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LOMA LINDA UNIVERSITY School of Allied Health Professions in conjunction with the Faculty of Graduate Studies

Effect of Adding Stretching Techniques to Standardized Intervention on Nonspecific Mechanical Neck Pain
by
Saad S. Alfawaz
A Dissertation submitted in partial satisfaction of the requirements for the degree Doctor of Science in Physical Therapy

Each person whose signature appears below certifies that this dissertation in hi is adequate, in scope and quality, as a dissertation for the degree Doctor of Scope and quality.	-
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ABBREVIATIONS

ACROM Active Range Of Motion

ANOVA Mixed Factorial Analysis of variance

BMI Body Mass Index

CI Confidence Interval

CM² Square Centimeter

CROM Cervical Rang of Motion

KG Kilogram

GROC Global Rating of Change

ICC Intraclass Correlation Coefficient

M Meter

M² Square Meter

NDI Neck Disability Index

NPRS Numeric Pain Rating scale

PPT Pressure Pain Threshold

ROM Range of Motion

SD Standard Deviation

SE Standard Error

ABSTRACT OF THE DISSERTATION

Effect of Adding Stretching Techniques to Standardized Intervention on Nonspecific Mechanical Neck Pain

by

Saad S. Alfawaz

Doctor of Science, Graduate Program in Physical Therapy Loma Linda University, June 2018 Dr. Everett Lohman III, Chairperson

Mechanical neck pain is becoming one of the leading causes of musculoskeletal disorders in the general adult population. Mobilization intervention is considered one of the most effective therapeutic techniques to treat non-specific neck pain. The purpose of this study was to investigate the benefit of adding stretching exercises as part of a rehabilitation program for patients with non-specific mechanical neck pain.

Methods: Thirty-eight subjects with non-specific neck pain for at least 2 weeks with mean± SD age 30.9±8.1 years and body mass index (BMI) 26.8±6.7 kg/m2 participated in the study. Participants were randomly assigned to either the combined intervention (passive cervical mobilization and stretching techniques) (n1=18) or standard intervention group (n2=20). The outcome measures were Cervical range of motion (CROM), Numeric Pain Rating scale, Neck Disability Index, Global Rating of Change (GROC), and pressure pain threshold.

Results: There was a significant difference in mean CROM during extension over time $(p=0.002, \eta 2=0.20)$, and a significant group by time interaction (p=0.02). The percent improvement from baseline to 4 weeks later was significant between the combined intervention and standard intervention groups (18.9% vs. 3.0%; p=0.02). Also, there was

a significant difference in mean CROM during right lateral flexion over time (p<0.001, η 2=0.30), and a significant group by time interaction (p=0.04). The percent improvement from baseline to 4 weeks was significant between the combined intervention and standard intervention groups (23.2% vs. 10.8%; p=0.04). However, subjective outcome measures including pain, patient's satisfaction and neck disability index significantly improved overtime with no significant differences between the two study groups. Over time, there was a significant difference in mean right upper trapezius muscle pain threshold (p=0.02), and for GROC (p<0.001, η 2=0.54), however, there was no significant group by time interaction, and the improvement over time did not differ by study group (p>0.05). Conclusions: Four weeks of combined techniques (cervical mobilization plus stretching exercises) showed to be more effective than standard intervention in terms of improving cervical extension and lateral flexion CROM.

CHAPTER ONE

INTRODUCTION AND REVIEW OF THE LITERATURE

Currently, neck pain is established as one of the major causes of musculoskeletal disorders in adults, often occurring in individuals between the ages of 40 and 50 years old. Snodgrass, Rivett, Sterling, Vicenzino² indicated that 30% to 50% of adults suffer from chronic neck pain in the course of a year. The prevalence of neck pain has increased in developed countries especially among office workers and workers who spend the majority of their time using computers. In addition, the prevalence of neck pain increased in women more than men by 27% to 17%, respectively.

Neck pain has several causes from mechanical to neurological, however, there are some sources of neck pain that cannot be clearly categorized or identified; these are known as non-specific neck pain. Non-specific mechanical neck pain often occurs due to the interaction of multiple etiological factors such as the mechanical, posture, depression, occupational, and sport activities.⁵ Individuals with non-specific neck pain often suffer from pain, restriction on cervical joint range of motion, and reduction in functional activity and quality of life. The treatment of non-specific neck pain costs 0.05% to 2% of gross national product of North America and Europe.⁴ Therefore, finding effective interventions is considered a high priority. Clinical guidelines were established by Childs, Cleland, Elliott, Teyhen, Wainner, Whitman, Sopky, Godges, Flynn, Delitto⁶ to find the most effective interventions for patients with neck pain in order to provide the best recommendations for therapists. The clinical guidelines contained many interventions that had various effects on patient condition from the intervention that was effective in terms of relieving symptoms to those that were more or less effective. The intervention

options according to clinical guidelines consisted of manipulation, mobilization, traction and stretching, strengthening, endurance, and coordination exercises.

Manipulation

Based on strong evidence (Table 1), manipulation is considered to be one of the most effective interventions to treat non-specific neck pain, as recommended and graded with an A grade in the clinical guidelines by Childs, Cleland, Elliott, Teyhen, Wainner, Whitman, Sopky, Godges, Flynn, Delitto. An intervention is considered a grade A when it contains at least one level one evidence, such as high-quality randomized controlled trials, prospective studies, or diagnostic studies, and some level two evidence, such as lower-quality randomized controlled trials, prospective studies, or diagnostic studies.⁶ Manipulation consists of high-velocity, low-amplitude thrust movement at the end of the cervical range of motion that the therapist uses to reduce patient symptoms.⁷ While manipulation may have adverse effects on the patient's condition, the chances of this effect occurring are very rare. Gross, Kay, Kennedy, Gasner, Hurley, Yardley, Hendry, McLaughlin⁸ reported that using thrust manipulation intervention might have some complications, but the chance of these occurring is quite rare. For instance, cervical manipulation may result in a stroke incident at a rate of 0.001%, while the chance to have permanent injury is 1 in 20,000.8

Regardless of the adverse effects of cervical manipulation, it has a significant effect on reducing the patient's level of pain. Gross, Miller, D'Sylva, Burnie, Goldsmith, Graham, Haines, Brønfort, Hoving⁹ indicated that using cervical thrust manipulation had immediate and short-term effects on relieving the patient's pain. Moreover, Snodgrass,

Cleland, Haskins, Rivett¹⁰ stated in their systematic review that improvement on the cervical range of motion was always reported in all the reviewed randomized controlled trials. The amount of improvement in cervical range of motion after cervical manipulation was significantly greater than the improvement from other therapeutic interventions, such as mobilization and therapeutic exercise. ¹⁰ Cervical thrust manipulation had some influence on improving patient function. Gross, Langevin, Burnie, Bédard-Brochu, Empey, Dugas, Faber-Dobrescu, Andres, Graham, Goldsmith¹¹ reported that cervical manipulation had immediate effects on improving the patient's function, however, this improvement did not result in any significant clinical change. Therefore, cervical manipulation is an effective intervention that has a significant influence on improving the patient's range of motion and reducing their level of pain.

 Table 1. Strength of evidence of neck pain clinical guidelines

Grade	Strength of Evidence	Basis of Strength Assignment
A	Strong	One or more level I systematic reviews support the recommendation, providing evidence for a strong magnitude of effect
В	Moderate	One or more level II systematic reviews or a preponderance of level III systematic reviews or studies support the recommendation, providing evidence for a mild to moderate magnitude of effect
C	Weak	One or more level III systematic reviews or a preponderance of level IV evidence supports the recommendation, providing minimal evidence of effect
D	Conflicting	Higher-quality studies conducted on this topic disagree with respect to their conclusions and effect. The recommendation is based on these conflicting studies
Е	Theoretical/ foundational evidence	A preponderance of evidence from animal or cadaver studies, from conceptual models or principles, or from basic science or bench research supports the recommendation, providing theoretical/foundational evidence of effect
F	Expert opinion	Best practice to achieve a beneficial effect and/or minimize a harmful effect, based on the clinical experience of the guidelines development team

Mobilization

Mobilization is another recommended intervention for individuals with nonspecific neck pain. Mobilization intervention is the application of passive force to cervical joints in certain directions and amplitudes. The amount of passive force, amplitude, and direction of mobilization is determined by the therapist based on the patient's condition.² Childs, Cleland, Elliott, Teyhen, Wainner, Whitman, Sopky, Godges, Flynn, Delitto⁶ recommended using joint mobilization for neck pain (see Table 1). Using the specific mobilization technique is not superior to other techniques. Gross, Langevin, Burnie, Bédard-Brochu, Empey, Dugas, Faber-Dobrescu, Andres, Graham, Goldsmith¹¹ stated that there was no significant difference in the effectiveness among the mobilization techniques on reducing pain level. Although there was no significant difference between the mobilization techniques, there was an obvious difference in terms of reducing the patient's pain, especially while conducting painful movements when comparing before versus after cervical mobilization. ¹² Furthermore, in their systematic review, Leaver, Refshauge, Maher, McAuley¹³ reported that using neck mobilization intervention had short-term effects on relieving the patient's pain. Hence, cervical mobilization intervention has a significant effect on reducing the patient's symptoms.

Stretching Exercises

Stretching exercises are another recommended intervention that helps regain normal muscle length. The benefits of stretching exercises for patients with non-specific neck pain are limited. Childs, Cleland, Elliott, Teyhen, Wainner, Whitman, Sopky, Godges, Flynn, Delitto⁶ indicated that evidence on the benefits of stretching exercises for

neck pain was weak, therefore, they classified stretching exercises as C grade (see Table 1). However, Childs, Cleland, Elliott, Teyhen, Wainner, Whitman, Sopky, Godges, Flynn, Delitto⁶ gave this low classification on the clinical guideline because few clinical trials had been conducted on the effect of stretching exercises on neck pain. Also, these clinical trials were not well designed to provide a strong recommendation.¹⁴ Despite the low recommendation for stretching exercises among the recent clinical guidelines, some studies have indicated that stretching exercises had a significant effect on reducing the pain of patients with chronic neck pain. Ylinen, Takala, Nykänen, Häkkinen, Mälkiä, Pohjolainen, Karppi, Kautiainen, Airaksinen¹⁵ reported that stretching exercises had a significant influence in reducing neck pain. In addition, when comparing the effect of stretching exercises and manual therapy, manual therapy had more advantages than stretching exercises. Ylinen, Kautiainen, Wirén, Häkkinen¹⁶ indicated that 52% of patients who received manual therapy reported significant reduction in pain while 39% of patients who received stretching exercises reported significant reduction of pain. This difference from the previous studies may be due to the influence of the placebo effect on patients who receive manual therapy. The placebo effect may occur because in manual therapy, the therapist may have a conversation with the patient, which may increase the chance of bias. Specifically, in their study, Ylinen, Kautiainen, Wirén, Häkkinen¹⁶ stated that the effect of manual therapy on relieving patient symptoms may involve some bias as the therapist may talk with patients during intervention, which may enhance the patient's belief in the efficacy of the treatment. Therefore, stretching exercises may not be highly recommended, but it is still one of the treatment options that is worthy of consideration.

Strengthening, Endurance, and Coordination Exercises

Strengthening, endurance, and coordination exercises are other effective interventions to reduce patient neck pain. Recent clinical guidelines by Childs, Cleland, Elliott, Teyhen, Wainner, Whitman, Sopky, Godges, Flynn, Delitto⁶ found that strengthening, endurance, and coordination exercises had a significant impact on reducing patient symptoms, therefore, they gave them a grade A (see Table 1). These therapeutic exercises had a significant effect on reducing pain. Gross, Kay, Paquin, Blanchette, Lalonde, Christie, Dupont, Graham, Burnie, Gelley¹⁴ reported in their review that endurance training had a moderate effect on relieving neck pain. Also, craniocervical flexion exercise, which is a type of strengthening, endurance, and coordination exercise, had an immediate effect on reducing neck pain.¹⁷ Moreover, Chiu, Lam, Hedley¹⁸ reported significant improvements in the disability score, neck muscle strength, and pain. In fact, the effect of strength, endurance, and coordination can be maintained over 12 months. Ylinen, Takala, Nykänen, Häkkinen, Mälkiä, Pohjolainen, Karppi, Kautiainen, Airaksinen¹⁵ indicated that patients who received strength exercises and endurance exercises reported a significant reduction of pain and disability score after 12 months of intervention.

To the best of our knowledge, there are no studies that have examined the effect of a combined intervention that includes both mobilization and stretching exercises on non-specific mechanical neck pain. Thus, the purpose of this research study was to assess the benefit of adding stretching exercises to cervical mobilization and cervical range of motion exercises on a cervical range of motion, pain, pain threshold, level of disability, and patient satisfaction for patients with non-specific mechanical neck pain.

Cervical mobilization was used because it had received high recommendations on the recent clinical guidelines by Cleland et al. and had less adverse effects than manipulation. In addition, Miller, Gross, D'Sylva, Burnie, Goldsmith, Graham, Haines, Brønfort, Hoving¹⁹ indicated that cervical mobilization or manipulation with exercise had a significant effect on reducing patient symptoms in comparison with cervical mobilization or manipulation alone. The results of this study will provide a clinical recommendation on the effect of using stretching exercises as part of the rehabilitation program for patients with non-specific mechanical neck pain. Furthermore, the results of this study will provide valuable information regarding further research in this area

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CHAPTER TWO

EFFECT OF ADDING STRETCHING TECHNIQUES TO STANDARDIZED INTERVENTION CERVICAL ACTIVE RANGE OF MOTION FOR PATIENTS WITH NONSPECIFIC MECHANICAL NECK PAIN

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Abstract

Background: Mobilization interventions are considered one of the most effective therapeutic techniques to treat non-specific neck pain. The purpose of this study was to investigate the benefit of adding stretching exercises as part of a rehabilitation program for patients with non-specific mechanical neck pain.

Design: Randomized controlled trial

Methods: Thirty-eight subjects with non-specific neck pain for at least 2 weeks with mean ± SD age 30.9±8.1 years and body mass index (BMI) 26.8±6.7 kg/m² participated in the study. Participants were randomly assigned to either standard intervention group (passive cervical mobilization, active range of motion exercise) (n₂=20) or the combined intervention (passive cervical mobilization, active range of motion exercise and stretching techniques) (n₁=18). The outcome measures were Cervical Range of Motion (CROM), Numeric Pain Rating scale, Neck Disability Index (NDI), Global Rating of Change(GROC), and Pressure Pain Threshold (PPT).

Results: There was a significant difference in mean CROM during extension by study group over time (p=0.002, η^2 =0.20), and a significant group by time interaction (p=0.02). The percent improvement from baseline to 4 weeks later was significantly different between the combined intervention and standard intervention groups respectively (18.9% vs. 3.0%; p=0.02). Also, there was a significant difference in mean CROM during right lateral flexion over time (p<0.001, η^2 =0.30), and a significant group by time interaction (p=0.04). The percent improvement from baseline to 4 weeks was significantly different between the combined intervention and standard intervention groups respectively (23.2%).

vs. 10.8%; p=0.04). In addition, there was a significant difference in mean CROM during left lateral flexion over time (p<0.001, η^2 =0.30), and a significant group by time interaction (p=0.02). The percent improvement from baseline to 4 weeks was significantly different between the combined intervention and standard intervention groups respectively ((20.0% vs. 7.7%, p=0.02). However, subjective outcome measures including pain, patient's satisfaction as measured by GROC and Neck Disability Index significantly improved overtime with no significant differences between both groups. **Conclusions:** Both study groups improved significantly in all outcome measures. However, four weeks of combined techniques (cervical mobilization, active range of motion exercise, and stretching exercises) showed to be more effective than standard intervention in terms of improving cervical extension and lateral flexion CROM. **Keywords:** Non-specific mechanical neck pain, Cervical, Stretching, Mobilization.

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Introduction

Mechanical neck pain is becoming one of the leading causes of musculoskeletal disorders in the general adult population.²⁰ Its prevalence ranges approximately 20-50% of the population with higher occurrence in women than men.^{4,21} The reported prevalence of mechanical neck pain disorders is attributed to the undetermined origin as well as the poor prognosis of the disorder. 5,16,22 It has been suggested that mechanical non-specific neck pain might occur due to interaction of multiple etiological dimensions such as pathoanatomical, neuromuscular and psychosocial factors. 5,22 Also, the poor prognosis for neck pain is related to the experience of persistent pain and disability in many neck pain sufferers following physical therapy intervention. ¹⁶ Individuals with non-specific neck pain often suffer from pain, restriction of cervical joint range of motion²³, limited functional activity, participation restrictions and reduced quality of life. 24,25 The associated symptoms have exerted socioeconomic issues on patients' well-being and the healthcare system. ²⁶ The costs related with treating mechanical neck pain disorders are approximately 0.05% to 2% of gross national product⁴, and it is expected to grow exponentially. Therefore, numerous studies have investigated the efficacy of many physical therapy interventions aiming to alleviate non-specific mechanical neck pain and associated dysfunctions.^{27,28}

Blanpied, Gross, Elliott, Devaney, Clewley, Walton, Sparks, Robertson, Altman, Beattie²⁹ reported that cervical manipulation (thrust) had significant impact on reducing neck pain, patient's satisfaction and reducing headaches. The observed effect of cervical manipulation, however, may potentially expose the patient to rare but serious adverse effects.³⁰ Using alternative, safer intervention options with equal effectiveness such as

mobilization (non-thrust manipulation) are recommended. 11 Despite the fact that cervical mobilization is considered a minimally invasive technique, it shows similar effectiveness in reducing patient's pain for only a short period of time.²⁹ Combined interventions, on the other hand, including manual therapy and exercise lead to a greater reduction in pain level and improvement in function when compared with other sole interventions such as non-manual physical therapy techniques, exercise alone, ergonomic advice, medications and primary physician care. 31 However, Ylinen, Kautiainen, Wirén, Häkkinen 16 reported that combined interventions including cervical mobilization, massage and selfadministered stretching exercises do not differ significantly when compared with therapist-administered stretching techniques of key muscles in terms of their effect on neck pain, such as upper trapezius, scalenes, levator scapulae and pectorals major and minor. 6,16 Similarly, Childs, Cleland, Elliott, Teyhen, Wainner, Whitman, Sopky, Godges, Flynn, Delitto⁶ recommended that resolving muscle length deficits for patients with neck pain might add benefit to the holistic plan of care. 6 However, this recommendation is based on weak evidence. Despite the inconsistent conclusions, adding stretching exercise is still considered in the early care for patients with neck pain due to the associated reduced cost. 6 This has created confusion among therapists to determine which interventions impact outcomes in patients with neck pain.^{6,16}

There is no evidence regarding the combined effect of mobilization, exercise, and stretching on cervical spine clinical outcomes. Thus, the purpose of this study was to compare the effectiveness of integrating stretching techniques with passive cervical mobilization and active range of motion exercise versus standard intervention on self-

reported pain level, cervical ROM, pressure pain threshold, disability and satisfaction of patients with non-specific mechanical neck pain.

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) (n₁=20) or standard intervention group (passive cervical mobilization and active range of motion exercises) (n₂=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 $26.9 \pm 6.7 \text{ kg/m}^2$ 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 Clinical Trials.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. ¹⁶ 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**.

Table 1. Mean (SD) of general characteristics (N=43)

	Combined Intervention (n1=18)	Standard Intervention (n2=20)	p- value
Female; (%)	13 (66.7%)	14 (60%)	0.47
Age (years)	31.4 (9.0)	30.6 (7.8)	0.76
Height (m)	1.6 (0.1)	1.7 (0.1)	0.17
Weight (kg)	68.0 (17.9)	77.1 (16.5)	0.11
BMI (kg/m2)	25.8 (5.5)	28.0 (7.5)	0.31

Abbreviations: SD, Standard deviation, m, meter, kg, kilogram.

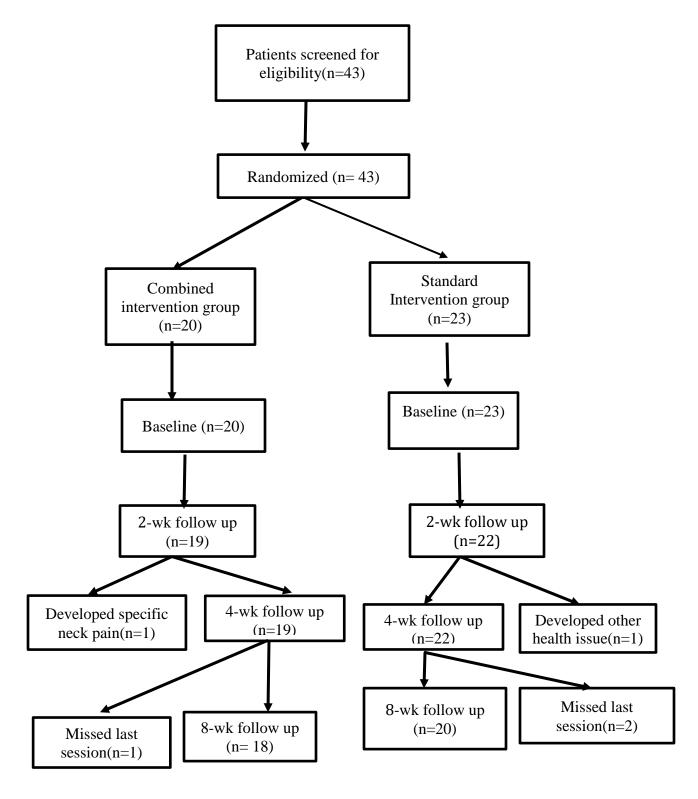


Figure 1. Flow diagram of participants' recruitment and retention.

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.³² Lee, Nicholson, Adams³³ 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: 0.66; 0.89) for right lateral flexion, an ICC of 0.81 (95% CI: 0.66; 0.89) for right lateral flexion, an ICC of 0.81 (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.³⁴ CROM has high validity with correlation coefficients of 0.97 for flexion and 0.98 for extension.³⁴

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).³⁵ It has high reliability and validity in measuring pain threshold for individuals with neck pain. Park, Kim, Park,

Kim, Jang³⁶ 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 0.98.³⁷

In order to measure neck pressure pain threshold, a handheld electronic pressure algometer with a surface area at the round tip of 1 cm² 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.³⁵ Three trials were performed at each side in each test session.³⁸

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. In addition, Boonstra, Preuper, Reneman, Posthumus, Stewart 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 $50.^{40}$ 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. 40 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 $0.90.^{41}$ 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. 42 In addition, Childs, Cleland, Elliott, Teyhen, Wainner, Whitman, Sopky, Godges, Flynn, Delitto⁶ 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 = 0.74.⁴³ Kamper, Maher, Mackay⁴³ 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) (n₁=18) and *standard intervention groups* (n₂=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

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.⁴⁴ Both groups received 10 minutes of cervical mobilization for 2 sessions per week for 4 weeks.

Active Cervical Range of Motion Exercises (ACROM)

Active Cervical Range of Motion Exercises 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. Both groups performed ACROM exercises. Subjects were advised to maintain their usual activity within the limits of pain.

Stretching Techniques

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.⁴⁶

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

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. ¹⁶ 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 deviation²⁰ 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 chisquare 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≤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/m² 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**)

Table 2. Mean (SE) cervical range of motion (°) by study group over time (N=43)

	Combined Intervention Group (n_1 =18)		Standard Intervention Group (n ₃ =20)						
	Baseline	One week later	4 weeks later	Baseline	One week later	4 weeks later	p-value over time	Effect Size	p-value between groups
Flexion	46.2 (2.6)	52.3 (2.4)	54.9 (2.5)	46.1 (2.2)	49.7 (2.3)	55.0 (2.3)	<0.001	0.36	0.77
Extension*	71.2 (3.4)	77.5 (2.7)	82.9 (3.1)	68.5 (2.4)	71.1 (3.7)	70.3 (3.1)	0.002	0.20	0.03
Right rotation	65.9 (3.0)	71.9 (3.1)	74.0 (3.4)	66.1 (2.5)	68.6 (2.4)	74.3 (2.5)	<0.001	0.30	0.80
Left rotation	60.1 (3.8)	66.8 (2.6)	73.0 (2.2)	62.7 (2.1)	67.8 (2.1)	70.6 (2.3)	<0.001	0.38	0.91
Right Lateral Flexion*	41.8 (2.5)	46.3 (1.7)	50.0 (2.1)	39.9 (1.7)	41.3 (2.0)	43.6 (1.8)	<0.001	0.30	0.04
Left Lateral Flexion*	43.9 (1.9)	48.4 (1.6)	51.6 (2.1)	42.2 (1.4)	44.3 (1.3)	45.3 (1.6)	<0.001	0.30	0.02
Right pain threshold	4.5 (0.4)	4.7 (0.3)	5.6 (0.5)	5.0 (0.5)	4.6 (0.4)	5.3 (0.5)	0.02	0.11	0.90
Left pain threshold	4.3 (0.4)	4.5 (0.3)	5.8 (0.6)	4.7 (0.4)	4.5 (0.4)	5.6 (0.5)	0.001	0.2	0.86

^{*:} significant difference between the two study groups (p<0.05); Abbreviations: SE, Standard error

Also, there was a significant difference in mean ROM during right lateral flexion over time ($F_{2,72}=13.8$, p<0.001, $\eta^2=0.30$), 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, $\eta^2=0.30$), 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**).

Table 3. Mean (SE) of pain threshold (lb), and pain, satisfaction, and neck disability index scores by study group over time (N=38)

	Combined Intervention Group (n ₁ =18)		Standard Intervention Group (n ₃ =20)						
	Baseline	One week later	4 weeks later	Baseline	One week later	4 weeks later	p-value over time	Effect Size	p-value between groups
Right pain	4.5 (0.4)	4.7 (0.3)	5.6 (0.5)	5.0 (0.5)	4.6 (0.4)	5.3 (0.5)	0.02	0.11	0.90
threshold	4.5 (0.4)	4.7 (0.3)	3.0 (0.3)	3.0 (0.3)	4.0 (0.4)	3.3 (0.3)	0.02	0.11	0.50
Left pain	4.3 (0.4)	4.5 (0.3)	5.8 (0.6)	4.7 (0.4)	4.5 (0.4)	5.6 (0.5)	0.001	0.2	0.86
threshold	1.3 (0.1)	1.5 (0.5)	2.0 (0.0)	1.7 (0.1)	1.5 (0.1)	3.0 (0.3)	0.001	0.2	0.00
Numeric Pain	(O 1)	2 - (2 - 1)	4 = (0.4)	1.0 (0.1)	20(0.4)	10(0.1)	0.004		0.4
Rating	5.2 (0.4)	3.6 (0.4)	1.7 (0.4)	4.3 (0.4)	3.0 (0.4)	1.8 (0.4)	< 0.001	0.57	0.24
scale									
Global rate of		2.6 (0.5)	4.9 (0.5)		2.1 (0.5)	4.5 (0.5)	< 0.001	0.54	0.40
change*		2.0 (0.3)	4.9 (0.3)		2.1 (0.3)	4.5 (0.5)	<0.001	0.54	0.40
Neck									
disability	12.2 (1.1)	7.2 (1.0)	3.8 (1.2)	10.6 (1.1)	8.1 (0.9)	5.1 (1.1)	< 0.001	0.52	0.98
index			11 411	d and a second	G. 1 1				

^{*:} Measurements were not taken at baseline; Abbreviations: SE, Standard error

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**)

Table 4. Mean (SE) of follow up results by study group (N=38)

	Combined	Intervention Group		ervention Group	
		$(n_1=18)$	$(n_3=20)$		
	4 weeks	8 weeks	4 weeks	8 weeks	
Flexion	54.1 (2.9)	53.9 (2.5)	53.9(2.4)	53.2 (2.6)	
Extension	82.0 (2.6)	79.2 2.8)	71.3 (3.6)	74.5 (4.0)	
Right rotation	73.2 (3.9)	78.5 (2.5)	76.2 (2.5)	71.5 (2.8)	
Left rotation	73.1 (2.3)	72.9 (2.4)	72.0 (2.4)	71.3 (2.1)	
Right Lateral Flexion	51.1(2.3)	51.2 (2.4)	45.2 (1.6)	47.3 (1.9)	
Left Lateral Flexion	52.1(2.6)	55.3(2.6)	45.7 (1.9)	47.4 (1.9)	
Forward Head Posture	15.1 (0.8)	15.8 (0.6)	15.4 (0.7)	15.1 (0.6)	
Right pain threshold	5.5 (0.5)	5.8 (0.6)	5.0 (0.5)	4.9 (0.4)	
left pain threshold	5.4 (0.6)	5.5 (0.7)	5.1 (0.5)	5.4 (0.6)	
Numeric Pain Rating scale	1.8 (0.5)	1.5 (0.5)	1.8 (0.5)	1.8 (0.6)	
Global rate of change	5.0 (0.6)	4.9(0.6)	4.5 (0.7)	3.3 (1.0)	
Neck disability index	3.9(0.9)	3.7(1.0)	5.7(1.7)	6.5(2.6)	

Abbreviations: SE, Standard error

Discussion

Objective Outcome Measures

At the 4-week follow-up, both groups had significant improvement in cervical ROM. However, when compared to the standard group, the combined intervention group had a significant increase in cervical extension and lateral flexion ROM. The extension ROM in the combined intervention group increased by 11.7 degrees from baseline which exceeded the clinical importance value (11.1 degrees) reported by Hoving, Pool, van Mameren, Devillé, Assendelft, de Vet, de Winter, Koes, Bouter⁴⁷ However, cervical lateral flexion did not reach the level of clinical importance of 10.4 degrees as outlined by Hoving, Pool, van Mameren, Devillé, Assendelft, de Vet, de Winter, Koes, Bouter⁴⁷ with increases motion for right and left lateral between baseline and 4-weeks of 8.2 degrees and 7.7 degrees, respectively. This improvement in cervical ROM was similar to results reported by Hanneya, Puentedura, Kolber, Xinliang, Pabian, Cheatham ⁴⁸ Hanneya, Puentedura, Kolber, Xinliang, Pabian, Cheatham⁴⁸ and Andersen, Hansen, Mortensen, Zebis⁴⁹ attributed the improvement in cervical extension and lateral flexion in manual stretching group to the reduction of pain level as a result of the release of trigger point of upper trapezius when stretching techniques were applied. However, in the present study, both groups had a significant reduction in pain level and upper trapezius pressure pain threshold over time with no reported differences between groups. Despite that, only the combined intervention group showed a significant improvement in cervical extension and bilateral lateral flexion ROM, which might be attributed to something else other than the reduced pain level alone. A possible explanation for the improvement seen in the combined intervention group could be credited to the potential increase in muscle

extensibility as a result of including stretching techniques to the combined intervention group. In our study, the anterior and middle scalenes were stretched bilaterally during the intervention period. Anterior scalenes work bilaterally to flex the neck and thus stretching these muscles might explain the noted improvement in cervical extension ROM.

Anterior, middle, posterior scalenes and upper trapezius work unilaterally to move the neck into same side lateral flexion direction and therefore stretching these muscles might explain the noted improvement in both sides cervical lateral flexion ROM. Hence, stretching the above-mentioned muscles in addition to the mobilization technique can further maximize the effect of the intervention as was noted in our results.

Subjective Outcome Measures

At the 4-week follow-up, subjective outcome measures including NPRS, pain threshold, disability and participants' satisfaction improved in both groups. However, the difference was not significantly different between groups. Similar improvement in NPRS and pressure pain threshold for both groups may reflect patients' experience of the efficacy of manual treatment/ mobilization techniques in reducing cervical pain which was also reported elsewhere by Ylinen, Kautiainen, Wirén, Häkkinen. Patients' expectations were shown to influence therapy outcomes and getting hands-on interventions might contribute to the results. 50

Additionally, the NDI scores improved overtime in both groups at 4-week followup. However, it was not significantly different between the two groups. It is important to note that the majority of the participants in our study had only mild disability ranging between 5 and 14 points; which might explain why the difference between groups were not significant. However, it is important to note that the combined intervention group demonstrated no disability level at 4-week follow up while the standard intervention group remained within the same mild disability. This can also support the benefit of adding stretching exercises to mobilization when compared with sole intervention.

Additionally, the lack of sensitivity of the instrument in detecting improvements might support our findings as was also reported by Ylinen, Kautiainen, Wirén, Häkkinen¹⁶ and Ylinen, Takala, Nykänen, Häkkinen, Mälkiä, Pohjolainen, Karppi, Kautiainen, Airaksinen. NDI is a categorical scale that may lack sufficient capacity to minimal changes in neck disability when compared with other continuous scales such as the Neck and Shoulder Pain.

Finally, the GROC scores showed significant improvement overtime in both groups, but not between groups. This is in line with a previous report by Miller, Gross, D'Sylva, Burnie, Goldsmith, Graham, Haines, Brønfort, Hoving. ¹⁹ The authors found greater reduction in self-reported pain, improvement in function, quality of life and patient satisfaction in combined intervention group, manual therapy and exercise, than when compared with sole intervention group or manipulation in adults with neck pain. In our study, at 4 weeks the Combined Intervention group and the Standard Intervention group were equally satisfied with their treatment outcomes (Moderate positive change = +4 to +5) with mean scores of 5.0 and 4.5, respectively (See Table 4); however, the Standard Intervention group was less satisfied at week 8. Four weeks following intervention (week 8), the Combined Intervention group still reported a moderate positive change (mean = 4.9) while the Combined Intervention group reported a small positive change (mean = 3.3). These findings can also be explained by the patient's feeling of

receiving hands-on therapy either by mobilization and stretching or standard intervention regardless of the assigned group. The effect of hands-on intervention was shown to influence therapy outcomes as described previously.⁵⁰

Study Limitations

This study had some limitations. A short follow up period was one of the study's limitations as extended follow-up would provide valuable information regarding which intervention had lasting effect on reducing pain and improving patient's function.

However, sole manual therapy for neck pain has not been shown to have lasting effects in contrast to cervical muscle training combined with stretching exercises. ¹⁵ In the clinical setting, mobilization may be administered during acute or severe stages of neck pain in order to provide pain relief and to minimize irritability associated with exercise. Thus, the structure of the study is justifiable on the basis of clinical practice.

In our study, we did not have a control group, but numerous other studies have already revealed manual therapy to be an effective intervention in cervical pain level when compared with controls. ^{47,51,52} The results of our study were in line with previous work by Hoving, Pool, van Mameren, Devillé, Assendelft, de Vet, de Winter, Koes, Bouter. ⁴⁷ The authors compared general practitioner care including advice and medications with physical therapy interventions including mobilization and found greater improvement with the latter group.

Lastly, though a sample size of 50 participants was estimated, only 38 completed the study. Post hoc power analysis revealed that the power based on this sample was 0.73. It is possible that we were not able to identify significant differences in outcome

measures between the two study groups due to the small sample size. Thus, we recommend conducting further studies with a larger sample size and longer follow-up time.

Conclusion

The results of the present study showed that both study groups improved significantly in all outcome measures. However, 4 weeks of combined intervention techniques (cervical mobilization, active cervical range of motion exercise, and stretching exercise) showed to be more effective than standard intervention (cervical mobilization and active range of motion exercises) in terms of improving cervical extension and lateral flexion ROM in adults with non-specific mechanical neck pain. Future studies with a larger sample size and a longer follow-up period are needed to further examine these findings.

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Conflict of Interest

The authors have no conflict of interest.

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CHAPTER THREE

DISCUSSION

Results of this study showed that after 4-weeks follow-up, both groups had significant improvement in cervical ROM. However, when compared to the standard intervention group, the combined intervention group had a significant increase in cervical extension and lateral flexion ROM. The extension ROM in the combined intervention group increased by 11.7 degrees from baseline which exceeded the clinical importance value (10.4 degrees) reported by Hoving, Pool, van Mameren, Devillé, Assendelft, de Vet, de Winter, Koes, Bouter. 47 However, cervical lateral flexion ROM did not reach the clinical importance value. This improvement in cervical ROM was similar to results reported by Hanneya, Puentedura, Kolber, Xinliang, Pabian, Cheatham. 48 The improvement in cervical extension and lateral flexion in manual stretching group may be related to the reduction of pain level as a result of the release of trigger point of upper trapezius. Reduction of pain level could also have attributed to the significant improvement seen in ROM in our study. Despite the improvement in pain level in both groups, only the combined intervention group showed a significant improvement in cervical extension and bilateral side bending ROM; and it reached clinical importance. Thus, stretching the muscle in addition to the mobilization technique can further maximize the effect of the intervention as was noted in our results.

At the 4-week follow-up, NPRS, pain threshold, disability and participant's satisfaction improved in both groups. However, the difference was not significantly different between groups. The finding may reflect participants' experience of the efficacy of manual treatment/ mobilization techniques in reducing cervical pain which

was also reported elsewhere by Ylinen, Kautiainen, Wirén, Häkkinen¹⁶. Patients' expectations are shown to influence therapy outcomes and getting hands-on interventions may contribute to the results.⁵⁰

In addition, the NDI scores improved overtime in both groups at 4-week follow-up. However, the improvement was not different between them. It is important to note that the majority of the participants in our study had only mild disability ranging between 5 and 14 points; which might explain why the difference between groups were not significant. However, more importantly, the combined intervention group demonstrated no disability level at 4-week follow up while the standard intervention group remained within the same disability level which is mild. This can also support the benefit of adding stretching exercises to mobilization when compared with sole intervention. Additionally, the lack of sensitivity of the instrument in detecting improvements might support our findings as was also reported by Ylinen, Kautiainen, Wirén, Häkkinen and Ylinen, Takala, Nykänen, Häkkinen, Mälkiä, Pohjolainen, Karppi, Kautiainen, Airaksinen. NDI is a categorical scale that may lack sufficient capacity to minimal changes in neck disability when compared with other continues scale instruments such as the Neck and Shoulder Pain. 16

In this study, the GROC scores improved significantly overtime in both groups, but not between groups. This is in line with a previous report by Miller, Gross, D'Sylva, Burnie, Goldsmith, Graham, Haines, Brønfort, Hoving. ¹⁹ The authors found greater reduction in self-reported pain, improvement in function, quality of life and patient satisfaction in combined intervention group: manual therapy and exercise than when compared with sole intervention group: manipulation or standard intervention in adults

with neck pain. In our study, both groups were significantly satisfied at 4-week when compared with 2-week follow-up. These findings can also be explained by the patient's feeling of receiving hands-on therapy either by mobilization and stretching or standard intervention regardless of the assigned group. This effect of hands-on intervention has shown to influence therapy outcomes as described previously.⁵⁰

This study had some limitations. A short follow up period was one of the study's limitations as extended follow-up would provide a valuable information regarding which intervention had lasting effect on reducing pain and improving patient's function. In our study, we did not have a control group, but numerous other studies have already revealed manual therapy to be an effective intervention in cervical pain level when compared with controls. ^{47,51,52} The results of our study, in both groups, who received mobilization were in line with previous work by Hoving, Pool, van Mameren, Devillé, Assendelft, de Vet, de Winter, Koes, Bouter. ⁴⁷ The authors compared general practitioner care including advice and medications with physical therapy interventions including mobilization and found greater improvement with the latter group. Lastly, the sample size was small. Post hoc power analysis revealed that the power based on this sample was 0.73. It is possible that we were not able to identify significant differences in the outcome measures between the two study groups due to the small sample size. Thus, we recommend replicating this study with a larger sample size and longer follow-up time.

The results of the present study suggest that 4 weeks of combined intervention techniques (cervical mobilization plus stretching exercise) showed to be more effective than standard intervention in terms of improving cervical extension and lateral flexion ROM in young adults with non-specific mechanical neck pain. However, subjective

outcome measures including pain, patient's satisfaction and neck disability index significantly improved overtime with no significant differences between the two study groups. Future studies with a larger sample size and a longer follow-up period are needed to further examine these findings.

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APPENDIX A

INFORMED CONSENT



TITLE: EFFECT OF ADDING STRETCHING TECHNIQUES

TO STANDARDIZED INTERVENTION FOR

PATIENTS WITH NONSPECIFIC MECHANICAL

NECK PAIN

SPONSOR: Department of Physical Therapy, Loma Linda

University

PRINCIPAL

INVESTIGATOR: Everett Lohman III, DSc, PT, OCS

Professor, Physical Therapy Department

Loma Linda University, Loma Linda CA

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

WHY IS THIS STUDY BEING DONE?

The purpose of this graduate student research study is to investigate the benefit of adding stretching as part of a rehabilitation program for people with non-specific neck pain.

You are invited to be in this graduate research study because you are between 18 and 60 years of age and have non-specific neck pain for at least 2 weeks.

You will not qualify if you have any of following:

Previous shoulder or neck surgery, disease or fracture, diabetes, vertigo, dizziness, multiple sclerosis, osteoporosis, rheumatoid arthritis or osteoarthritis.

Approximately 50 subjects will participate at LLU. Your participation in this study may last up to 10 weeks, for 10 visits, and for 30 minutes for each visit.

HOW WILL I BE INVOLVED?

Participation in this study involves the following:

- You will come to Nichol Hall, Room A620 on the Loma Linda University (LLU) campus or Redlands Physical Therapy Clinic to sign the informed consent and start the study.
- You will be randomly assigned to one of two groups: group one receiving stretching, passive mobilization, and a home program (stretching and range of motion exercises) or group two getting passive mobilization and home program (range of motion exercises).

Procedure for Group 1 (stretching, and passive mobilization with home program) is:

- Visit one (30 minutes) includes:
 - Completing neck pain, neck disability, and patient satisfaction questionnaires.
 - o Measuring neck range of motion and neck pain threshold.
- Visit two and three (30 minutes each) include: Stretching and passive neck mobilization.
- Visit four and five (30 minutes each) include: Stretching, passive neck mobilization, questionnaires, and measurements.
- Visit six and seven (30 minutes each) include: Stretching and passive neck mobilization.
- Visit eight and nine (30 minutes each) include: Stretching, passive neck mobilization, questionnaires, and measurements.
- No intervention for four weeks.
- Visit ten (30 minutes) include: Questionnaires and measurements.

Procedure for Group 2 (Passive Mobilization) is:

• Visit one (30 minutes) includes:

- Completing neck pain, neck disability, and patient satisfaction questionnaires.
- o Measuring neck range of motion, and neck pain threshold.
- Visit two and three (30 minutes each) include: Passive neck mobilization.
- Visit four and five (30 minutes each) include: Passive neck mobilization, questionnaires, and measurements.
- Visit six and seven (30 minutes each) include: Passive neck mobilization.
- Visit eight and nine (30 minutes each) include: Passive neck mobilization, questionnaires, and measurements.
- No intervention for four weeks.
- Visit ten (30 minutes) include: Questionnaires and measurements.

WHAT ARE THE REASONABLY FORESEEABLE RISKS OR DISCOMFORTS I MIGHT HAVE?

This study poses no greater risk to you than what you routinely encounter in day-to-day life. Participating in this study may involve the following risks: Muscle discomfort after passive neck mobilization and possible breach of confidentiality.

All records and research materials that identify you will be held confidential. Any published document resulting from this study will not disclose your identity without your permission. Information identifying you will only be available to the study personnel. All records will be confidential and stored in a locked cabinet in a locked room.

WILL THERE BE ANY BENEFIT TO ME OR OTHERS?

Although you may not personally benefits from this study, you participation may help practitioners provide insight into the benefits of adding stretching to rehabilitation program for individual with nonspecific mechanical neck pain and provide additional information that may guide a further studies.

WHAT ARE MY RIGHTS AS A SUBJECT?

Your participation in this study is entirely voluntary. You may refuse to participate or withdraw once the study has started. Your decision whether or not to participate or terminate at any time will not affect your future standing with the researchers or your caregivers either at Redland Physical Therapy Clinic or LLUH. You do not give up any legal rights by participating in this study. If at any time you feel uncomfortable, you may refuse to answer questions.

WHAT COSTS ARE INVOLVED?

There is no cost to you for participating in this study.

WILL I BE PAID TO PARTICIPATE IN THIS STUDY?

You will receive a \$50 gift card for completion of the study in full. In order to receive such payment, you may be asked to provide your home address and/or your Social Security number.

WHO DO I CALL IF I AM INJURED AS A RESULT OF BEING IN THIS STUDY?

If you feel you have been injured by taking part in this study, consult with a physician or call 911 if the situation is a medical emergency. No funds have been set aside nor any plans made to compensate you for time lost for work, disability, pain or other discomforts resulting from your participation in this research.

WHO DO I CALL IF I HAVE QUESTIONS?

Call 909-558-4647 or e-mail <u>patientrelations@llu.edu</u> for information and assistance with complaints or concerns about your rights in this study.

SUBJECT'S STATEMENT OF CONSENT

- I have read the contents of the consent form and have listened to the verbal explanation given by the investigator.
- My questions concerning this study have been answered to my satisfaction.
- Signing this consent document does not waive my rights nor does it release the investigators, institution or sponsors from their responsibilities.
- I may call Dr. Everett Lohman during routine office hours at (909) 558- 4632 or leave a voice mail message at this number during non- office hours
- I hereby give voluntary consent to participate in this study.

I understand I will be given a copy of	this consent form after signing it.	
Signature of Subject	Printed Name of Subject	
Date		

INVESTIGATOR'S STATEMENT

I have reviewed the contents of this consent form with the person signing above. I have explained potential risks and benefits of the study.					
Signature of Investigator	Printed Name of Investigator				
Date					

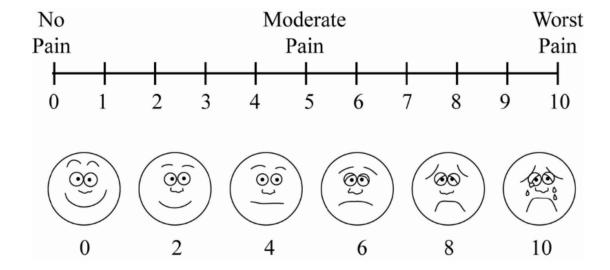
APPENDIX B

NUMERIC PAIN RATING SCALE QUESTIONNAIRE

Name:

Visit no.:

Please circle your pain level at this moment



APPENDIX C

GLOBAL RATING OF CHANGE QUESTIONNAIRE

Name:
Date:/
Please rate the overall condition of your neck from the time that you began the study
until now (check only one):
☐ A very great deal worse (-7)
☐ A great deal worse (-6)
☐ Quite a bit worse (-5)
☐ Moderately worse (-4)
☐ Somewhat worse (-3)
☐ A little bit worse (-2)
\Box A tiny bit worse (almost the same) (-1)
☐ About the same (0)
☐ A very great deal better (+7)
☐ A great deal better (+6)
☐ Quite a bit better (+5)
☐ Moderately better (+4)
☐ Somewhat better (+3)
\Box A little bit better (+2)
\Box A tiny bit better (almost the same) (+1)

APPENDIX D

NECK DISABILITY INDEX QUESTIONNAIRE

Neck Disability Index

THIS QUESTIONNAIRE IS DESIGNED TO HELP US BETTER UNDERSTAND HOW YOUR NECK PAIN AFFECTS YOUR ABILITY TO MANAGE EVERYDAY -LIFE ACTIVITIES. PLEASE MARK IN EACH SECTION THE ONE BOX THAT APPLIES TO YOU.

ALTHOUGH YOU MAY CONSIDER THAT TWO OF THE STATEMENTS IN ANY ONE SECTION RELATE TO YOU, PLEASE MARK THE BOX THAT MOST CLOSELY DESCRIBES YOUR PRESENT -DAY SITUATION.

Section 1 - Pain Intensity	Section 6 – Concentration
I have no neck pain at the moment. The pain is very mild at the moment. The pain is moderate at the moment. The pain is fairly severe at the moment. The pain is very severe at the moment. The pain is the worst imaginable at the moment.	I can concentrate fully without difficulty. I can concentrate fully with slight difficulty. I have a fair degree of difficulty concentrating. I have a fot of difficulty concentrating. I have a great deal of difficulty concentrating. I can't concentrate at all.
Section 2 - Personal Care	SECTION 7 - WORK
I can look after myself normally without causing extra neck pain. I can look after myself normally, but it causes extra neck pain. It is painful to look after myself, and I am slow and careful ineed some help but manage most of my personal care. I need some help but manage most of self-care. I do not get dressed. I wash with difficulty and stay in bed.	I can do as much work as I want. I can only do my usual work, but no more. I can do most of my usual work, but no more. I can't do my usual work. I can hardly do any work at all. I can't do any work at all. SECTION 8 — DRIVING
SECTION 3 — LIFTING I can lift heavy weights without causing extra neck pain. I can lift heavy weights, but it gives me extra neck pain. Neck pain prevents me from lifting heavy weights off the floor but I can manage if items are conveniently positioned, ie. on a table. Neck pain prevents me from lifting heavy weights, but I can manage light weights if they are conveniently	I can drive my car without neck pain. I can drive my car with only slight neck pain. I can drive as long as I want with moderate neck pain. I can't drive as long as I want because of moderate neck pain. I can hardly drive at all because of severe neck pain. I can't drive my care at all because of neck pain.
positioned I can lift only very light weights. I cannot lift or carry anything at all.	SECTION 9 — SLEEPING I have no trouble sleeping.
SECTION 4 - READING I can read as much as I want with no neck pain. I can read as much as I want with slight neck pain. I can read as much as I want with moderate neck pain. I can't read as much as I want because of moderate	My sleep is slightly disturbed for less than 1 hour. My sleep is mildly disturbed for up to 1-2 hours. My sleep is moderately disturbed for up to 2-3 hours. My sleep is greatly disturbed for up to 3-5 hours. My sleep is completely disturbed for up to 5-7 hours.
neck pain. I can't read as much as I want because of severe neck pain. I can't read at all.	SECTION 10 - RECREATION I am able to engage in all my recreational activities with
SECTION 5 — HEADACHES I have no headaches at all. I have slight headaches that come infrequently. I have moderate headaches that come infrequently. I have moderate headaches that come frequently. I have severe headaches that come frequently. I have headaches almost all the time.	no neck pain at all. I am able to engage in all my recreational activities with some neck pain. I am able to engage in most, but not all of my recreational activities because of pain in my neck. I am able to engage in a few of my recreational activities because of neck pain. I can hardly do recreational activities due to neck pain. I can't do any recreational activities due to neck pain.
PATIENT NAME	DATE
SCORE[50]	COPYRICHT: VERNON H & HACING C, 1991

APPENDIX E

HOME PROGRAM EXERCISE 1

Home Program Instruction: Combined intervention group

Posterior Scalene Stretch

Stretch)

Place your hand over your upper trapezius (muscles above the collar bone). Gently rotate your head to the opposite side and tuck your chin down toward your shoulder and feel for a pulling of the muscle under your hand, hold for 10 seconds and then rest. Perform 10 stretches, three times per day



With your fingers gently press into the muscles above your collar bone. Gently rotate your neck to the same side as your fingers and then extend it backwards. Feel for a stretch on the front diagonal muscles of your neck as you slowly move your head away from your fingers, hold for 10 seconds, and then relax. Perform 10 stretches, three times per day.

Front of Neck Diagonal Muscle Stretch Below Collar Bone (Platysma Stretch)

With your fingers gently press into the muscles below your collar bone. Gently rotate and side bend your head away from your fingers in an opposite direction diagonally. Feel for a stretch on the front diagonal muscles of your neck as you slowly pull down on the tissues with your fingers, hold for 10 seconds, and then relax. Perform 10 stretches, three times per day.



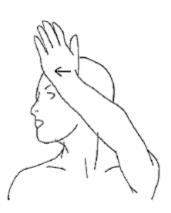
Back and Side of Neck Stretch (Chin Tuck with Side-Bend)

Roll your head forward and tuck your chin as far as comfortable. Then gently side-bend your head (ear to shoulder) and apply gentle pressure with your hand to help the stretch towards your shoulder, hold for 10 seconds, then relax. Perform 10 stretches, three times per day.



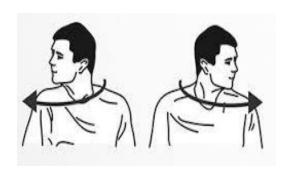
Neck Rotation Assisted

Rotate your head to its comfortable end point looking in one direction as far as comfortable. Place your hand on the side of your head and gently accentuate the rotation of your head, hold for 10 seconds, then relax. Repeat to the opposite direction. Perform 10 stretches, three times per day.



Neck Range of Motion Exercise (ROM rotation)

Rotate your head to its comfortable end point looking in one direction as far as you can, hold for 2 seconds, then return to middle. Perform 10 repetition, three times per day.



APPENDIX E

HOME PROGRAM EXERCISE 2

Home Program Instruction: Standard Intervention Group

Neck Range of Motion Exercise (ROM rotation)

Rotate your head to its comfortable end point looking in one direction as far as you can, hold for 2 seconds, then return to middle. Perform 10 repetition, three times per day.

