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ID: 5160230

Benefit of Adding Stretching to Standard Intervention for Patients with Nonspecific Mechanical Neck Pain

NCT03194490

Date: October 09, 2019

Methods

Participants

Forty-three participants who had at least two weeks of non-specific mechanical neck pain were randomly assigned to either the combined intervention (passive cervical mobilization, active range of motion exercises, and stretching techniques) (n_1=20) or standard intervention group (passive cervical mobilization and active range of motion exercises) (n_2=23). At two-weeks follow-up, 2 participants dropped out of the study due to health conditions, and at 8 weeks, 3 participants withdrew. (Refer to Figure 1) Thus, 38 participants with a mean age 31.0 ± 8.3 years, height 1.6 ± 0.1 m, mass 72.8 ± 17.5 kg, and body mass index 26.9 ± 6.7 kg/m^2 completed this study. All participants read and signed a consent form that was approved by the institutional review board at Loma Linda University. This study was registered in ClinicalTrials.gov with Protocol #5160230. The participants met the following inclusion criteria: between 18 and 60 years of age, had non-specific neck pain for at least 2 weeks, and pain intensity of more than 2 points on a numeric pain rating scale (NPRS) in the past week. Participants were excluded from the study if they had one or more of the following conditions: specific diagnosis of the cervical spine, such as spinal stenosis, disc prolapse, previous surgery in the neck and shoulder areas, shoulder pathology (bursitis, tendonitis, adhesive capsulitis), history of severe trauma, ligamentous instability, hypermobility syndrome, migraine (frequency more than twice per month), spasmodic torticollis, radiculopathy due to peripheral nerve entrapment, fibromyalgia, severe psychiatric illness, inflammatory rheumatic diseases, pregnancy or other on-going therapies.

The identification of the study's excluding criteria was conducted through clinical examination, medical history and self-reported questionnaires [6]. Participants were randomly assigned to either the combined intervention group or the standard intervention group using a random number table. Demographic and general characteristics of the participants are presented in **Table 1**.

Instrumentation

Cervical ROM

The Gravity Inclinometer method using the Cervical ROM Device (CROM) was used to assess active ROM for flexion, extension, lateral flexion, and rotation. The CROM was used in many clinical trials and deemed to have good reliability and validity [19]. Lee, Nicholson, Adams [20] indicated that the cervical ROM device has high intra-examiner reliability with an ICC of 0.84 (95% CI: 0.72;0.91) for flexion, an ICC of 0.81 (95% CI: 0.67;0.89) for extension, an ICC of 0.81 (95% CI: 0.66; 0.89) for right lateral flexion, an ICC of 0.81 (95% CI: 0.68; 0.90) for left lateral flexion, an ICC of 0.74 (95% CI: 0.56;0.85) for right rotation, and an ICC of 0.76 (95% CI: 0.59;0.86) for left rotation. The CROM device has high concurrent validity compared to

radiograph [21]. William et al. (2010) reported that CROM has high validity with correlation coefficients of 0.97 for flexion and 0.98 for extension.

In order to measure cervical ROM, the participant sat on a stool facing the west, feet flat on floor, and arms hanging at each side. One examiner positioned the CROM device on the participant's head. Then 3 trials were recorded for six different direction: flexion, extension, right and left lateral flexion, and left and right rotation. The other examiner then recorded the average of the three trails for each position.

Pressure Pain Threshold

The digital algometer is an electronic device used to measure the amount of force that is required to produce pain or pressure pain threshold (PPT) [22]. It has high reliability and validity in measuring pain threshold for individuals with neck pain. Park, Kim, Park, Kim, Jang [23] indicated that pressure pain threshold has a high intra rater reliability ranging from 0.94 to 0.98. The validity of the electric algometer ranged from 0.95 to 0.98 [24].

In order to measure neck pressure pain threshold, a handheld electronic pressure algometer with a surface area at the round tip of 1 cm^2 was utilized. The participant laid prone on a treatment table and was instructed to report the first point when pressure sensation turned into pain sensation. The examiner increased the pressure gradually at rate of 1 kg/sec perpendicularly to the right upper trapezius at the upper border of muscle between the lateral border of acromion and the midline and then on the left side with a 30-second pause between each trial [22]. Three trials were performed at each side in each test session [25].

Numeric pain rating scale

Numeric pain rating scale (NPRS) was used to determine the level of the participant's pain. It consists of a straight 100 mm line that is scored from 0 to 10 with 10 mm intervals. The zero represents no pain while a 10 represents very severe pain. The Numeric pain rating scale has moderate reliability with correlation coefficients ranging from 0.60 to 0.77 [26]. In addition, Boonstra, Preuper, Reneman, Posthumus, Stewart [26] indicated that NPRS has high validity in detecting pain with correlation coefficients ranging from 0.64 to 0.84.

Neck Disability Index

The Neck Disability Index (NDI) consists of ten items that each range from 0 to 5 that help measure the level of disability for patients with neck pain. The NDI score ranges from 0 to 50 [27]. The level of disability determined by the score of NDI is as follows: 0 - 4 = no disability, 5 - 14 = mild, 15 - 24 = moderate, 25 - 34 = severe, and above 34 = complete disability [27]. The NDI has a high test-retest reliability with an intra class correlation (ICC) between 0.88 and 0.95 and high internal consistency with Cronbach's α values ranging from 0.85 to 0.90 [28]. For NDI score, the ICC was 0.83 (95% CI, 0.75–0.90), which indicates that the NDI has high validity to detect any

small change in the patient's condition [29]. In addition, Childs, Cleland, Elliott, Teyhen, Wainner, Whitman, Sopky, Godges, Flynn, Delitto [18] reported that NDI has high sensitivity and specificity of 0.83 and 0.72, respectively.

Global rating of change

The Global Rating of Change was used to measure the amount of improvement that the patient achieves from the intervention or rehabilitation program. The score ranges from -7 to 7 in which -/+3 to -/+ 1 represents a small change, -/+ 4 to -/+5 represents moderate change and -/+6 to -/+7 means a large change. The negative and positive signs determine whether the patient's condition worsens or improves respectively. GROC has a high test-retest reliability with an ICC value of 0.90 (95% confidence interval (CI) 0.84 to 0.93). In addition, GROC has high face validity with Pearson's r= 0.72 – 0.90 and ICC = 0.74 [30]. Kamper, Maher, Mackay [30] reported that the GROC has high construct validity when compared to other gold standard measurements such as the Roland Morris, Oswestry, and pain rating scale.

Procedures:

The study was conducted over 8 weeks. Participants were randomly allocated into two groups: *combined intervention* (passive cervical mobilization, active range of motion exercises, and stretching techniques) (n_1=18) and *standard intervention groups* (n_2=20). The randomization was performed by a person who was blind to the patient's allocation. Participants in the *combined intervention group* received 30 minutes of passive manual therapy consists of (i) cervical mobilization and (ii) active cervical range of motion exercises to be performed at home 3-4 times daily, (iii) stretching techniques for 2 sessions per week for 4 weeks (iv) a self-administered stretching exercises to be performed at home 5 times a week. Participants in *standard intervention group* received 15 minutes of manual therapy consists of (i) cervical mobilization and (ii) active range of motion exercises to be performed at home 3-4 times daily.

Cervical Mobilization techniques were used in the study and consisted of low-velocity non-thrust cervical joint mobilizations for unilateral symptoms: postero-anteroior unilateral vertebral pressure, traction, and transfer vertebral pressure. For bilateral symptoms, the following joint mobilization were applied: postero-anterior central vertebral pressure, postero-anterior unilateral vertebral pressure (2 sides), longitudinal movement, traction and rotation. These techniques have been described previously by Anandacoomarasamy, Barnsley [31]. Both groups received 10 minutes of cervical mobilization for 2 sessions per week for 4 weeks.

Active Cervical Range of Motion Exercises (ACROM) were performed 10 repetitions 3–4 times daily. The ACROM exercise consisted of the subject placing four fingers over the manubrium bone and placing chin on the fingers. The subject was then instructed to rotate to one side as far as possible and return to neutral and then actively rotate to the other side [32]. Both groups performed ACROM exercises. Subjects were advised to maintain their usual activity within the limits of pain.

Stretching techniques were performed in the combined intervention group for 30 seconds for each muscle and repeated 3 times twice a week to the following muscles: anterior, middle and posterior scalene, upper fibers of trapezius, pectoralis minor muscles and interspinous muscles as described by Ylinen, Chaitow, Nurmenniemi, Hill [33].

The cervical mobilization and stretching exercise techniques were performed by a licensed physical therapist who has 6 years of experience in manual physical therapy.

Self-administered stretching exercises were performed by participants in the combined intervention group to the following muscles: the extensor muscles, the upper part of the trapezius, and the posterior scalene [6]. Each movement was held for 30 seconds and repeated 3 times. Lastly, the participant was instructed to perform a neck straightening exercise by retracting the neck (Chin tuck) 5 times for 3-5 seconds. Subjects in the combined intervention group were provided with written instruction of the stretching exercises and directed to perform stretching exercise 5 times a week, each exercise session takes about 10 minutes. Patients were also instructed to keep a stretching diary to track their stretch exercise frequency.

Data collection:

Data was collected at baseline, one week after intervention, and week 4. The final data collection date was set at week 8 as a follow up to determine whether the participant was able to maintain gains at one month following the interventions.

Statistical Analyses

A sample size of 50 participants was estimated using a moderate effect size of 0.25, level of significance 0.05, and power of 0.80. Data was summarized using mean and standard deviation [1] for quantitative variables and counts (%) for qualitative variables. The normality of continuous variables was examined using Shapiro Wilk's test. The distribution of the participants' characteristics by study group were evaluated using chi-square for qualitative variables and independent t- test for quantitative variables. Mixed factorial analysis of variance (ANOVA) was used to examine changes in cervical ROM variables, pressure pain threshold, NPRS, GROC, and NDI scores by study group over time. Post hoc comparisons using Bonferroni test and effect size were computed to identify significant differences over time. We compared percent change (4 weeks vs. baseline) for all outcome variables between the two study groups using independent t-test and Mann- Whitney test. To examine whether there were any changes in the outcome variables at 4 weeks follow up paired t- test was used. The level of significance was set at $p \leq 0.05$. Statistical analysis was performed using IBM SPSS Software version 24 for Windows (Chicago, IL, USA).

Results

Thirty-eight (38) subjects with a mean± SD age 30.9±8.1 years and body mass index (BMI) 26.8±6.7 kg/m^2 participated in the study. Sixty- five percent of the participants were females (n=

26). There was no significant difference between the two study groups in terms of age, Body Mass Index (BMI), cervical ROM and pressure pain threshold at baseline. Demographic and general characteristics are presented in **Table 1**.

Changes in ROM

Results of the mixed factorial ANOVA for ROM is displayed in **Table 2**. There was a significant difference in mean ROM during extension over time ($F_{2,72}$=6.8, p=0.002, η^2=0.20), and a significant group by time interaction ($F_{2,72}$=3.6, p=0.02). Bonferroni post hoc comparison revealed that the difference was significant between baseline and one week later (70.2±2.1 vs. 74.3±2.4, p=0.04), baseline and 4 weeks later (70.2±2.1 vs. 76.6±2.0, p=0.001), however, there was no significant difference between one week later and 4 weeks (p=0.15). In addition, the % improvement from baseline to 4 weeks later was significantly different between the combined intervention and standard intervention groups respectively (18.9% vs. 3.0%; t=2.4, p=0.02). (Refer to **Table 2**)

Also, there was a significant difference in mean ROM during right lateral flexion over time ($F_{2,72}$=13.8, p<0.001, η^2=0.30), and a significant group by time interaction ($F_{2,72}$=2.9, p=0.04). Bonferroni post hoc comparison revealed that the difference was significant between baseline and one week later (40.8±1.5 vs. 43.8±1.3, p=0.03), baseline and 4 weeks later (40.8±1.5 vs. 46.8±1.4, p<0.001), and between one week later and 4 weeks (43.8±1.3 vs. 46.8±1.4, p=0.001). In addition, the % improvement from baseline to 4 weeks later was significantly different between the combined intervention and groups respectively (23.2% vs. 10.8%; t=1.8, p=0.04). (Refer to **Table 2**).

There was a significant difference in mean ROM during left lateral flexion over time ($F_{2,72}$=3.0, p=0.03, η^2=0.30), and a significant group by time interaction ($F_{2,72}$=3.0, p=0.03). Bonferroni post hoc comparison revealed that the difference was significant between baseline and one week later (43.0±1.1 vs. 46.3 ±1.0, p=0.01), baseline and 4 weeks later (43.0±1.1 vs. 48.5±1.3, p<0.001), and between one week later and 4 weeks (46.3±1.0 vs. 48.5±1.3, p=0.01). In addition, the percent improvement from baseline to 4 weeks later was significantly more for the combined intervention as compared to the standard intervention group (20.0% vs. 7.7%; t=2.1, p=0.02).

For the other ROM directions, flexion, right rotation, and left rotation, both groups had a significant improvement in mean ROM over time (p<0.05), however, this improvement was not significantly different between the two groups. (Refer to **Table 2**).

Change in Pressure Pain Threshold (PPT)

There was a significant difference in mean right upper trapezius muscle pressure pain threshold over time ($F_{2,72}$=4.3, p=0.02, η^2=0.11), however, there was no significant group by time

interaction ($F_{2,72}$=0.98, p=0.38), and the change over time was not significantly different between the two groups ($F_{2,72}$=0.02, p=0.90). Bonferroni post hoc comparison revealed that the difference was significant between baseline and 4 weeks later (4.7±0.3 vs. 5.5±0.3, p=0.01), and between one week later and 4 weeks (4.7±0.3 vs. 5.5±0.3, p=0.01). For left pressure pain threshold, there was a significant difference over time ($F_{2,72}$=8.4, p=0.001, η^2=0.20), however, there was no significant group by time interaction ($F_{2,72}$=0.48, p=0.59), and the change over time was not significantly different between the two groups ($F_{2,72}$=0.02, p=0.86). Bonferroni post hoc comparison revealed that the difference was significant between baseline and 4 weeks later (4.5±0.3 vs. 5.7±0.4, p=0.005), and between one week later and 4 weeks (4.5±0.2 vs. 5.7±0.4, p=0.001). (Refer to **Table 3**).

Changes in NPRS

There was a significant difference in mean NPRS over time ($F_{2,72}$=47.8, p<0.001, η^2=0.60), however, there was no significant group by time interaction ($F_{2,72}$=1.5, p=0.23), and the improvement did not differ significantly by study group ($F_{1,36}$=1.4, p=0.24). Bonferroni post hoc comparison revealed that the difference was significant between baseline and one week later (4.7±0.3 vs. 3.3±0.3, p<0.001), baseline and 4 weeks later (4.7±0.3 vs. 1.7±0.3, p<0.001), and between one week later and 4 weeks (3.3±0.3 vs. 1.7±0.3, p<0.001).

Change in GROC

For GROC, there was a significant difference over time ($F_{1,36}$=42.9, p<0.001, η^2=0.54), however, there was no significant group by time interaction ($F_{1,36}$=0.001, p=0.98), and the improvement was not significantly different by study group ($F_{1,36}$=0.7, p=0.40). Bonferroni post hoc comparison revealed that the difference was significant between one week later and 4 weeks (2.4±0.3 vs. 4.7±0.4, p<0.001). (Refer to **Table 3**).

Change in NDI

There was a significant difference in mean NDI over time ($F_{2,72}$=38.2, p<0.001, η^2=0.52), however, there was no significant group by time interaction ($F_{2,72}$=2.8, p=0.07), and the improvement over time did not differ by study group ($F_{1,36}$=0.0, p=0.98). Bonferroni post hoc comparison revealed that the difference was significant between baseline and one week later (11.2±0.8 vs. 7.6±0.7, p<0.001), baseline and 4 weeks later (11.2±0.8 vs. 4.5±0.8, p<0.001), and between one week later and 4 weeks (7.6±0.7 vs. 4.5±0.8, p<0.001). After 4 weeks follow up, there were no significant changes in all the outcome variables by study group. (Refer to **Table 4**)