EFFECT OF COMBINED MANUAL THERAPY AND THERAPEUTIC EXERCISE PROGRAM IN PATIENTS WITH CHRONIC MECHANICAL NECK PAIN: A RANDOMIZED CLINICAL TRIAL

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Abstract

Background: Mechanical neck pain (MNP) is a significant health issue that impacts more severely on daily functioning and professional productivity than low back pain, highlighting the need for effective treatments.

Objectives: This study aimed to address the gap in existing research by investigating the synergistic effects of combining manual therapy and exercises, on pain, functional abilities, ROM and deep cervical flexor muscle endurance in MNP patients.

Methods: This is a randomized experimental study recruited 45 female patients with chronic mechanical neck pain from Jouf University, assigning them to one of three groups: group A: manual therapy, group B: therapeutic exercises, and group C: a combination of both treatments. Assessments was done at baseline and after 4 weeks of treatment utilizing the Neck Disability Index, Range of Motion measurements, the Pain Numeric Rating Scale and Cranio-Cervical Flexion Test (CCFT).

Results: All treatment groups experienced significant improvements post-treatment, with notable decreases in the Numerical Pain Rating Scale (NPRS) and Neck Disability Index (NDI), and increases in Cranio-Cervical Flexion Test (CCFT) and neck Range of Motion (ROM), each with p values less than 0.005. Particularly noteworthy was Group C, which received a combination of manual therapy and therapeutic exercises, exhibited significantly better outcomes in reducing NPRS and NDI, as well as enhancing CCFT and neck ROM, compared to Groups A and B ($p < 0.05$). However, there was no significant difference observed between Groups A and B in their post-treatment outcomes ($p > 0.05$), indicating similar efficacy when manual therapy and therapeutic exercises are employed independently.

Conclusions: The study concluded that an integrated approach combining manual therapy, therapeutic exercises was more effective in improving pain, disability, and neck functionality in patients with chronic mechanical neck pain compared to singular treatment approaches.

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Introduction

One of the most pervasive and significant health issues affecting societies worldwide is mechanical neck pain (MNP) (1). Studying MNP is important because of the negative effects it has (2). MNP patients frequently struggle to maintain their regular work schedules, which negatively impacts their professional productivity (3). Notably, those with MNP are found to experience this disruption in daily functioning even more severely than those with low back pain (LBP) do (4). This highlights the urgent need for finding efficient therapeutic interventions to address MNP and raises important questions about its distinctive features (5).

Numerous studies have examined the causes of MNP and different treatment modalities for its relief over the years. Numerous of these studies have placed a focus on specific approaches, such as manual therapy, exercises, finding a thorough strategy that incorporates both modalities, though, reveals a clear gap in the literature. Our research aimed to close this gap. There is still a lack of knowledge regarding the synergistic effects of combining manual therapy and exercises, even though each of the individual treatments has shown benefits when used in isolation. (6)

The major objective of this study was to investigate and assess the effects of an integrated therapeutic approach on pain, ROM, functional abilities and deep flexors muscle endurance in MNP patients, which involves manual therapy and exercises. In addition to lowering symptoms of MNP, we aimed to better understand the efficacy of this holistic approach in enhancing functional endurance and overall health in MNP patients. By comparing the findings from this integrated methodology with those from individual approaches, this study attempted to clarify the best results and plan a more informed future for MNP management.

Methods and materials

Study Design

A four week randomized experimental study was conducted from September 2023 to November 2023 at Jouf University in Alquarryat. Patients who agreed to participate in the study were asked to sign written consent after a detailed explanation of the study purpose. This study followed the principles of the Declaration of Helsinki 1975, revised Hong Kong 1989.

Participants

A total of 45 female patients with chronic mechanical neck pain were included in the study

Inclusion Criteria

Participants eligible for the study were adhered to specific criteria to ensure consistency and relevance to the research objectives. The participants were female, had chronic mechanical neck pain and fall within the age ranged between 21 and 45 years. A Pain Numeric Rating Scale (PNRS) score greater than 3 is a requirement, which indicates a meaningful level of pain. [7, 8].

Exclusion Criteria

Certain conditions can influence the accuracy and clarity of the study's results. Thus, individuals with these conditions were not deemed suitable for the research. Specifically, participants were excluded if they are currently pregnant, possess disc pathology, or are diagnosed with chronic illnesses, such as hypertension and diabetes. Additionally, conditions like disc herniation resulted in an individual's exclusion from the study. These exclusions are in line with the research conducted by prior studies [7, 8].

Sampling and Randomization:

Fifty seven patients were checked for eligibility. Medical records were reviewed to assure the fulfillment of inclusion criteria of the study [e.g., diagnosis and location] without any of the exclusion criteria. Forty-five patients met the inclusion criteria and were randomly assigned into three equal groups, **Group A**: received manual therapy, **Group B:** received therapeutic exercises **Group C:** received manual therapy and therapeutic exercises for four weeks, 2 sessions per week. The allocation was performed before initiating the study program using sealed envelopes prepared with random numbers. Distribution was hidden in sequentially numbered opaque envelopes

Outcome measures

The following tools were employed for assessment:

Neck Disability Index (NDI): The NDI is a widely-used patient-reported outcome measure specifically designed to assess self-rated disability in patients with neck pain. It consists of 10 items, each scoring 0 to 5, with higher scores

indicating greater disability. It covers areas such as pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation. The NDI results were expressed as a percentage. "Disability levels according to the NDI are categorized as follows: 0–8% signifies no disability; 10–28% represents mild disability; 30–48% indicates moderate disability; a score of 50–64% is classified as serious disability; and a range of 70–100% denotes complete disability [7].

Range of Motion (ROM): ROM is a measure of the movement available at a particular joint, quantified typically in degrees. For neck assessments, ROM encompasses movements such as flexion, extension, lateral flexion, and rotation. An inclinometer is commonly utilized to accurately measure these movements, offering precise degree measurements of the neck's range in various directions. Utilizing this device aids in determining the functional status of the neck, providing a baseline and tracking any improvements or deteriorations over time [7, 8].

Pain Numeric Rating Scale (PNRS): The PNRS is a straightforward tool where patients rate their pain on a scale from 0 (no pain) to 10 (worst possible pain). It provides a subjective measure of pain intensity and is widely used due to its simplicity and effectiveness in capturing a patient's perceived pain level , Pain scores were classified as follows: 0 (no pain), 1-3 (mild), 4-7 (moderate), and 8-10 (high) [9].

Deep cervical endurance by using a pressure biofeedback device is positioned behind the neck and inflated to 20 mmHg. The patient performs cervical flexion in a graduated manner at five different levels of pressure (22, 24, 26, 28, and 30 mmHg) while maintaining stability in the back of the head. [10]

Interventions

Group A: Manual Therapy

Participants assigned to this group will undergo a comprehensive "Manual therapy" protocol, as delineated in prior studies [7].

Cervical Articular Mobilization:

- Positioning: Prone, with hands placed beneath the forehead.
- Technique: Targeting the T1 vertebra's spinous process, grade III poster anterior impulses are rendered at for 1 minute, segmented into three intervals, each separated by a minute of rest.

Group B: Therapeutic Exercise

Participants in this group will follow a structured "Therapeutic exercise" protocol, rooted in a load progression framework [8].

Week 1

Week 1 Incorporates Exercises 1 & 2

1. **Cranio-Cervical Flexion (CCF)-Supine Position:** A towel is placed at the neck's posterior area to support during the exercise, consisting of three sets of 10 repetitions, with each repetition involving a 10-second contraction followed by a 10-second rest period.

2. **CCF in Seated Position:** Similar to the supine exercise, the seated variant also involves three sets of 10 repetitions with the 10-second contraction and rest periods.

Week 2 Engages in Exercises 1 through 4

3. **Supine Decubitus Co-contraction:** This exercise engages both deep and superficial neck flexors, with the protocol involving 10 repetitions of 10-second contractions and rest periods.

4. **Co-Contraction Exercise for Flexors, Rotators, and Lateral Flexors:** During CCF, patients are instructed to tilt, rotate, and gaze sideways while resisting applied force, for 10 repetitions.

Week 3 and 4 Encompasses Exercises 1 through 6:

5. **Eccentric Exercise for Extensors:** Patients seated perform cervical extension, transition into CCF, and end with cervical flexion, for 10 repetitions.

6. **Eccentric Flexor Exercise:** Starting in a neutral, quadruped position, patients perform neck flexion, transition into CCF, extend the neck while maintaining posture, and then release the CCF, repeated for 10 cycles.

Group C (Combined Group): Participants in this group will receive a combination of both manual therapy and therapeutic exercises, alongside patient education. The manual therapy component will be conducted in the same manner as administered to Group 1. For the therapeutic exercise component, participants in Group C will engage in a modified, lighter version of the exercises given to Group 2. Specifically, participants will perform 15 repetitions of exercises in both the supine and sitting positions. Each exercise repetition will involve a hold phase of 10 seconds followed by a 5-second rest phase. This adjusted protocol ensures that participants receive the benefits of both therapeutic approaches without undue stress or strain [7].

Data Analysis

Prior to analysis, the normality of data was checked using Shapiro-Wilk test. Levene's test for homogeneity of variances was conducted to test the homogeneity between groups. Data were normally distributed and there was homogeneity of variance. MANOVA test was conducted for comparison of the subject characteristics between groups. Chi squared test were conducted for comparison of sex distribution between groups. Two-way mixed design MANOVA was used to investigate the effect of treatment on NRS, NDI, CCFT and neck ROM. Post-hoc tests using the Bonferroni correction were carried out for subsequent multiple comparison. The level of significance for all statistical tests was set at $p < 0.05$. Statistical analysis was performed through the statistical package for social studies (SPSS) version 25 for windows.

Results

Subject characteristics

Table (1) showed the subject characteristics and baseline data of the group A, B and C. There was no significant difference between groups in subject characteristics ($p > 0.05$). Also, there was no significant difference in baseline data between groups ($p > 0.05$).

Effect of treatment on NRS, NDI, CCFT and neck ROM

Mixed MANOVA revealed that there was a significant interaction of treatment and time (Wilk's A = 0.251, F = 3.76, p = 0.001, $\eta^2 = 0.49$). There was a significant main effect of time (Wilk's A = 0.016, F = 230.61, p = 0.001, $\eta^2 = 0.98$). There was a significant main effect of treatment (Wilk's A = 0.455, F = 1.83, p = 0.04, $\eta^2 = 0.33$).

Within group comparison

There was a significant decrease in NRS, NDI and a significant increase in CCFT and neck ROM post treatment compared with that pre-treatment in the group A ($p > 0.001$), group B ($p < 0.001$) and group C ($p < 0.001$) (Table 1-3).

Between groups comparison

There was no significant difference between groups in all parameters pre-treatment ($p > 0.05$).

There was a significant decrease in NRS, NDI and a significant increase in CCFT and neck ROM of group C compared with that of group A ($p < 0.05$) and group B ($p < 0.05$); while there was no significant difference between group A and group B ($p > 0.05$) (Table 4).

Discussion

This Randomized Clinical Trial examined the efficacy of manual therapy, therapeutic exercise, and their combination on pain perception, cervical ROM, deep cervical flexors muscle endurance and neck function perceived by individuals with chronic neck pain.

The result obtained in the present study showed clear improvement in

Table 1. Demographic and baseline clinical characteristics of subjects (N = 45)*.

	Group A (n = 15)	Group B (n = 15)	Group C (n = 15)
Age (years)	22.47 ± 2.61	22.66 ± 2.76	23.13 ± 2.23
Weight (kg)	60.73 ± 7.21	59.13 ± 5.98	61.09 ± 5.44
Height (cm)	163.20 ± 6.33	162.46 ± 7.31	163.53 ± 7.01
BMI (kg/m²)	22.74 ± 1.82	22.39 ± 1.61	22.85 ± 1.65
NPRS	5.40 ± 1.12	5.47 ± 0.83	5.27 ± 1.33
NDI (%)	28.17 ± 4.19	27.85 ± 4.21	27.81 ± 3.36
CCFT (mmHg)	23.20 ± 1.08	22.93 ± 1.38	22.73 ± 1.03
ROM (degrees)			
Flexion	46.33 ± 5.16	47.13 ± 7.34	48.53 ± 6.92
Extension	41.73 ± 6.38	43.33 ± 4.87	42.60 ± 7.51
Right bending	36.67 ± 4.87	35.66 ± 3.73	36 ± 4.84
Left bending	35.33 ± 5.16	34.67 ± 3.52	33.66 ± 2.96
Right rotation	52.66 ± 3.72	50.67 ± 5.93	51.33 ± 5.16
Left rotation	53.67 ± 4.81	51.33 ± 6.67	52.93 ± 6.58

Abbreviations: NPRS, Numerical Pain Rating Scale; NDI, Neck Disability Index, CCFT, Cranio-Cervical Flexion Test

*Data are mean ± SD

Table 2. Clinical characteristics of subjects after intervention (N = 45)*.

Outcome	**Group A (n = 15)**	**Group B (n = 15)**	**Group C (n = 15)**	**F-value**	**p value**
NPRS	2.80 ± 0.77	3.06 ± 0.88	1.93 ± 0.79	7.825	0.001
NDI (%)	15.98 ± 3.73	17.52 ± 3.47	12.28 ± 2.12	10.711	0.001
CCFT (mmHg)	28.33 ± 1.95	27.86 ± 1.34	30.73 ± 1.53	13.368	0.001
ROM (degrees)					
Flexion	58 ± 6.21	60.66 ± 4.95	66.46 ± 5.80	8.712	0.001
Extension	62.67 ± 6.51	64.33 ± 3.72	69.86 ± 4.65	8.208	0.001
Right bending	42.33 ± 3.72	43.66 ± 2.96	47.33 ± 2.58	10.301	0
Left bending	42.66 ± 3.20	42.33 ± 3.19	45.67 ± 2.58	5.588	0.007
Right rotation	66.33 ± 6.11	68 ± 6.27	73.66 ± 3.52	8.567	0.001
Left rotation	68.66 ± 4.80	67.33 ± 5.62	74.33 ± 4.95	7.841	0.001

Abbreviations NPRS, Numerical Pain Rating Scale; NDI, Neck Disability Index, CCFT, Cranio-Cervical Flexion Test; p, probability value; p < 0.05 indicates statistical significance

*Data are mean ± SD

Table 3. Within groups changes pre-post intervention.

	Group A		**Group B**		**Group C**	
Outcome	MD (95% CI)	p value	MD (95% CI)	p value	MD (95% CI)	p value
NPRS	2.6 (2.08, 3.11)	0.001	2.41 (1.88, 2.91)	0.001	3.34 (2.82, 3.84)	0.001
NDI (%)	12.19 (9.77, 14.59)	0.001	10.33 (7.93, 12.74)	0.001	15.53 (13.13, 17.94)	0.001
CCFT (mmHg)	-5.13 (-5.96, -4.31)	0.001	-4.93 (-5.76, -4.11)	0.001	-8 (-8.82, -7.17)	0.001
ROM (degrees)						
Flexion	-11.67 (-14.43, -8.90)	0.001	-13.53 (-16.30, -10.76)	0.001	-17.93 (-20.70, -15.17)	0.001
Extension	-20.94 (-24.77, -17.09)	0.001	-21 (-24.84, -17.16)	0.001	-27.26 (-31.11, -23.42)	0.001
Right bending	-5.66 (-8.02, -3.31)	0.001	-8 (-10.35, -5.65)	0.001	-11.33 (-13.68, -8.98)	0.001
Left bending	-7.33 (-9.50, -5.17)	0.001	-7.66 (-9.83, -5.49)	0.001	-12.01 (-14.17, -9.83)	0.001
Right rotation	-13.67 (-16.41, -10.92)	0.001	-17.33 (-20.07, -14.59)	0.001	-22.33 (-25.07, -19.59)	0.001
Left rotation	-14.99 (-18.11, -11.89)	0.001	-16 (-19.11, -12.89)	0.001	-21.4 (-24.51, -18.29)	0.001

Abbreviations: NPRS, Numerical Pain Rating Scale; NDI, Neck Disability Index, CCFT, Cranio-Cervical Flexion Test;

MD, Mean difference; CI, Confidence interval; p, probability value. P < 0.05 indicates statistical significance.

*Data are mean ± SD

Table 4. Between groups effects after intervention.

Outcome	**Group A vs B**		**Group A vs C**		**Group B vs C**		**Partial Eta Square**
	MD (95% CI)	p value	MD (95% CI)	p value	MD (95% CI)	p value	
NPRS	-0.26 (-0.99, 0.46)	0.64	0.87 (0.14, 1.59)	0.01	1.13 (0.41, 1.86)	0.001	0.271
NDI (%)	-1.54 (-4.36, 1.28)	0.39	3.70 (0.87, 6.52)	0.008	5.24 (2.41, 8.07)	0.001	0.338
CCFT (mmHg)	0.47 (-0.97, 1.91)	0.71	-2.4 (-3.84, -0.95)	0.001	-2.87 (-4.31, -1.42)	0.001	0.389
ROM (degrees)							
Flexion	-2.66 (-7.71, 2.37)	0.41	-8.46 (-13.51, -3.42)	0.001	-5.8 (-10.83, -0.76)	0.02	0.293
Extension	-1.66 (-6.18, 2.85)	0.64	-7.19 (-11.72, -2.67)	0.001	-5.53 (-10.05, -1.01)	0.01	0.281
Right bending	-1.33 (-4.11, 1.43)	0.47	-5 (-7.77, -2.22)	0.001	-3.67 (-6.44, -0.89)	0.007	0.329
Left bending	0.33 (-2.33, 3.01)	0.95	-3.01 (-5.66, -0.33)	0.02	-3.34 (-6, -0.66)	0.01	0.21
Right rotation	-1.67 (-6.18, 2.84)	0.64	-7.33 (-11.84, -2.82)	0.001	-5.66 (-10.18, -1.15)	0.01	0.29
Left rotation	1.33 (-3.22, 5.89)	0.75	-5.67 (-10.22, -1.11)	0.01	-7 (-11.56, -2.44)	0.002	0.272

Numeric Rating Scale (NRS) and Neck Disability Index (NDI) scores, Cranio-Cervical Flexion Test (CCFT) and neck range of motion (ROM) post-treatment compared to pre-treatment in groups A,B, and C. Which are in line with some previous research that evaluate the neck pain and function abilities through physical therapy intervention based on manual therapy and therapeutic exercise (11-14).

Our trial concluded that there was no significant difference between group A and B in term of pain and function improvement, according to these results, it seems that adding manual therapy or therapeutic exercise to physiotherapy program will give similar effects on treating pain and disability in chronic mechanical neck pain. These results are comparable to those of previous studies by Bernal-utrera et al. (12) who reported that there were no significant differences between treatments in reducing functional limitations associated with cervicogenic headaches. By contrast, study by gonzale González-Rueda et al found that manual therapy had better effect on neck disability and neck movement when comparing to other therapeutic intervention (13)

Moreover, a multimodal physiotherapy approach that included both manual therapy and therapeutic exercises (group C) showed an improvement in neck function, endurance, neck movement and reduce of pain compared to each approach alone. Other authors have support the use of a multimodal approach as Rodríguez-Sanz et al who concluded that add four sessions 20-min of manual therapy along with home exercise maximize the effectiveness than use one techniques in improve neck pain and functional abilities. (11-13)

Based on the available evidence, these finding could be explained through neurophysiological mechanism generated by manual therapy and therapeutic exercise, as manual therapy can reduce muscle spasm by activation of primary efferent fibers of the neuromuscular spindles and Golgi organs (11) And therapeutic exercise to CCFT muscle group enhance postural stability and target the exact muscle fiber (14) and reorganization in motor patterns and neuromuscular adaptation .all that leading to an increase in cervical mobility and pain perception (12)

To sum up, each result from our study contributes additional nuances to the

existing findings from previous research. By comparing them side by side, we can see that while individual modalities have their strengths, a combined approach may offer a broader range of benefits, potentially leading to more comprehensive and sustained outcomes for individuals with chronic neck pain.

Limitations

There were some limitations to the current study: Small sample size, the study was limited to female participants only and no follow up for the participants after the end of the study. So, further studies are recommended to be applied on large group, male participants and long term follow up.

Conclusion

Based on the obtained results and previous studies results, our study supported the use of combined manual therapy and therapeutic exercise for the management of chronic neck pain, demonstrating significant improvements in pain relief, muscle endurance, and range of motion. To further enhance clinical practice, we recommended future research to explore the long-term benefits and cost-effectiveness of integrating these therapies into a broader pain management program.

Competing interests

The authors declare that they have no competing interests.

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