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Research Article

The Effects of Deep Neck Muscle Exercises on Chronic Non-Specific Neck Pain

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ABSTRACT

Introduction: The study aimed to investigate the effects of deep neck flexor (DNF) and deep neck extensor (DNE) muscle exercises on pain, passive range of motion (PROM), craniovertebral angle (CVA), neck flexor endurance (NFE), neck extensor endurance (NEE), and the number of weekly painkiller usage (NWPKU) in chronic non-specific neck pain (CNNP) patients.

Materials and Methods: A total of 27 CNNP patients, incuding intervention group (n=15) and control group (n=12), were recruited for this study. Patients in the intervention group participated in 6 weeks of DNF and DNE exercises plus traditional physiotherapy. After 10 sessions (3 weeks), the exercise protocol was followed for 3 weeks of the home-based exercise form. Control group patients received traditional physiotherapy alone. The numeric pain rating scale (NPRS), PROM, CVA, NFE, NEE, and NWPKU were examined and compared between groups, at the baseline and after six weeks.

Results: Numeric pain rating scale, PROM, CVA, NFE, NEE, and NWPKU improved significantly in both groups after treatment ($P<0.001$). The NPRS, passive flexion, passive extension, passive right-side bending, passive left rotation, CVA, NFE, NEE, and NWPKU differences were significant ($P<0.05$).

Conclusion: The study supports the positive effects of combination therapy (DNF and DNE exercises plus traditional physiotherapy) on pain, passive neck range of motion, neck lordosis posture, and neck muscle endurance in CNNP patients.

Keywords:

Neck pain; Exercise; Deep neck muscles

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Introduction

Neck pain is one of the most common musculoskeletal disorders with an increasing prevalence in modern societies [1]. In many cases, there is no particular pathophysiology based on the main structure involved in neck pain occurrence, and when it becomes chronic, it is called chronic non-specific neck pain (CNNP) [2]. Almost two-thirds of the adult population has experienced neck pain at least once in their life, which is imposed by the public health system [3].

Neck pain leads to an alteration in the cervical muscle's neuromuscular pattern. Deep neck flexor muscles undergo structural and functional changes, such as a decrease in their cross-sectional area (CSA) and atrophy. Based on electromyography records (EMG), they show a delay at the beginning of their activation. Superficial neck flexor muscles such as anterior scalene and sternocleidomastoid (SCM) experience compensatory excessive activity and spasms. Superficial neck muscle hypertonicity occurs as a result of deep neck flexor (DNF) weakness and endurance reduction by motor control strategy changing post-CNNP chronicity [4]. Therefore, craniocervical flexion (CCF) exercises are added to the CNNP patients' rehabilitation program as a treatment method that has decreased pain and neck disability, furthermore, these exercises re-educate DNF muscles [5]. The semispinalis cervicis (SSC) and multifidus as the key DNE muscles, play an important role in cervical zone stabilization, coordinate intersegmental movements, and have an essential function in maintaining neck lordosis posture with DNF muscles [6]. Although numerous studies have pointed out their importance as DNF, less attention has been paid to the DNE muscles in research. Based on the latest clinical guidelines, exercise is the most effective intervention in a patient's treatment process and a set of physiotherapy treatment strategies should be included in the CNNP patient's rehabilitation program [7]. Deep neck extensor (DNE) muscles play an important role in cervical spine segmental and postural stabilization during sustained posture, specifically while using an electronic device such as a computer, as the significant increase in remote work by computers during the Coronavirus pandemic. There is a need for more studies concerning DNE muscles. The SSC and multifidus, have a delay within the beginning of electromyographic activity due to long-term pain inhibitory behavior and decreasing the muscles' CSA in CNNP patients [8, 9]. These changes have a direct relationship with pain and disability [10].

A recent study report has shown that the impact of DNE muscle (SSC) training by applying local pressure by the therapist's fingers on the C_2 arch during isometric neck extension can be as effective as DNF muscle exercise in improving pain, craniovertebral angle (CVA), NFE, and NEE in CNNP patients [11]. Following previous research, neck pain directly correlates with a CVA decrease. Also, pain may lead individuals to avoid active use of the affected muscles/body region. As the active range of motion (AROM) measurement requires subjects' active participation, pain inhibition or fear may have an influence on the neck ROM in CNNP patients. In PROM assessment, movement is produced by an external force, eliminating some of those factors, such as pain that is increased by muscle active contraction [12].

To the best of our knowledge, there is no study to investigate the effect of adding a combination of DNF and DNE muscle exercises to the traditional physiotherapy program on their important role in the neck zone. In this way, this randomized clinical trial (RCT) aimed to investigate these exercises' effects on the numeric pain rating scale (NPRS), neck passive range of motion (PROM), CVA, NFE, NEE, and the number of weekly painkiller usage (NWPKU) in CNNP patients in 2 groups (intervention group: DNF and DNE muscle exercises+traditional physiotherapy program, control group: Traditional physiotherapy program).

Materials and Methods

The present study was a double-blinded RCT to determine the effects of adding DNF and DNE muscle exercises to the traditional physiotherapy program on NPRS, PROM, CVA, NFE, NEE, and NWPKU in CNNP subjects.

Participants

Thirty women aged 18-45 years were recruited as study subjects, and 27 of the subjects completed their treatment program. The inclusion criteria were: 1) Pain occurrence by touch, movement, or a static posture for a long time in the back part of the neck between the upper cervical line and the first thoracic vertebra spinous process [13], 2) Pain symptoms persisted for at least three months [14], 3) More than 3 pain score based on 10 grades of the NPRS [15], and 4) Age range from 18 to 45 years. Subjects were excluded if they reported a history of spinal surgery and discopathy [15], malignancy [15], any disorder in the peripheral or central nervous system [16], trauma history [15], participation in physiotherapy treatment protocols during the last three months, hypertension history, and subjects' unwillingness to continue the treatment process.

Time and place of the study

The current study was done from February to May 2022 at the Tehran University of Medical Sciences, School of Rehabilitation.

Study procedure

Instrumentation and data reduction

A simple non-probability sampling method was used. All subjects were recruited via public announcement at Tehran University of Medical Sciences, School of Rehabilitation. All volunteers signed an informed consent form after they were educated about the study objectives and procedures. All eligible participants were asked to complete the demographic data questionnaire. Then, a blinded assessor measured pain intensity using an NPRS, PROM [12], and CVA [17, 18] using a manual goniometer and photogrammetry, NFE by a clinical neck flexor muscle endurance test [19], and NEE by a clinical neck extensor muscle endurance test [20], respectively. Next, they were asked about the NWPKU they had used during the last week. The volunteers were randomly allocated to the intervention and control groups. The patients were assessed at baseline and after 6 weeks.

Neck-pain intensity

The level of pain intensity was measured utilizing the NPRS with an 11-point scale ranging from 0 to 10. A sentence was defined for each number for a more accurate evaluation and a higher validity level.

Neck passive range of motion

PROM was evaluated by the blind assessor using a hand-held goniometer after warming up. At first, the patient was tied to a chair with a backrest. The patient's chest was fixed with a wide strap to a solid frame to prevent trunk movement. The patient's feet were flat on the floor and she was instructed to keep her lower back firmly against the backrest. The body and head were in the upright neutral position so that the base of the skull and tip of the nose were at the same horizontal level. The cervical PROM in flexion (FLX), extension (EXT), right side bend (RSB), left side bend (LSB), right rotation (RROT), and left rotation (LROT) were measured with a hand-held goniometer. The measurement was done in the following order, with about a half-minute pause between measured directions. First, the assessor showed the movements to patients and instructed them to perform correctly, not to move the thoracic zone. Next, the patient was asked to move their heads in three anatomical planes in six directions and the assessor measured their neck PROM [12].

Flexion-extension measurement

To measure flexion and extension PROM, the center of the hand-held goniometer was placed over the external auditory meatus, the stationary arm was perpendicular to the ground and the moving arm was aligned parallel to the longitudinal axis of the nose. The assessor asked the patient to bend her neck forward to measure flexion ROM. Then, she pressed the back of the skull with her hand until the end-range stiffness was felt. The final degree was read and recorded from the goniometer. To assess the extension, the patient was asked to open her mouth and bend her neck backward. Then, the assessor pressed the forehead with her hand until the end-range stiffness was felt [12].

Axial rotation measurement

To assess rotational PROM, the center of the goniometer was placed over the center of the cranial aspect of the head, the stationary arm was parallel to an imaginary line passing between the two acromial processes, and the moving arm was aligned with the tip of the nose. The assessor stood behind the patient, placed his hands on the patient's cheeks, and rotated her head to the left or right until the end-range stiffness was felt and the degree had been noted. Also, the same procedure was repeated in the opposite direction [12].

c) Side bending measurement

To measure the side-bending PROM, the center of the goniometer was placed over the center of the head's cranial aspect. The stationary arm was parallel to an imaginary line passing between the two acromial processes, and the moving arm was aligned with the tip of the nose. The assessor stood behind the patient and a wide strap held the patient's trunk, then, the assessor placed her hand on the patient's shoulder to control possible trunk movement. Next, the patient was asked to bend her neck sideways to the side opposite the assessor's hand, without rotating or tilting her head. The assessor pressed the side of the patient's head with her other hand until the end-range stiffness was felt [12].

Cranio-vertebral angle

Patients were asked to stand in a comfortable position to measure the CVA. First, the left tragus and the seventh cervical vertebra (C_7) spinous process were marked on their skin by two square adhesive labels with a size of 1×1 centimeter. Next, patients were shot by a digital camera (Canon EOS 4000 D, Japan) set on a tripod at a distance of 1.5 m from the patient's shoulder level. Then, the photo was taken from the sagittal view of the left side of the patient in a standing position. The CVA was measured on the taken photographs by calculating the angle of the horizontal line passing through the C_7 and the line passing through the tragus to the C_7 by Protractor software version 3.1.2. The CVA was smaller than 48-50 degrees indicating the forward head posture (FHP) [17, 18].

Neck flexor endurance

Neck flexor endurance was assessed by a clinical neck flexor muscle endurance (NFME) test. The patient was laid down in a supine position with bent knees in such a way that the soles of both feet were in contact with the bed and her arms were next to his body. An inclinometer was placed in the middle of the person's forehead using a strap to prevent head deviation. Then, the assessor asked the patient to raise his head about 2 cm from the bed surface while maintaining the chin-tucked position and keeping it in the same position. If the chin-tucked position was lost for more than one second or the head hit the surface due to extension, or if the person did not want to continue the test for any reason, the test was stopped. The test duration was measured using a stopwatch. The person's posture was visually monitored by the assessor. To avoid aggravating the pain, the test was performed only once [19].

Neck extensor endurance

Neck flexor endurance was assessed by a clinical neck extensor muscle endurance (NEME) test. The patient was laid down in a prone position on the bed while her head was outside the bed so that the sternoclavicular joint was on the outer edge of the bed and was supported on a stool. She put her arms beside her body, for better support, and the patient was fixed to the bed with a strap at the cervical and thoracic junction. By tying the strap around the patient's head, an inclinometer was fixed in the upper area of the left ear. After pulling the stool from her head, the physiotherapist instructed the patient to maintain her head in a horizontal position (head and neck parallel to the ground and looking in a straight line towards the ground) by performing the chin-tuck. If the flexion and extension ROM changed for more than 5 seconds and more than 5 degrees or 5 times more than 5 degrees, the test was stopped. The time was recorded with a stopwatch (accurate to hundredths of a second). To improve the test's reproducibility, an inclinometer with good reliability and validity was used to evaluate the changes in the ROM during the test. If for any reason the patient did not want to continue the test or the patient's head deviated from the initial position of the test, the test was completed, and the time of maintaining the position was recorded [20].

Intervention procedure

Control group

A traditional physiotherapy period was performed for 10 sessions, 3 days per week. First, patients received conventional TENS for 20 minutes (710 P electrical stimulation device manufactured by Novin Medical Engineering Company) [21]. Then, for 15 minutes, a hot pack was placed behind the neck. Muscle energy techniques (MET) for the upper trapezius, levator scapula, suboccipital, and SCM muscles were performed using a post-isometric relaxation technique with 20% of the maximum voluntary isometric contraction holding for 7 seconds and 3 repetitions for each muscle in every treatment session by a physiotherapist [22].

Upper trapezius, levator scapula, SCM, and suboccipital muscle stretching exercise instructions were given to the patient in the first session, and exercises were performed 3 days a week under the physiotherapist's supervision. Also, it was continued at home after using a hot water bag for 15 minutes on the back side of the neck, each position was maintained for 20 seconds and twice a day in 1 set and two repetitions in each set for six weeks, and the stretching exercises were done in the home-based form [22]. Some recommendations for postural ergonomic corrections were made to patients [23].

Intervention group

The patients in the intervention group received a combination of DNF and DNE muscle exercises in addition to the control group treatment protocol. The exercises were done in the clinic under physiotherapists' supervision for the first 10 sessions and from the tenth session until the end of the sixth week as a home-based treatment protocol as a control group plus exercises.

Figure 1. Semispinalis cervicis specific exercise by localized resistance

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Cranio-cervical flexion in the supine position

The patient lay down on the bed in a supine position with bent knees and relaxed hands beside her. A thin layer of a towel had been placed under the patient's head to keep her head and neck in a neutral position. The patient was asked to take a deep breath and make a nodding movement (like moving the head in saying yes) while slowly exhaling. They must hold the contraction for 10 seconds and slowly return the head to the neutral position. After 10 seconds of rest, according to the patient's tolerance level, she performed 7 to 10 repetitions in 2 sets per day (once in the morning, once at night) during the first three sessions [23].

Cranio-cervical flexion in the standing position

To increase the exercise difficulty and exercise progression, in the second three sessions, CCF exercises were changed from a supine posture to a more functional position, so it was performed with the previous exercise parameters in the standing position while the back was resting against the wall [23].

Cranio-cervical flexion in the sitting position

After the sixth session, the exercise was changed to CCF in the sitting position to increase the CCF exercise difficulty level due to the frequent sitting position during daily activities [23].

Deep neck extensor exercise

The SSC was selectively activated relative to the splenius capitis (SC) by applying manual static resistance to the second cervical (C_2) vertebral arch and the patient was asked to push her head and neck backward [24]. The exercise was performed while patients were sitting on a stool without a backrest with hips and knees flexed at 90° and feet placed on the floor. The physiotherapist stood on the patient's left side, facing them, and placed her right-hand thumb and index finger approximately on the patient's C_2 vertebral arch and pushed her fingers firmly/gently (slowly to increase resistance) into flexion (anteriorly). The patient's left shoulder was stabilized by the left hand to monitor the compensatory movements [11]. Patients were asked to resist the movement in the extension direction without neck pain provocation, 10 seconds hold, 3 sets of 10 in each session, and 30 seconds of rest between sets [25]. After 10 sessions, the exercise has been followed in the form of segmental extension with 10 repetitions and a 10-second rest, two sets per day (once in the morning and once at night) as a home exercise (Figure 1).

Cervical extension in prone/4-point kneeling

After ensuring the correct posture of the lumbar, pelvic, thoracic, and cervical arches in a neutral position, the patient was asked to bend her spine segmentally from the upper to lower part in a 4-point kneeling position by performing the CCF and upper thoracic flexion (eccentric

Figure 2. Eccentric neck extensor exercise

Figure 3. Concentric neck extensor exercise

control of the movement by the neck extensor muscles) (Figure 2). After 10 seconds of hold, the patient returned the head and neck to the initial position of the exercise (concentric contraction of neck extensor muscles) (Figure 3) [25].

Statistical analysis

All obtained data were analyzed using SPSS software, version 19. The α level was 0.05. A one-sample Kolmogorov-Smirnov test was used to determine the normal distribution of all variables (P>0.05). An independent t-test was employed to check the demographic variables and to compare the mean of outcome measures between the two groups. The paired t-test was used to compare before-after intervention mean values of NPRS, PROM, CVA, NFE, NEE, and NWPKU in each group.

Results

The demographic data of the patients are presented in Table 1. The Kolmogorov-Smirnov test showed the normal distribution of the study variables (P>0.05). Table 2 presents the paired t-test results for assessing the changes

Table 1. Demographic information of intervention and control groups

Variables	Mean±SD		Mean Difference	95% Confidence Interval	P
	Intervention Group (n=15)	Control Group (n=12)			
Age (y)	30.93±5.10	32.17±4.48	-1.23	-5.09-2.63	0.39
Height (cm)	161.33±5.03	161.66±3.79	-0.75	-7.08-5.58	0.37
Weight (kg)	61.0±9.28	61.0±5.81	-0.33	-3.95-3.28	0.21
BMI (kg/m²)	23.34±2.83	23.59±1.57	-0.24	-2.13-1.64	0.09

BMI: Body mass index; SD: Standard deviation.

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in each outcome measure, and the independent t-test to compare the mean of each outcome measure between the two groups. The paired t-test results demonstrate a significant improvement in all outcome measures within 6 weeks of the study procedure in the intervention and control groups (P<0.001 for all variables). According to the independent t-test results, the intervention group's improvements were superior to the control group. NPRS and NWPKU decreased significantly, PROM (FLX, EXT, RSB, LROT), CVA, NFE, and NEE increased significantly (P=0.031, P=0.014, P=0.002, P=0.000, P=0.020, P=0.097, P=0.478, P=0.008, P=0.046, P=0.005, P=0.000, respectively) (Table 2).

Discussion

The present study results are in line with previous studies [11, 24], and indicated a significant improvement in NPRS and PROM in six main directions except for passive LSB and passive RROT, as well as CVA, DNEE, and NFE, in the intervention group superior to the control group. Exercise therapy is a safe and effective option in the CNNP patients' treatment process [8-10]. Price et al. in a systematic review, investigated that motor control and segmental exercises are one of the most efficient exercise types in CNNP cases [26]. Up to now, exercise ideal parameters are unknown and different from one study to another study [26]. To the best of our knowledge, no study has examined the effects of specific exercises, including both DNF and DNE muscles, on CNNP patients.

Patients with CNNP demonstrated a reduction in DNF muscle strength [27]. The DNF muscles, including the longus colli, longus, and capitis, have an important role in stabilizing the cervical spine [28]. The present study shows statistically significant increases in NFE and NEE in the intervention group compared to the control group. Similar to the previous reports, 6 weeks of CCF exercise significantly improved CCF muscle's isometric performance in CNNP patients and also increased flexor muscles' strength [11, 29-31]. In addition, the DNE muscles are equally as important as DNF in the CNNP patients' rehabilitation protocol [32]. So, DNE activation should also be emphasized in their treatment procedures. Schumacher (2012) suggests that cervical isometric resistance exercise can improve the relative activation of SSC to splenius capitis [24]. Also, Suvarnato et al. (2019) concluded that neck-muscle strength in the SSC-exercise group improved significantly more than the control group in neck-extensor strength after 6 weeks of exercise training [11].

A combination of DNF and DNE exercise training plus traditional PT for six weeks significantly reduced pain in agreement with past studies [30, 33, 34, 35]. Specific deep neck exercises may improve neuromuscular function and restore cervical spine sensorimotor control [36]. One possible mechanism to describe the effect of exercise therapy in reducing pain is that muscle contraction stimulates mechanoreceptors, and signals from the receptors cause the release of endogenous opioids and stimulate the release of endorphins from the pituitary gland [36].

In a previous EMG study, the concept of CCF exercise focused more specifically on motor control and also on training coordination between superficial and deep cervical muscles [30]. The aim of focusing on the longus colli and longus capitis muscles is to control head movement also cervical spine stabilization [37]. CCF exercise training may affect cervical spine lordosis, which leads to FHP improvement in CNNP cases. Previous studies indicated that DNF exercises are essential for CVA improvement in CNNP patients [38]. Also, the current study confirms that DNF and DNE exercise training is effective in CVA improvement in CNNP subjects.

Table 2. Intragroup and intergroup comparisons

Variables	Group	Mean±SD		P	Effect Size	Mean Difference	P
		Before	After				
NPRS (0-10)	Intervention	7.33±1.67	2.53±0.83	<0.001*	3.64	-0.80	0.031*
	Control	7.08±1.37	3.33±0.98	<0.001*	3.15		
NWPKU	Intervention	3.40±2.13	1.6±0.35	<0.001*	1.63	-1.10	0.014*
	Control	3.50±1.44	1.83±1.26	<0.001*	1.23		
PFLX (degree)	Intervention	48.20±2.88	56.20±2.24	<0.001*	3.10	3.03	0.002*
	Control	46.91±2.53	53.16±2.28	<0.001*	2.59		
PEXT (degree)	Intervention	45.80±3.72	54.66±2.25	<0.001*	2.88	5.16	<0.001*
	Control	44.58±2.81	49.50±3.03	<0.001*	1.68		
PRSB (degree)	Intervention	34.73±3.01	43.13±1.35	<0.001*	3.60	1.38	0.020 *
	Control	33.41±3.05	41.75±1.54	<0.001*	3.45		
PLSB (degree)	Intervention	35.93±4.33	43.66±1.87	<0.001*	2.31	1.58	0.097
	Control	35.83±3.37	42.08±2.87	<0.001*	1.99		
PRRot (degree)	Intervention	62.40±4.18	70.93±2.08	<0.001*	2.58	0.516	0.478
	Control	64.0±2.98	70.41±1.50	<0.001*	2.71		
PLRot (degree)	Intervention	62.53±3.11	72.33±2.19	<0.001*	3.64	2.33	0.008*
	Control	63.50±3.47	70.00±1.95	<0.001*	2.30		
CVA (degree)	Intervention	42.37±1.32	45.11±1.26	<0.001*	2.12	1.15	0.046*
	Control	43.11±1.55	43.96±1.59	<0.001*	.54		
NFE (second)	Intervention	12.06±3.63	27.20±4.90	<0.001*	3.51	4.70	0.005*
	Control	13.08±3.28	22.50±2.27	<0.001*	3.33		
NEE (second)	Intervention	16.26±2.57	31.00±3.50	<0.001*	4.80	6.75	<0.001*
	Control	16.75±3.38	24.25±3.46	<0.001*	2.19		

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Abbreviations: NPRS: Neck pain rating scale; NWPKU: Number of weekly pain killer usage; PFLX: Passive flexion; PEXT: Passive extension; PRSB: Passive right side bending; PLSB: Passive left side bending; PRRot: Passive right rotation; PLRot: Passive left rotation; CVA: Craniovertebral angle; NFE: Neck flexor endurance; NEE: Neck extensor endurance.

*Significant ($P<0.05$).

Salehi et al. (2016) presented that deep head and neck muscle strengthening exercises plus upper trapezius muscle stretching and its tone decrease increased neck flexion ROM [39]. Due to the exercise effect on the biomechanical movement components, it can be beneficial to increase the head and neck ROM; however, the previous results are not comparable with the present study findings as we assessed PROM.

A recent study showed that an isometric head/neck extension performed at 20% of the MVC activated both the deep and superficial extensors [38], and another study reported that SSC-specific exercise can improve the activation of SSC relative to the SC muscle [40]. In addition, the current study supported SSC-specific exercise training to increase DNEE in CNNP.

Furthermore, the neuromuscular control and morphological adaptations of deep neck muscles did not automatically improve after pain reduction to increase muscle endurance, exercise therapy should be focused on specific muscle impairments, particularly on DNF and DNE muscles.

According to the present study results, combination therapy (electrotherapy, MET, stretching exercise, DNF, and DNE exercises) increases PROM, NFE, and NEE and also decreases NPRS and WPKUN in CNNP subjects.

One of the mechanisms presented for the effectiveness of deep neck exercises in pain reduction is that muscle contraction during exercise stimulates the muscle spindle, Golgi tendon, and joint proprioceptive receptors and the signals sent from these peripheral receptors to the central nervous system will release pain-relieving compounds, such as endorphins from the pituitary gland that leads to a reduction in pain [41]. The neck ROM improvement following DNF exercise can be related to CVA increase that is improved by DNF exercises as it stretches shortened muscles and strengthens the weak deep neck muscles in CNNP subjects [39].

Conclusion

According to our results, a combination of DNF and DNE exercises added to traditional physiotherapy programs is an appropriate intervention to increase PROM, NFE, and NEE and also decrease NPRS and NWPKU in CNNP patients. This study offers an effective treatment protocol for CNNP patients and healthcare system providers, particularly physiotherapists.

There are some limitations to the current study. Future studies should measure other clinical outcomes to describe the effects of these exercises on sensory and motor function in CNNP patients, such as joint position sense, headache frequency, disability, balance, and muscle activity with a long-term follow-up. In the present study, we measured only the global muscle endurance of neck extensor and flexor muscles and not specific activation or changes in deep neck muscle morphology. To extend the study results, further studies in the future are suggested, using the electromyography test and ultrasound imaging to measure neck muscle activation or cervical muscle stiffness and to investigate deep neck muscle CSA change in CNNP patients to provide additional objective findings.

Ethical Considerations

Compliance with ethical guidelines

This study was approved by the Ethics Committee of Tehran University of Medical Sciences (Code: IR.TUMS.MEDICINE.REC.1400.1218) and the Iranian Registry of Clinical Trials (IRCT) (Code: IRCT20220122053793N1).

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Authors' contributions

Conceptualization and supervision: Azadeh Shadmehr, Mohammad Reza Hadian Rasanani, and Sara Fereydounnia; Methodology: Azadeh Shadmehr, Sara Fereydounnia, and Atefe Najafi; Data collection: Atefe Najafi; Data analysis: Sara Fereydounnia and Atefe Najafi; Investigation and writing: Azadeh Shadmehr, Sara Fereydounnia, and Atefe Najafi; Funding acquisition and Resources: Azadeh Shadmehr.

Conflict of interest

The authors declared no conflict of interest..

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