

The effectiveness of two different treatment approaches in individuals with chronic non-specific neck pain: a randomized control trial

Kronik non-spesifik boyun ağrısı olan bireylerde iki farklı tedavi yaklaşımının etkinliği: randomize kontrollü çalışma

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Abstract

Abstract

The aim of this study is to examine the effectiveness of conventional treatment and mobilization exercises in individuals with chronic nonspecific neck pain (CNNP). A total of 28 patients enrolled in the study. The Mobilization group (MG) completed a 4-week combined conservative physiotherapy and cervical mobilization program, whereas the control group (CG) received only the 4 weeks of conservative physiotherapy. Pain severity according to the Visual Analogue Scale (VAS) was used as primary outcome. Secondary outcomes were included the Bourdon Attention Test (BAT), Beck Anxiety Scale (BAS), range of motion (ROM), muscle strength. All outcomes were assessed both prior to and following the treatment. In 2-way mixed-design repeated-measures ANOVA analysis, when the change in time was analyzed between the groups (Group*Time [interaction]), a statistical difference was found for the VAS ($p = .000$, $\eta^2 = .007$), BAT score ($p = .001$, $\eta^2 = .082$), BAS ($p = .000$, $\eta^2 = .001$), ROM flexion ($p = .000$, $\eta^2 = .104$), ROM extension ($p = .000$, $\eta^2 = .076$), ROM right rotation ($p = .006$, $\eta^2 = .033$), ROM left rotation ($p = .05$, $\eta^2 = .006$), ROM right lateral flexion ($p = .000$, $\eta^2 = .060$), ROM left lateral flexion ($p = .002$, $\eta^2 = .019$), muscle strength flexion ($p = .000$, $\eta^2 = .008$), muscle strength extension ($p = .000$, $\eta^2 = .019$), muscle strength right rotation ($p = .000$, $\eta^2 = .012$), muscle strength left rotation ($p = .000$, $\eta^2 = .001$), muscle strength right lateral flexion ($p = .000$, $\eta^2 = .001$) and muscle strength left lateral flexion ($p = .000$, $\eta^2 = .011$) parameters in favour of MG. Cervical mobilization produced a significant benefit to recovery of pain, ROM, muscle strength, attention and anxiety outcomes of patients with CNNP when added to a conventional CNNP physical therapy program.

Keywords: Chronic non-specific neck pain, cervical mobilization, pain

The study was registered on the Clinical Trials Registry (registration number: NCT05377645)

Özet

Bu çalışmanın amacı kronik nonspesifik boyun ağrılı (KNBA) bireylerde mobilizasyon egzersizleri ile geleneksel tedavinin etkinliğinin karşılaştırılmasıdır. Çalışmaya 28 hasta dahil edildi. İki gruba da 4 hafta boyunca haftada 3 gün geleneksel tedavi uygulandı. Mobilizasyon grubuna (MG) geleneksel tedaviye ek olarak servikal mobilizasyon egzersizleri yapıldı. Primer sonuç ölçüğü olarak ağrı, Vizüel Analog Skala (VAS) ile ölçüldü. Sekonder sonuç ölçüğü olarak Burdon Dikkat Testi (BDT), Beck Anksiyete Skalası (BAS), eklem hareket açıklığı (ROM), kas gücü ölçümü yapıldı. Tüm ölçümler tedavi başlangıcında ve sonunda yapıldı. Gruplar arası iki yönlü tekrarlı ANOVA analizi sonucunda VAS ($p = .000$, $\eta^2 = .007$), BDT skoru ($p = .001$, $\eta^2 = .082$), BAS skoru ($p = .000$, $\eta^2 = .001$), ROM fleksiyon ($p = .000$, $\eta^2 = .104$), ROM ekstansiyon ($p = .000$, $\eta^2 = .076$), ROM sağ rotasyon ($p = .006$, $\eta^2 = .033$), ROM sol rotasyon ($p = .05$, $\eta^2 = .006$), ROM sağ lateral fleksiyon ($p = .000$, $\eta^2 = .060$), ROM sol lateral fleksiyon ($p = .002$, $\eta^2 = .019$), fleksör kas gücü ($p = .000$, $\eta^2 = .008$), ekstansör kas gücü ($p = .000$, $\eta^2 = .019$), sağ rotasyon kas gücü ($p = .000$, $\eta^2 = .012$), sol rotasyon kas gücü ($p = .000$, $\eta^2 = .001$), sağ lateral fleksiyon kas gücü ($p = .000$, $\eta^2 = .001$) ve sol lateral fleksiyon kas gücü ($p = .000$, $\eta^2 = .011$) parametreleri mobilizasyon grubu lehine anlamlı bulunmuştur. KNBA'lı hastalarda konvansiyonel tedavi programına ek olarak uygulanan servikal mobilizasyon ağrı, ROM, kas gücü, dikkat ve anksiyete parametrelerinde sadece geleneksel tedavi uygulanan gruba göre anlamlı düzeyde iyileşme sağlamıştır.

Anahtar Kelimeler: Kronik non-spesifik boyun ağrısı, servikal mobilizasyon, ağrı

Bu çalışma klinik denemeler listesine kaydedilmiştir (kayıt numarası NCT05377645).

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Introduction

Chronic non-specific neck pain (CNNP) is known as a common public health problem in the modern world, (1) and although its lifetime prevalence is approaching 50% (2) it is frequently seen in adolescents (3). CNNP is considered severe discomfort in the lateral and posterior of the neck lasting more than 3 months (4) resulting from neck cancer, infection, poor posture, degenerative and mechanical changes (5, 6). CNNP causes disability, limitation of activities of daily living, job dissatisfaction, and increased economic and social costs (7, 8).

Various applications such as physiotherapy, exercise, massage, chiropractic, spinal mobilization and manipulation are used in the treatment (9, 10). Manual therapy (MT) is an increasingly popular treatment for people with CNNP, and many countries include it in their national guidelines for the treatment of musculoskeletal disorders (11-13). Overall, this treatment is considered to be more beneficial than non-invasive or placebo treatments(14-17). MT includes both passive techniques and active techniques. Palmgren et al. concluded that chiropractic practices positively affect proprioception and pain in patients with chronic neck pain (13). In another randomized controlled trial, Zaproudina et al. demonstrated that mobilization techniques reduce the level of disability and pain in patients with chronic neck pain (17). Also, Cleland et al. reported that thoracic spine manipulation had analgesic results in individuals with mechanical neck pain (18).

When the literature was examined, we could not find any comprehensive study examining the effects of conventional treatment and cervical mobilization exercises on pain, muscle strength, neck joint range of motion, anxiety and attention in individuals with CNNP. Therefore, the aim of this study is to examine the effectiveness of conventional treatment and mobilization exercises in individuals with CNNP.

Methods

Trial Design

The study design was a randomized, single-blind 1:1 parallel-group study and it was held at Kırşehir Ahi Evran University School of Physical Therapy and Rehabilitation between December 2021 and June 2022. The study proposal was approved by the local ethics committee, and conducted in accordance with the Declaration of Helsinki principles (12/24/2021). Prior to the study, written and oral consent was given by all participants and their families. The authors confirm that all ongoing and related trials for this study were registered. Due to an error of omission, the trial was registered retrospectively on May 17, 2022, before the data was analyzed (ClinicalTrials.gov Identifier: NCT05377645). We hereby state that all future trials will be registered prospectively.

Participants

The participants of the study were people who applied to Kırşehir Ahi Evran University Physical Therapy Hospital with chronic non-specific neck pain. Inclusion criteria for the study: 18-65 years of age, current neck pain lasting at least 3 months. Exclusion criteria: previous neck surgery, spinal fractures and tumors, people with visual and mental impairments that would affect the assessment.

Interventions

Participants received only the treatment determined by the investigators; they did not combine treatment with medications or other physiotherapy practices. Any additional intervention to the treatment was grounds for exclusion and they were warned about it. The treatment was applied in 12 sessions for 4 weeks.

Group 1: Conventional Group (CG)

Conventional Transcutaneous Electrical Nerve Stimulation (TENS- Elettronica Pagani Class1 type BF brand device with a frequency of 100 Hz, pulse duration 200 µsec and current strength between 20-35 mA) was applied to the neck area for 20 minutes along with hot application for 20 minutes in the patients in the CG (Figure 1) (19). In addition, neck isometric exercises were applied.

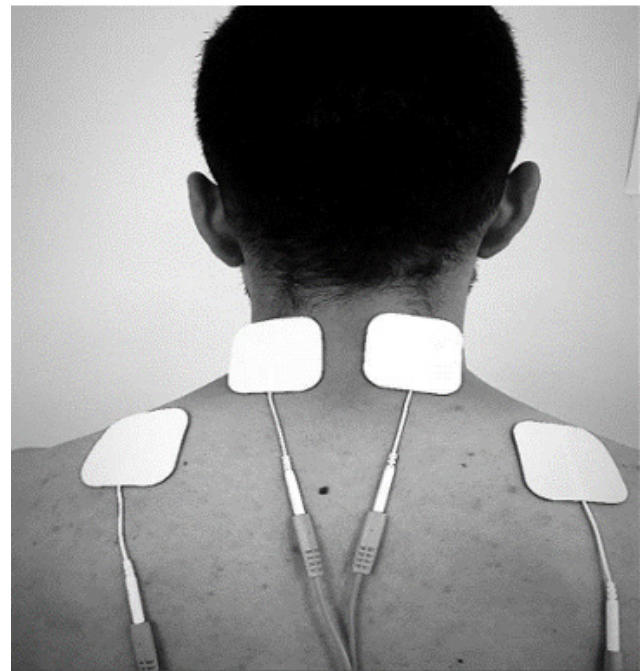


Figure 1. TENS application electrode placement

Group 2: Mobilization Group (MG)

In addition to the conventional physiotherapy program, cervical region mobilization was applied to the patients in MG. Cervical mobilization bridging technique (Figure 2), manual traction (MT) (Figure 3) with MT rotation (Figure 4), anterior-posterior with MT gliding (Figure 5), lateral gliding (Figure 6) was applied (20).



Figure 2. Bridge technique



Figure 3. Manuel traction



Figure 4. Rotation with manual traction



Figure 5. Anterior-posterior with MT gliding



Figure 6. Lateral gliding

Outcomes

All measurements were repeated in the same way after the treatment.

Primary Outcome

Pain

Pain intensity was evaluated by marking the Visual Analogue Scale (VAS) on a 10 cm horizontal line (21).

Secondary Outcome

Anxiety

Anxiety levels of the patients were evaluated using the Beck Anxiety Scale (BAS). BAS individual lives evaluate the frequency of anxiety symptoms. Consisting of twenty-one items, between 0-3 a scored self-assessment is the scale. Trouble with questions asked to the patient how much has your feeling been in him for the past week? disturbing is questioned. Score Range is 0-63. The high score obtained from the scale, the severity of the anxiety experienced by the individual shows (22).

Cognitive assessment

The Bourdon Attention Test was used to assess the cognitive levels of the participants. The test developed in 1955 by Benjamin Bourdon. Turkish validity and reliability studies were carried out by Karaduman (23).

Range of Motion

The neck is active and passive range of motion (ROM) using the universal goniometer evaluated. Pivot of the goniometer with the patient in the sitting position designated point, fixed arm and movable arm placed in reference regions. The patient is active was asked to do the movements and actively passive after the end of ROM passively by continuing the movement joint ROM was measured (24).

Muscle Strength

Muscle strength of patients Lovett's levels were assessed using a manual muscle test scale ranging from 0 to 5. Muscle strength was evaluated bilaterally and the averages were recorded (24).

Sample Size

To determine the sample of the study, version 3.1.9.4 of the G*Power program (HeinrichHeine-Universita't Dusseldorf, Germany) was used (25). According to previous studies, it was determined that the effects of mobilization exercises on neck pain were determined to be from small to moderate (0.16–0.38)(26, 27). To obtain 80% statistical power ($1 - \beta$ error probability) with an α error level probability of 0.05, we performed repeated measure analysis of variance (ANOVA) within and between interactions, used a medium effect size of 0.30 to consider the two groups, and used two measurements for the primary outcome, generating a sample size of 28

participants. Considering the drop-out rate of 15% and aiming to increase the statistical power of the results, a total of 28 participants (14 for each group) were recruited into the study.

Randomization

A randomization process was performed to divide the 28 CNNP patients randomly between the two study groups (MG and CG), using matched-pairs randomization based on their age and sex. Matched-pairs randomization was performed with numbers sorted using the Research Randomizer program on the www.randomizer.org website (28).

Blinding

At the baseline and after application of the 4-week treatment period, all assessments were evaluated by the investigator, who was blinded to the groups throughout the study (İ.C.).

Statistical Methods

Statistical analyzes were performed using SPSS (IBM Corporation, Armonk, NY) version 24 software. The conformity of the variables to the normal distribution was examined using visual (histogram and probability graphs) and analytical methods (Shapiro-Wilk tests). Descriptive analyzes were given using the mean and standard deviation for normally distributed variables. Number and % were given for nominal variables. Student's T test was used to test the significance of the difference between the two means in the comparison of the measured values of the mobilization and control groups. Chi-square test (Pearson chi-square) was used to examine the relationship between categorical variables. Two-way analysis of variance (Mixed design repeated measures ANOVA) was used in repeated measurements to evaluate the changes in the variables determined by measurement in the mobilization and control groups over time and the group-time interactions. For statistical significance, the total type-1 error level was determined as 5%.

RESULTS

Thirty-three volunteers applied for the study, and 28 satisfied the inclusion criteria. The patients distributions were $n=14$ for the MG and $n=14$ for the CG after randomization. The flow chart of the study is shown in Figure 7.

Demographic characteristics of the MG and CG are shown in Table 1. There was no statistically significant difference between the MG and CG in terms of demographic characteristics ($p>0.05$). This result shows that the groups are similar in terms of demographic characteristics distribution.

Baseline, after treatment and score changes for BAS, BAT, VAS, ROM, and muscle strength parameters of MG and CG are given in Table 2. According to the 2-way mixed design repeated-measures ANOVA analysis, when the change in time was analyzed between the groups (Group*Time (interaction)), no

statistical difference was found for all parameters ($p>0.05$). In other words, when the mean change scores of the groups were examined, similar score changes occurred in the mobilization and control groups for all parameters (Table 2). This result shows that the treatment methods applied to individuals with neck pain have a similar effect. When the changes within the groups (within group (Time-Main effect)) were examined, a statistical difference was found for all parameters except the left rotation range of motion subparameter ($p<0.05$). In other words, the treatment methods applied to individuals with neck pain are effective for both groups.

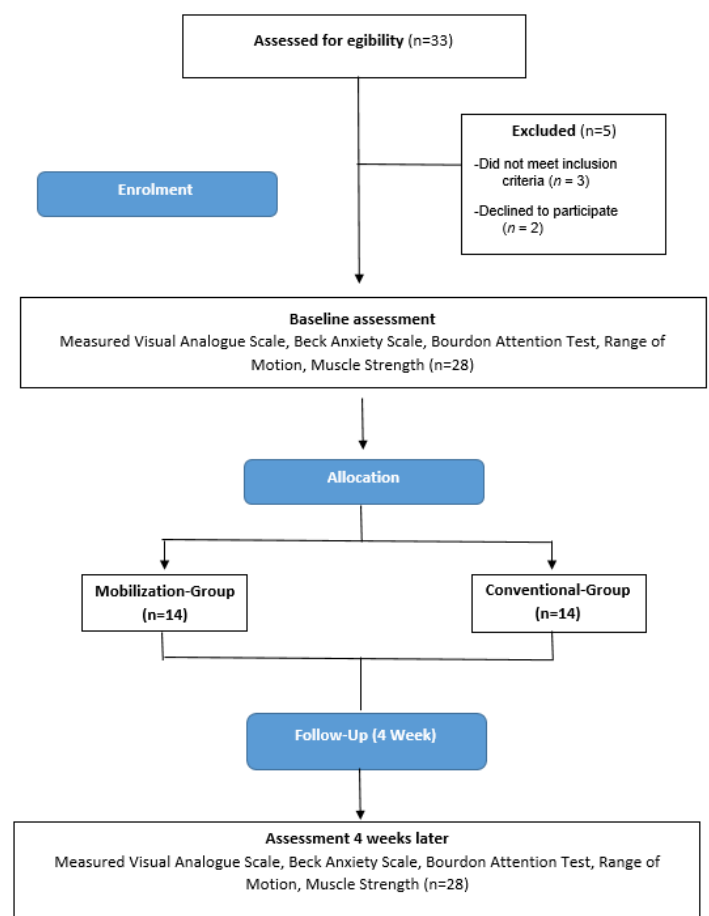


Figure 7. Study flowchart

DISCUSSION

The most important result of our work; we concluded that both conventional and cervical mobilization treatment approaches decrease the pain severity level in patients with CNNP. In addition, both treatment approaches were found to have positive results on muscle strength, ROM, cognitive level and anxiety. However, it turned out that the groups did not have superiority over each other.

There are many risk factors for neck pain such as physical problems, work-load, psycho-social factors and health-related behaviors have been identified in the literature (29). Ganesh et

Table 1. Demographic characteristics of mobilization and control groups

		MG(n=14)		CG(n=14)		t	p
		X	SD	X	SD		
Age (years)		38.4	15.2	41.7	12.2	-0.63	0.531
BMI (kg/m2)		27.6	5.0	27.1	4.8	0.29	0.772
		n	(%)	n	(%)	X ²	p
Gender	Female	8	57.1	8	60	0.24	0.876
	Male	6	42.9	6	40		

BMI; Body Mass Index, t, Student T Test, X², Chi-square Analysis, X; mean, SD; Standart Deviation

Table 2: Baseline, after treatment and score changes for BAS, BAT, VAS, ROM and muscle strength parameters of the groups included in the study

		MG (n=14)		CG (n=14)		Between-group difference in change scores	Time (Main effect)	Group*Time (Interaction)	η ²	
		in change scores	Time (Main effect)	Group* Time (Interaction)	SD	Mean	p	F/ p value		
BAS	Baseline	14.1	7.3	22.8	13.8	0.4	0.000	0.03/0.863	0.001	
	After treatment	8.0	4.2	16.3	12.1					
BAT	Baseline	77.4	21.5	80.6	26.5	8.9	0.001	2.39/0.133	0.082	
	After treatment	92.2	15.3	86.5	27.2					
VAS	Baseline	5.6	1.7	7.5	1.8	0.3	0.000	0.20/0.657	0.007	
	After treatment	2.4	1.5	4.0	2.6					
ROM	Flexion	Baseline	41.2	9.6	39.3	7.8	4.7	0.000	3.30/0.080	0.109
		After treatment	51.1	6.8	44.5	5.4				
ROM	Extansion	Baseline	32.9	7.8	36.3	7.7	3.2	0.000	2.21/0.148	0.076
		After treatment	40.7	6.1	41.0	7.1				
ROM	Right Rotation	Baseline	46.6	9.8	43.7	11.9	2.5	0.006	0.92/0.344	0.033
		After treatment	51.8	8.7	46.3	10.6				
ROM	Left Rotation	Baseline	50.0	9.1	45.3	10.9	0.9	0.050	0.15/0.696	0.006
		After treatment	52.9	8.7	47.3	11.4				
ROM	Right Lateral Flexion	Baseline	33.1	10.7	30.5	7.4	-3.8	0.000	1.71/0.201	0.060
		After treatment	37.1	8.4	38.3	6.4				
ROM	Left Lateral Flexion	Baseline	34.5	10.3	33.1	7.0	-2.0	0.002	0.510/0.481	0.019
		After treatment	38.2	10.6	38.9	6.2				
Muscle Strength	Flexion	Baseline	4.4	0.8	4.0	0.7	-0.1	0.000	0.21/0.647	0.008
		After treatment	4.9	0.3	4.6	0.6				
Muscle Strength	Extension	Baseline	4.4	0.7	4.3	0.7	0.2	0.000	0.52/0.477	0.019
		After treatment	4.9	0.3	4.7	0.5				
Muscle Strength	Right Rotation	Baseline	4.2	0.8	4.1	0.7	-0.1	0.000	0.33/0.566	0.012
		After treatment	4.6	0.5	4.5	0.6				
Muscle Strength	Left Rotation	Baseline	4.1	0.8	4.1	0.7	0.0	0.000	0.02/0.879	0.001
		After treatment	4.6	0.5	4.5	0.6				
Muscle Strength	Right Lateral Flexion	Baseline	4.3	0.7	4.0	0.7	0.0	0.000	0.03/0.862	0.001
		After treatment	4.7	0.5	4.5	0.6				
Muscle Strength	Left Lateral Flexion	Baseline	4.2	0.7	4.1	0.6	-0.1	0.000	0.30/0.589	0.011
		After treatment	4.6	0.5	4.6	0.5				

BAS: Beck anxiety scale, BAT: Bourdon attention test VAS: Visual analogue scale, ROM: Range of Motion, 2-way mixed design repeated-measures analysis of variance, SD: Standard deviation, η²: Effect size

al. divided the patients with chronic neck pain into 3 groups. Maitland mobilization technique and exercise were given to the 1st group; Mulligan applied the mobilization technique and exercise to the 2nd group, and only exercise to the 3rd group. They did not find a significant difference between the 3 groups in terms of pain parameters after the treatment and at the control at the end of the 12th week (30). Palmgren et al. concluded that chiropractic practices in patients with nontraumatic chronic neck pain caused an improvement in pain and proprioception (13). In another study, Acet et al. concluded that manual therapy approaches are more effective than traditional physiotherapy programs in terms of pain, range of motion and disability in patients with non-specific neck pain (19). In our study, it was revealed that the exercises given to both groups decreased the level of pain.

Cervical suboccipital muscles have been shown to have 36 muscle spindles per gram of muscle tissue; the gluteus maximus, by contrast, has 0.7 spindles per gram (31). The high number of stretch receptors in these tissues, and their essential link from the eye movements to coordination of the rest of the back musculature, ensure their central role for cognitive performance (32). Neuroimaging studies have demonstrated structural and functional changes in regions of the brain responsible for cognitive and emotional modulation of pain in individuals with chronic neck pain. Some studies have revealed that compared to healthy volunteers, patients with chronic neck pain exhibit worse cognitive performance, especially in areas such as attention, concentration, working memory and processing speed abilities (33, 34). In the current study The BAT was used to assess the attention levels of the participants. When the test data were examined, there was an increase seen in the post-treatment measurements for both groups, although there was no significant difference found between the groups.

Farooq et al. concluded that both the traditional physiotherapy program and cervical mobilization exercises applied in addition to the traditional physiotherapy program in patients with chronic mechanical neck pain resulted in improvements in pain, disability and cervical ROM (35). Ganesh et al. Maitland and Mulligan compared the effectiveness of mobilization exercises in patients with mechanical neck pain. According to the results of the study, they concluded that both mobilization techniques were effective in reducing pain, improving ROM and disability (30). Snodgrass et al found no change immediately after mobilization, but a reduction in stiffness by day 4. The mobilization group in the painful area was 17% less stiff compared to the placebo group (36). In our study, improvement in cervical region ROMs was observed in both treatment groups, but neither treatment was superior to each other.

Lee et al. applied Maitland mobilization of the thoracic and cervical region to patients with chronic neck pain and stated

that there was a significant improvement in the muscle strength of the upper trapezius muscle after the treatment (37). Copurgensli et al. investigated the effect of kinesiotaping application and Mulligan mobilization in patients with cervical spondylosis and concluded that Mulligan mobilization increased cervical region flexor muscle strength (38). Our study is compatible with the literature, and cervical region muscle strength increased in both MG and CG, but there was no statistically significant difference between the groups.

In a 2015 study, Lopez et al. stated that cervical mobilization techniques reduce anxiety (39). In another study, Santos et al. stated that there is a decrease in the rates of anxiety and depression in personnel who have undergone spinal mobilization at work (40). Yıldırım et al. stated that mobilization techniques had a positive effect on anxiety in the acute period. (41). In this study Beck Anxiety Scale (BAS) was used to determine the risk of anxiety in patients and/or to measure the level of anxiety symptoms and the change in its severity (22). As a result of this study, both groups showed a decrease in anxiety levels, and this decrease was found to be higher in the mobilization group.

CONCLUSION

This study showed that mobilization exercises and conventional therapy used in the treatment of CNNP are effective in improving pain level, muscle strength, cognitive level, ROM and anxiety level.

Limitations

This study has a limitations. In our study, we evaluated pain with VAS based on patient statement, but a more objective evaluation such as algometry could be made.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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