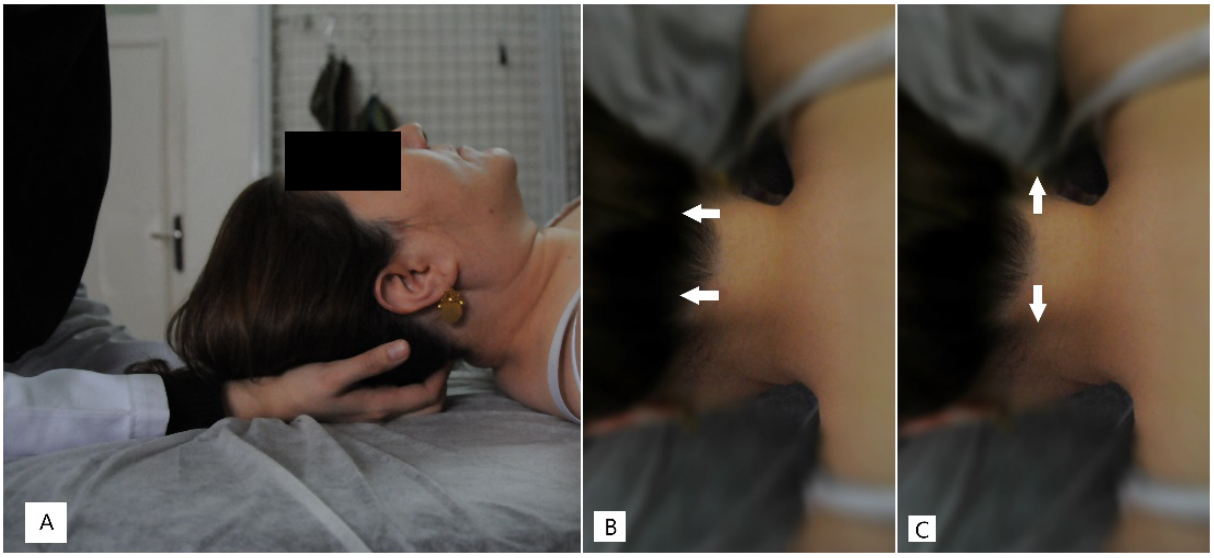

Figure 2. Suboccipital myofascial release

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A) Position of patient and therapist, B) Caudocephalic direction of pressure, C) Horizontal direction of pressure

Table 1. Eligibility criteria (international classification of headache disorders [ICDH])

Inclusion Criteria	Exclusion Criteria
Age between 18 and 55 years; confirmed diagnosis of CTTH based on ICHD-3; CVA≤49 degrees; Suboccipital muscle TrPs; ability to understand and read Persian language	Participants with another type of headache; pain provocations with head movement or routine physical activity; severe pain or significant limitation in cervical spine range of motion; history of cervical spine trauma; Prior interventions, including injections, surgery, severe disc protrusion, or cervical/shoulder fractures impacting treatment; metabolic or neurological disorders (e.g. bow hunter's syndrome or epilepsy); laxity of cervical soft tissues;mUse of narcotic analgesics or participants with medical overuse headache; receiving physiotherapy interventions for headaches within 6 months preceding treatment initiation; contraindications to manual therapy include: a) Presence of substance or alcohol abuse; b) Haphephobia; c) Symptoms become more bothersome with palpation; pregnancy; severe anxiety, according to the STAI; failure to attend two or more consecutive treatment sessions; Alter the type and dosage of prophylactic medication throughout the trial

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The exercise was repeated for three sets, with the target pressure increasing by two mm Hg per set. The pressure increased from 20 to 32 mm Hg over the 4-week treatment period (exercise schedule in Supplementary 3). Each target was maintained for 10 s and repeated 10 times, with a 5-second rest between repetitions and a 2-minute rest between sets.

The second intervention was 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 was applied. Similar to the opposite group, the sham treatment in this group lasted 10 minutes.

Participants could leave the study at any time and for any reason without consequences. They were 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. An increase in pain of more than two VAS scores post-intervention is another criterion for discontinuing the intervention.

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

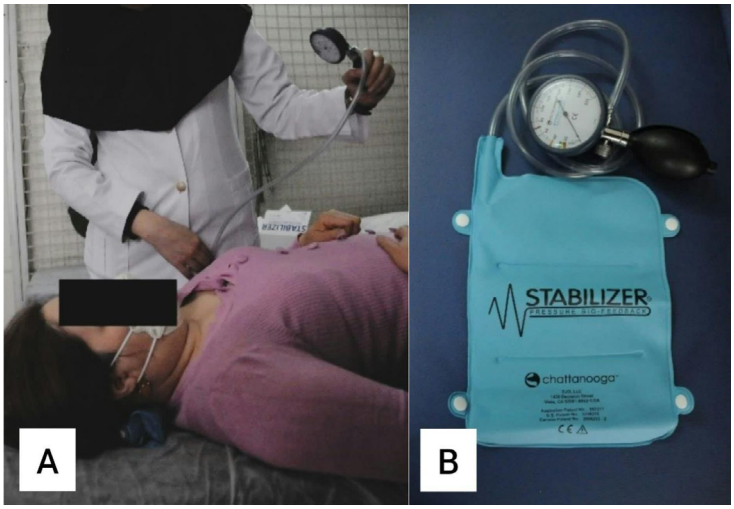

Figure 3. DNF exercise procedure

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A) Position of patient and therapist, B) PBU

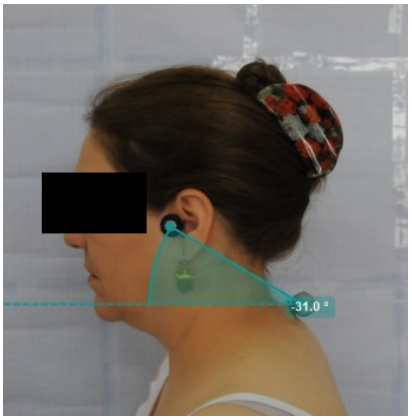

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Figure 4. CVA assessment using Kinovea software

Results

Primary outcomes

Headache intensity: The mean headache intensity is measured using the VAS (0-10 cm). In the initial evaluation, participants are asked to record their headache intensity during the past month using the headache questionnaire. This outcome is assessed using a daily headache diary post-treatment and 6 weeks' follow-up.

CVA: Another primary outcome is FHP based on the CVA, which is assessed utilizing a 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. A CVA of less than 49 degrees is known as FHP. This method is highly reliable for the assessment of CVA (ICC=0.93) [37]. This approach places light-reflective markers on the spinous process of the C7 vertebra and auricular tragus. The participant sat on a chair aligned with their shoulder, positioned 100 cm from a fixed camera mounted on a tripod at 120 cm. 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, version 0.9.5 as CVA. Kinovea is a motion analysis software that, after importing pictures, zooming and adjusting points, can export angles (ICC=0.99) (Figure 4) [38].

Secondary outcomes

Headache duration: The pain duration is measured according to the duration of headache episodes (hours/day). Like headache intensity, this outcome is assessed using the headache questionnaire at baseline and the headache diary in the subsequent assessments.

Headache frequency: The headache frequency is determined according to the number of headache episodes (days/week). This outcome is assessed using the two headache parameters.

Disability: This outcome is assessed using the Persian version of the Henry Ford Hospital headache disability inventory (HDI) questionnaire (Supplementary 4) [39]. The questionnaire consists of 25 questions covering both functional and emotional aspects. The internal consistency of this for the whole questionnaire with Cronbach's α is 0.91 (ICC=0.97)

Quality of life: The Persian version of the headache impact test-6 (HIT-6) questionnaire (ICC=0.77) (Supplementary 5) [40] subjectively assess quality of life. This brief questionnaire contains six questions that reflect the last four 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 to be 0.8 (retesting), 0.9 (peer forms) and 0.89 (internal consistency).

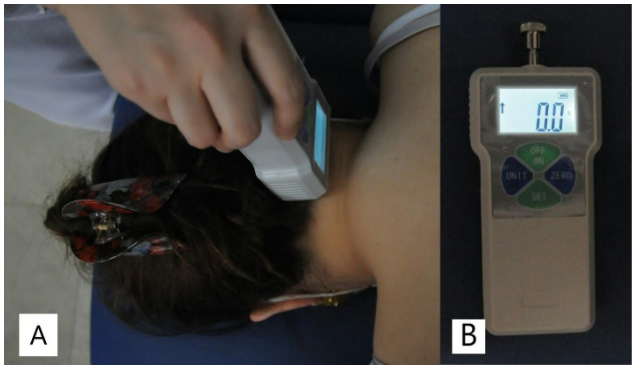

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Figure 5. PPT assessment

A) Position of patient and therapist, B) Pressure dynamometer tool

PPT: The PPT of suboccipital muscles is measured in the prone position on a manual physical therapy table, and pressure is 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). The pressure is measured when the sensation changes from pressure to pain. The assessment is repeated thrice with 30-second intervals to prevent habituation, and the mean is calculated [41].

Both groups are treated for 12 sessions over 4 weeks (3×/week) and study outcomes include pain parameters, FHP, disability, quality of life, and PPT. Headache parameters are evaluated at baseline using a headache questionnaire and these are evaluated at post-treatment assessments using a headache diary. Other primary and secondary outcomes are measured as in the baseline assessments. Furthermore, anxiety status is determined using the Persian version of the Spielberger state-trait anxiety inventory (STAI) questionnaire in the baseline assessment session.

Appendix A Table 1 presents the study's SPIRIT schedule of enrolment, interventions and assessments checklist.

Sample size

The sampling for this study was simple and continuous and from the available samples. A neurologist referred the samples. Because already no established minimal clinically important difference (MCID) for CVA exists in CTTH patients; in this trial, the MCID is considered equivalent to 0.5 pooled SD to determine the sample size. This was measured using the CVA outcome data from a study by Eunsang Lee [26-29].

The sample size was determined using the Sampsi command in Stata software, version 16.0 (Appendix B Figure 1). 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 aimed to enroll 44 participants to compensate for an estimated 30% dropouts.

Recruitment and allocation

Participants are recruited via social media, neurology clinics, and bulletin board leaflets. Voluntary patients are 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 met the study's inclusion criteria were enrolled in the trial.

After enrollment, participants are randomly assigned to two treatment groups: the DNF exercise and MFR group, in a 1:1 ratio using the block-balanced randomization method.

The randomization process was conducted according to computer-generated randomization, using block sizes of four, including even and odd numbers with two even digits and two 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 conducted random assignments before the trial begins. The allocation sequence, concealed from the outcome assessor, is stored in sequentially numbered opaque, sealed, and stapled envelopes that the therapist disclosed.

A physical therapist with over five years of clinical experience who has passed the MFR training course intervene.

Blinding

The participants and outcome evaluators remained blinded to the group allocation in this study. Due to the intervention's nature, blinding the administering investigator was not feasible. Participants were unaware of the study hypothesis and their group allocations. They were not informed about the specific treatments administered to the other group or the distinctions between them. Participants were instructed not to reveal their treatments to the assessor or other participants until the trial is concluded.

Each participant is given an identification code, and all data are 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 are only accessible to the primary investigator. To enhance data management and confidentiality, all data are digitized and securely stored in a locked file by the therapist and lateral view photos are deleted in the same session after the CVA is measured.

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 were reported.

Statistical methods

Data were analyzed using IBM-SPSS software, version 27. Depending on the data type, descriptive data were presented as mean, median, or count (percent). Normal-

ity was verified using the Shapiro-Wilk test. Mauchly's test assessed sphericity, and Levene's test assessed variance homogeneity; then, violations were addressed. The effects of interventions on outcomes in each group were examined using a repeated measures analysis of variance for between- and within-group comparisons, 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 (α=0.05) and 80% study power were 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) the Bonferroni correction was 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 were determined through 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].

A per-protocol analysis was performed to address missing data and ensure a precise evaluation of treatment effectiveness.

Oversight and monitoring

This was a single-center trial. All activities were coordinated within the Faculty of Rehabilitation Sciences at the Iran University of Medical Sciences. The conductor, corresponding author, and other study authors organized the trial project oversight group. This team maintained daily communication and oversaw study progress and data collection. The trial's steering committee includes two physiotherapist authors, a headache specialist neurologist, and a statistician who double-checks and analyzes data repeatedly after entering them into the software. The committee meets monthly to discuss the study procedures and 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 are documented and reported.

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 are mentioned in the final paper.

Protocol amendments

Any modifications are discussed in the monitoring committee, justified in ClinicalTials.gov and IRCT.ir after being approved by the Ethics Committee and mentioned in a separate section titled "amendments" in the final paper.

The collected data are analyzed and published in international journals upon trial completion. The findings are also presented at neurology and physiotherapy conferences.

Discussion

FHP may exacerbate pain following sustained upper cervical extension or a pain-avoidance posture of the suboccipital muscle TrPs [26]. However, this posture appears to be a common finding of chronic primary headaches (supported by moderate to strong evidence). However, the association between FHP and headache parameters is still being debated [30]. In contrast, 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, the results of systematic reviews have shown that physical therapy employing both top-down and bottom-up treatments effectively reduces the symptoms of CTTH patients by decreasing hypersensitivity of active TrPs or postural re-education programs [18, 44]. This study aimed to investigate the effect of DNF exercises as a top-down intervention compared to suboccipital MFR as a bottom-up intervention on headache, CVA, disability, quality of life, and PPT in these patients in the short- and medium-term.

To date, studies have not compared the two treatments separately in these patients from the perspective of two different mechanisms. There is also a lack of studies assessing which type of treatment has a faster affect and which one has a longer-lasting effect. 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 a crucial 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 have 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 powerpoint.

Conclusion

TTH is the most common headache disorder. This type of headache has many activating factors, a vital cervical spine musculoskeletal disorder. These include mechanical, musculoskeletal (e.g. suboccipital muscle tenderness), and postural dysfunctions (e.g. FHP). 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.

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

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. Furthermore, no published research has directly compared these two 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, 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; CVA; disability; quality of life; and PPT in patients with chronic TTH and FHP over short- and medium-term periods. This study will provide critical insights into optimizing physiotherapy interventions for TTH management, potentially guiding evidence-based clinical practice.

Delimitations and limitations

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

Ethical Considerations

Compliance with ethical guidelines

This study was approved by the Ethics Committee of Iran University of Medical Sciences, Tehran, Iran (Code: IR.IUMS.REC.1400.1239), the Iranian Registry of Clinical Trials (IRCT) (Code: IRCT20220219054060N1), and ClinicalTrials.gov (Code: NCT05383365). All eligible participants received details regarding the study. Then the written informed consent form was signed.

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Authors' contributions

Conceptualization: Mohammadreza Pourahmadi and Mansoureh Togha; Methodology, review and editing: Mohammadreza Pourahmadi, Mansoureh Togha and Reza Salehi; Project conductor, data collection and writing the original draft: Mobina Ahmadi; Final approval: All authors.

Conflict of interest

The authors declared no conflict of interest.

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SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

Supplementary 1. SPIRIT 2013 checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/Item		Item No	Description	Addressed on Page Number
Administrative information	Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	P1. L2-6
	Trial registration	2a	Trial identifier and registry name. If not yet registered, the name of the intended registry	P14. L423-431
		2b	All items from the WHO trial registration data set	P14. L423-431
	Protocol version	3	Date and version identifier	P14. L432-433
	Funding	4	Sources and types of financial, material, and other support	P14. L422
	Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	P1. L8-17
		5b	Name and contact information for the trial sponsor	NA
		5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA
		5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see item 21a for data monitoring committee (DMC)	P11. L322-328
Introduction	Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	P3. L42-114
		6b	Explanation for the choice of comparators	P6. L147-153
	Objectives	7	Specific objectives or hypotheses	P4. L115-120
	Trial design	8	Description of trial design, including type of trial (e.g. parallel group, crossover, factorial, and single group), allocation ratio, and framework (e.g. superiority, equivalence, noninferiority, and exploratory)	P4. L122-131
Methods: Participants, interventions, and outcomes	Study setting	9	Description of study settings (e.g. community clinic, academic hospital) and list of countries where data will be collected. Reference to where a list of study sites can be obtained	P5.L132-137
	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (e.g. surgeons, psychotherapists)	P5. L138-146
	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	P6. L154-186
		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g. drug dose change in response to harms, participant request, or improving/worsening disease)	P8. L187-192
		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (e.g. drug tablet return, laboratory tests)	P8. L195-200
		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	P8. L188-192

Section/Item		Item No	Description	Addressed on Page Number
Methods: Participants, interventions, and outcomes	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (e.g. systolic blood pressure), analysis metric (e.g. change from baseline, final value, time to event), method of aggregation (e.g. median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	P8. L202-241
	Participant timeline	13	Schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	P10. L242-253
	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	P10. L254-266
	Recruitment	15	Strategies for achieving adequate participant enrolment to reach the target sample size	P10. L267-273
Methods: Assignment of interventions (for controlled trials)	Allocation:			
	Sequence generation	16a	Method of generating the allocation sequence (e.g. computer-generated random numbers), and list any factors for stratification. To reduce the predictability of a random sequence, details of any planned restriction (e.g. blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	P10. L274-276
	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (e.g. central telephone; sequentially numbered, opaque, and sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	P11. L277-284
	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	P11. L285-286
	Blinding (masking)	17a	Who will be blinded after assignment to interventions (e.g. trial participants, care providers, outcome assessors, and data analysts), and how	P11. L287-294
		17b	If blinded, the circumstances under which unblinding is permissible, and the procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g. duplicate measurements, training of assessors) and a description of study instruments (e.g. questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	P10. L246-249
		18b	Plans to promote participant retention and complete follow-up, including a list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	P10. L195-200
	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g. double data entry and range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	P11. L295-300
	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	P11. L304-319
		20b	Methods for any additional analyses (e.g. subgroup and adjusted analyses)	NA
		20c	Definition of analysis population relating to protocol non-adherence (e.g. as randomised analysis), and any statistical methods to handle missing data (e.g. multiple imputation)	P11. L320-321
Methods: Monitoring	Data monitoring	21a	Composition of DMC; summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	P12. L328-330
		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	P12. L335-337
	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	P12. L330-332

Section/Item		Item No	Description	Addressed on Page Number
Ethics and dissemination	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	P14. L429-430
	Protocol amendments	25	Plans for communicating important protocol modifications (e.g. changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g. investigators, REC/IRBs, trial participants, trial registries, journals, and regulators)	P12. L338-341
	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	P5. L140-141
		26b	Additional consent provisions for the collection and use of participant data and biological specimens in ancillary studies, if applicable	P5. L145-146
	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained to protect confidentiality before, during, and after the trial	P11. L301-303
	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	P14. L441-444
	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	P14. L436-437
	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
	Dissemination policy	31a	Plans for investigators and sponsors to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g. via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	P12. L342-344
		31b	Authorship eligibility guidelines and any intended use of professional writers	P14. L418-421
		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	P14. L436-437
Appendices	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	P5. L142
	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and future use in ancillary studies, if applicable	NA

JMR

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 explanation & elaboration for crucial clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT group copyrights the SPIRIT checklist under the creative commons "attribution-noncommercial-noderivs 3.0 unported" license.

Supplementary 2.

رضایت نامه شرکت در طرح بررسی اثر تمرینات عضلات خم کننده عمقی گردن در مقایسه با آزادسازی بافت همبند و عضلات ناحیه پس سری بر درد و وضعیت سر به جلو آمده در بیماران سردرد تنشی مزمن به همراه وضعیت سر به جلو

آقا/ خانم محترم.....

بدینوسیله از شما جهت شرکت در این پژوهش دعوت به عمل می آید. اطلاعات مربوط به این پژوهش در این برگه خدمتتان ارائه شده است و شما برای شرکت یا عدم شرکت در این پژژهش آزاد هستید، شما مجبور به تصمیم گیری فوری نیستید و برای تصمیم گیری در اینباره می توانید سوالات خود را از تیم پژوهشی بپرسید و با هرفردی که مایل باشید مشورت کنید. قبل از امضای این رضایت نامه مطمئن شوید که متوجه تمامی اطلاعات این فرم شده اید و به تمامی سوالات شما پاسخ داده شده است

۱. من میدانم که اهداف این پژوهش عبارتند از، مقایسه میزان اثرگذاری دو نوع از درمانهای مختلف فیزیوتراپی بروی بهبود شدت، مدت و تکرار سردرد، بهبود وضعیت سر نسبت به گردن ، بهبود ناتوانی و کیفیت زندگی و بهبود آستانه فشار نقاط دردناک عضلات پس سری در افرادی که بصورت طولانی مدت به بیماری سردرد تنشی مبتلا بوده و دارای وضعیت سر به جلو نیز هستند، این دو درمان شامل تمرینات عضلات خم کننده عمقی کردن و ازادسازی بافت همبند و عضلات ناحیه پس سری است.

۲. من می دانم که شرکت من دراین پروژه کاملا داوطلبانه است و مجبور به شرکت در این پروژه نیستم، به من اطمینان داده شد که اگر حاضر به شرکت در این پروژه نباشم، از مراقبت های معمول تشخیصی و درمانی محروم نخواهم شد و رابطهٔ درمانی من با مرکز درمانی و پزشک معالجم دچار مشکل نمی شود.

۳. من می دانم که حتی پس از موافقت با شرکت در پژوهش؛ میتوانم هرزمان که بخواهم؛ پس اطلاع به مجری طرح از پژوهش خارج شوم و خروج من از پژوهش باعث محرومیت من از دریافت خدمات درمانی پزشکی معمول نخواهد شد.

۴. نحوه همکاری اینجانب در این پژوهش به صورت زیر است:

- دراین مداخله بصورت تصادفی در یکی از دو گروه درمانی موجود دراین مطالعه شرکت خواهم کرد اما تا پایان مطالعه به من گفته نخواهد شد که عضو کدام گروه درمانی هستم، در هر گروهی که وارد شوم یک درمان را بصورت کامل دریافت خواهم کرد، درصورتی که عضو گروه اول درمانی باشم درمان تمرینات را بصورت واقعی و درمان آزادسازی بافت همبند و عضلات را بصورت غیرواقعی دریافت میکنم و اگر عضو گروه دوم درمانی باشم درمان آزادسازی بافت همبند و عضلات را بصورت واقعی و درمان تمرینات را بصورت غیرواقعی دریافت خواهم کرد.

- دراین مطالعه اطلاعاتی درباره نام و نام خانوادگی، آدرس و شماره تماس، سن، قد، وزن، جنس، شغل، سطح تحصیلات، دست غالب، میزان مصرف سیگار، بیماری های زمینه ای، نوع داروهای مصرفی، میزان اضطراب و سوالاتی به منظور تایید تشخیص نوع سردرد من پرسیده خواهد شد.

- ارزیابی من توسط پرسشنامه و دفترچه ثبت وقایع روزانه شدت، مدت و تکرار سردرد، پرسشنامه ناتوانی و کیفیت زندگی، عکس برداری از پهلو به منظور اندازه گیری زاویه بین سر و گردن و سنجش آستانه فشار نقاط دردناک عضلات ناحیه پس سری انجام خواهد شد، ارزیابی ها قبل از شروع درمان؛ پس از پایان جلسات درمانی و ۶ هفته بعد از اتمام درمان انجام خواهد شد.

- درمانگر موظف است پس از اندازه گیری های لازم در عکس های گرفته شده و ثبت اندازه ها عکس هارا در حضور من پاک کند.

- زمان انجام مطالعه ۴ هفته است که در هر هفته ۳جلسه درمانی وبه فاصله ۴ ساعت انجام می شود. در مجموع من ۱۲ جلسه درمان رادر طی ۴ هفته دریافت خواهم کرد.

- طول جلسات از ۳۰ دقیقه تا ۱ ساعت متغیر خواهد بود

- هرروز باید دفترچه ای که به منظور ثبت علائم سردرد دراختیار من قرار گرفته را با دقت پر کنم.

- درصورتی که دو جلسه متوالی از جلسات درمانی غیبت داشته باشم، از مطالعه خارج خواهم شد.

- درپایان مطالعه (گذشت هفته از آخرین جلسه درمانی) درصورت تمایل می توانم درمانی را که بصورت غیرواقعی دریافت کرده بودم، بصورت واقعی دریافت نمایم.

۵. آسیب احتمالی شرکت در این مطالعه به شرح زیر است:

ممکن است پس از درمان آزادسازی بافت همبند و عضلات درد ناشی از فشار دست درمانگر در ناحیه پس سری احساس شود که معمولا کمتر از ۲۴ ساعت این علامت برطرف خواهد شد.

۶. من میدانم که دست اندرکاران این پژوهش، کلیه اطلاعات مربوط به من را نزد خود بصورت محرمانه نگه داشته و فقط اجازه دارند تا نتایج کلی و گروهی این پژوهش را بدون ذکر نام و مشخصات اینجانب ، منتشر کند.

۷. من می دانم که کمیته اخلاق در پژوهش با هدف نظارت بر رعایت حقوق اینجانب می تواند به اطلاعات من دسترسی داشته باشد.

۸. من می دانم که هیچ یک از هزینه های انجام مداخلات پژوهشی به شرح ذیل برعهده من نخواهد بود:

- درمان تمرینات عضلات خم کننده عمقی گردن به کمک دستگاه بیوفیدبک فشاری
- درمان آزادسازی بافت همبند و عضلات ناحیه پس سری

۹. آقای محمدرضا پوراحمدی جهت پاسخگویی به اینجانب معرفی شد تا بتوانم در هرزمانی که مشکل یا سوال در رابطه با شرکت در پژوهش داشتم با ایشان در میان گذاشته و راهنمایی بخواهم.

آدرس و شماره تماس ایشان به شرح زیر به من ارائه شده است

- آدرس: تهران، بلوار میرداماد، خیابان شاه نظری، کوچه مدد کاران دانشکده علوم توانبخشی دانشگاه علوم پزشکی ایران
- تلفن همراه:

۱۰. من می دانم اگر در حین یا بعد از انجام پژوهش هرمشکلی اعم از جسمی و روحی به علت شرکت در مطالعه برای من پیش آید؛ درمان عوارض و هزینه های آن بر عهده مجری طرح خواهد بود.

۱۱. من می دانم اگر اشکال یا اعتراضی نسبت به دست اندرکاران یا روند پژوهش دارم میتوانم با کمیته اخلاق در پژوهش دانشگاه علوم یزشکی ایران به آدرس، بزرگراه همت، بین بزرگراه چمران و شیخ فضل الله، دانشگاه علوم پزشکی ایران ستاد مرکزی، طبقه پنجم مراجعه کرده و مشکل خود را بصورت شفاهی یا کتبی مطرح نمایم.

۱۲. این فرم اطلاعات زمینه ای در دو نسخه تنظیم شده و پس از امضاء، یک نسخه در اختیار من و نسخه دیگر در اختیار مجری طرح قرار خواهد گرفت.

اینجانب.....موارد ذکر شده را خواندم و فهمیدم و براساس آن رضایت آگاهانه خود را برای شرکت در این پژوهش اعلام میکنم

امضاء شرکت کننده

اینجانب.....خود را ملزم به اجرای تعهدات مربوط به مجری در موارد فوق دانسته و متعهد می گردم در تامین حقوق و ایمنی شرکت کننده در این پژوهش تلاش نمایم

مهر و امضاء مجری پژوهش

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Supplementary 3. DNF exercise schedule

Sets / Weeks	Set 1	Set 2	Set 3
1st	20 to 22	22 to 24	24 to 26
2nd	22 to 24	24 to 26	26 to 28
3rd	24 to 26	26 to 28	28 to 30
4th	26 to 28	28 to 30	30 to 32

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Supplementary 4. 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
به خاطرسردردهایم احساس ناتوانی می کنم.			
به خاطر سردردهایم در انجام کارهای روزانه ام محدودیت دارم.			
کسی درک نمیکند که سردردها چه تاثیری بر زندگی من دارد.			
فعالیتهای تفریحی خود)مانند عادات ورزشی(را به دلیل سردردهایم محدود می کنم.			
سردردهایم مرا عصبانی میکند.			
گاهی اوقات احساس میکنم به دلیل سردردهایم، کنترلم را از دست می دهم.			
به دلیل سردرد تمایل کمی به حضوردراجتماع دارم.			
همسرم با خانواده و دوستانم نمی دانند من به خاطر سردردهایم در چه شرایط سختی قرار دارم.			
سردردهایم آنقدر بد هستند که حس میکنم دارم دیوانه می شوم.			
تصورم نسبت به دنیا بر اثر سردردهایم تغییر میکند.			
زمانی که احساس می کنم سردردی در حال شروع شدن است از بیرون رفتن واهمه دارم			
به خاطر سردردهایم احساس ناتوانی و درماندگی میکنم.			
از تاثیری که سردرد روی کار روزانه در محل کار و منزل دارد، نگران هستم.			
سردردهایم در روابطم با خانواده یا دوستان تنش ایجاد می کند.			
زمانی که سردرد دارم از بودن کنار مردم اجتناب می کنم.			
فکر میکنم سردردهایم باعث شده به اهدافم در زندگی نرسم.			
به خاطر سردردهایم نمی توانم خوب فکر کنم.			
به خاطر سردردهایم دچار سفتی بدن مثل گرفتگی عضلات میشوم.			
به خاطر سردردهایم از دورهمی های دسته جمعی لذتی نمی برم.			
به خاطر سردردهایم زودرنج شده ام.			
به خاطر سردردهایم از مسافرت اجتناب میکنم.			
سردردهایم مرا گیج میکند.			
سردردهایم مرا سرخورده میکند.			
به خاطر سردردهایم مطالعه برایم دشوار است.			
به سختی می ت وانم توجه ام را از سردرد دور و به سایر چیزها معطوف کنم.			

با تشکر از همکاری شما

Supplementary 5. Headache impact test-6

Appendix A Table 1. SPIRIT schedule of enrolment, interventions, and assessments

	Timepoint	Study-period													
		Enrol-ment	Alloca-tion	Post-allocation											Close-out
		$-w_1$	0	w_1			w_2			w_3			w_4		W_{10}
				t1	t2	t3	t4	t5	t6	t7	t8	t9	t 10	t 11	t 12	
Enrollment	Eligibility screen	X													
	Informed consent	X													
	Background information form	X													
	STAI questionnaire	X													
	Allocation		X												
Intervention	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

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Abbreviations: MFR: Myofascial release; DNF: Deep neck flexor; exs: Exercise; CVA: Craniovertebral angle; PPT: Pressure pain threshold; HDI: Headache disability index; HIT-6: Headache impact test-6; W: Weak; T: Time.

```
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
```

Appendix B Figure 1. Sampsi command in stata 16.0 software for sample size calculation

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