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Effects of Neck Stabilization and Isometric Neck Exercises on Non-Specific Chronic Neck Pain: A Pilot Study

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[1]Concept and design, Interpretation of data and drafting of the manuscript, reviewing the manuscript [2]Data collection, [3]analysis and reviewing the manuscript. All authors revised, discussed the outcome, commented and approved the final version of the manuscript

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A B S T R A C T

Objectives: To evaluate the efficacy of neck stabilization and isometric neck exercises on pain-related disability, sleep disturbance, psychological status and cardiopulmonary parameters in patients with non-specific chronic neck pain (NSCNP).

Methodology: This study was done within a period of May-October, 2019. 14 patients with NSCNP were involved in this research. The patients were enrolled into the research from two post secondary health facilities in Lagos state and distributed into groups A, B and C with the aid of random numbers generated by the computer: Group A received Neck stabilization exercises only, Group B received Neck stabilization and isometric neck exercises, Group C received Isometric neck exercises only. Subjects were evaluated for pain-related disability, sleep disturbance, psychological status (anxiety and depression), systolic and diastolic blood pressure (SBP, DBP), heart rate (HR), respiratory rate (RR), mean arterial pressure (MAP), rate pressure product (RPP), forced vital capacity (FVC), forced expiratory volume in 1 second (FEV1), peak expiratory flow rate (PEFR) and perceived exertion rate (RPE) before intervention and end of 4th week.

Results: This research showed that neck stabilization combined with isometric exercise improved pain-related disability (p=0.04), anxiety (p=0.04) and depression (p=0.04) after 4 weeks intervention. Some pulmonary parameters, FVC (p=0.05, p=0.02), FEV1 (p=0.02, p=0.01) improved significantly post intervention in both neck stabilization exercise alone and neck stabilization combined with isometric neck exercise groups. While PEFR (p=0.02, p=0.01) improved significantly in both neck stabilization combined with isometric neck exercises and isometric neck exercise group alone post intervention.

Conclusion: This study draws the conclusion that neck stabilization exercise only and neck stabilization combined with isometric exercise will better improve pain-related disability, anxiety, depression, sleep disturbance and some selected pulmonary parameters (FVC, FEV1, PEFR) in patients with NSCNP.

Introduction

Neck pain is a well-known disorder after low back pain and it tends to become chronic in 43% of individuals. The level of psychological status and disability rises due to severe pain seen in chronic neck pain individuals. [1]

The rise in the occurrence of chronic neck pain affects the productivity and lifestyle of individuals living with this condition in high income society.[2] The severity of symptoms of non-specific neck pain comprises of impaired ambulation, lack of sensation in the limbs and migraines.[3] The standard medical practice has not given the lung function of individuals with neck pain much concern. In general, it is assumed that some selected lung function variables (maximal voluntary ventilation, respiratory muscles strength and chest expansion) are compromised in chronic neck pain individuals.[4]

Angane and Navari [5] in their own study revealed a rise in Forced vital capacity (FVC) and Forced expiratory volume (FEV1) of lung function variables. This was attributed to the strengthening of respiratory muscles which in turn increased the rate and depth of respiration and also improved FVC, oxygen consumption and diffusion rate.

Sleep disturbance has also been found to be linked with chronic neck pain. A study carried out by Artner *et al* [6] found that out of 118 patients with chronic neck pain, 41% complained of insomnia while on analgesic medications and 13% complained of severe insomnia.

The increase in resting blood pressure, pain sensitivity, clinical pain intensity, has been found in individuals with chronic neck pain.[7] Existing scientific proof suggests that there is a proportion of less than 10 percent of hypertension in individuals with chronic pain in contrast to persons' without.[8] The ability of the blood vessels to dilate result from the effect of exercise or hormonal changes. Exercise also improved the supply of Oxygen to the muscles.[9]

Muscle strengthening, flexibility and endurance are forms of exercises used for the restoration of injured tissues which aid sustenance of daily activities. Thus, exercise is a regular modality used in managing individuals with neck pain.[10] This differs considering time, training, rate, level, and method. Earlier study reported that isometric exercises and strength training improve neck pain symptoms. [11]

Neck stabilization exercises (NSE) can be utilized for the management of NSCNP. The therapeutic power is derived from its capacity to increase joint movement, sensorimotor function and enhance relaxation.[12] Kaka *et al* [13] carried out a study which concluded that neck stabilization exercise produced a superior effect in decreasing pain level in patients with neck pain than its combination with dynamic exercise. Neck stabilization exercises also improve pain, disability, depression and anxiety in individuals with NSCNP. [13, 14, 15]

Another exercise discovered to be effective in increasing muscle performance is isometric exercise. It is useful due to the isometric manner in which it activates many postural muscle work and dynamic strengthening.

The strengthening and development of endurance of weak muscles during proprioceptive neuromuscular facilitation is achieved through Isometric exercise training.[16]

This research determined the effects of neck stabilization and isometric neck strengthening exercises on pain-related disability, psychological status, sleep disturbance and cardiopulmonary parameters in individuals with NSCNP.

Methodology

Fourteen (14) subjects with non-specific chronic neck pain (NSCNP) took part in this single blinded randomized controlled study, Trial Registration number PACTR201907694769013.

Enrollment of the NSCNP patients was from the Physiotherapy Outpatient Clinic and orthopaedic clinic of Lagos University Teaching Hospital, Idi-Araba (LUTH), Lagos and the National Orthopaedic Hospital, Igbobi, Lagos.

Subjects that participated in this research were diagnosed of NSCNP of not less than 12 weeks. Subjects with cognitive limitations or history of cardiovascular, pulmonary or endocrine disease, Subjects with health conditions which might prevent them from participating in exercise, Subjects with chronic neck pain with symptoms indicating a particular red flag were all excluded. Health research and ethics committee of college of medicine, University of Lagos gave the approval for the study with identification number: (CMUL/HREC/04/19/519) and written informed consent was gotten from the subject before commencing the research.

Sample size determination for comparing proportions was used to estimate the sample size for this research [17] using an alpha value of 1.96 and beta value of 0.84, prevalence of 0.71 [18] and D of 0.5.

Subjects' demographic characteristics including age, sex, body mass and height were documented and the body mass index was computed with the formula weight/height^2

Baseline assessment of pain-related disability, sleep disturbance, psychological status, cardiopulmonary parameters and rate of perceived exertion were done prior to engaging the subjects in the research using Neck Pain disability index (NPDI)[19], Insomnia severity index(ISI) [20], Hospital anxiety and depression scale (HADS)[21], Sphygmomanometer, Stethoscope, spirometer and borg's scale of perceived exertion respectively. These

assessments were measured and recorded at baseline and 4th week.

Consecutive sampling technique was employed to select the subjects into the research. The researcher recruited subjects based on who met the inclusion criteria and they were allotted into 3 different groups (A, B and C) using computer generated random number sequence. This was generated before meeting each subject; this enabled patients to fall into any of the three groups according to their order of their presentation. Twenty-one subjects were recruited into the study, 03 were excluded based on the exclusion criteria. 05 subjects were allocated into group A, 07 subjects into group B while 06 subjects were in group C, but 14 subjects completed the study, 4 did not complete due to travel, and proximity to the clinic. Figure 1 shows the consort flow chart of subjects.

Subjects in group A received neck stabilization exercises, subjects in group B received neck stabilization exercises plus isometric neck exercises, while subjects in group C received isometric neck exercises only (control group). All the exercises were performed 2 times in a week for one month. Assessment of neck pain-related disability, sleep disturbance, psychological status,

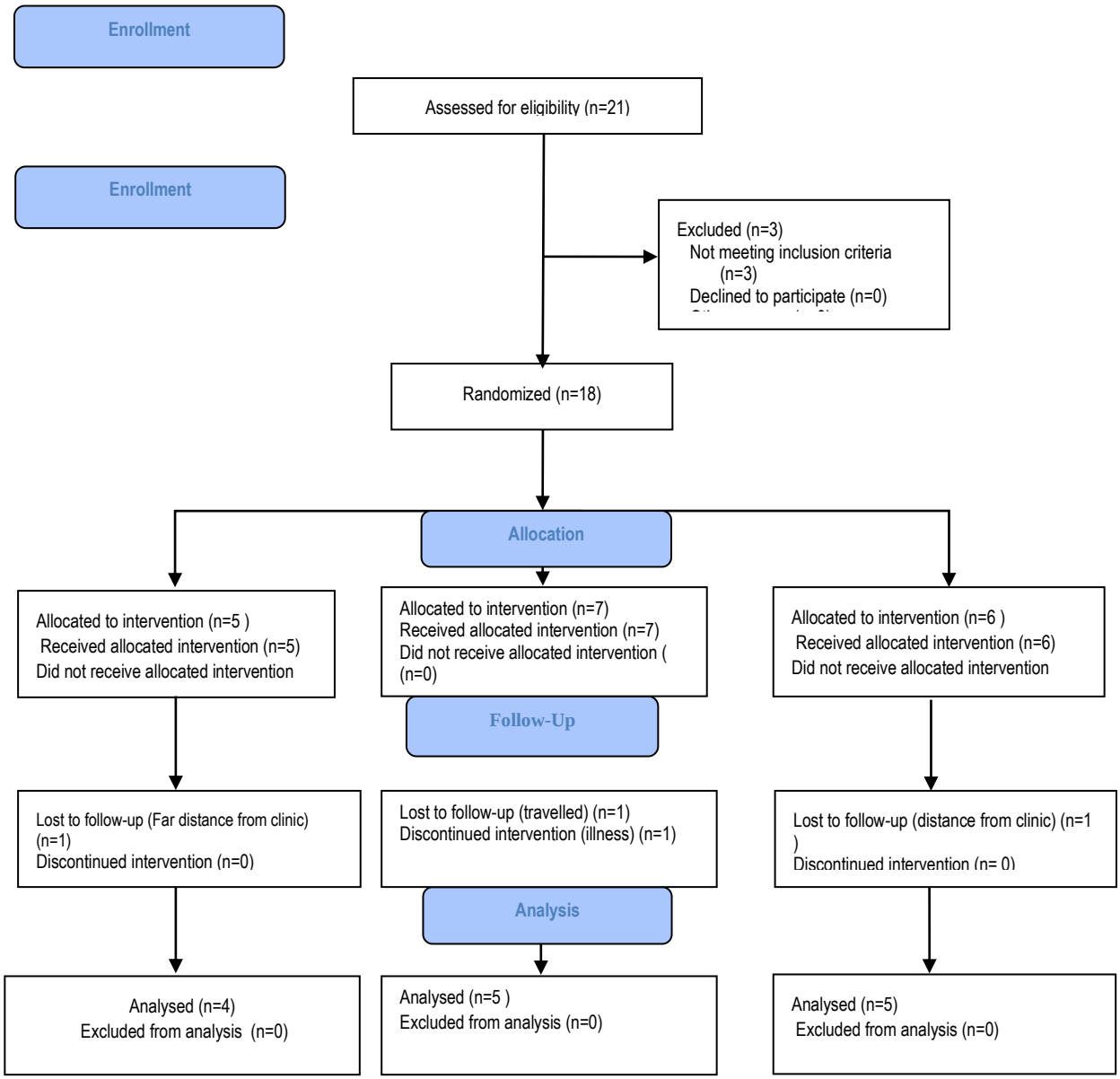

Figure 1: Flow of patients into the study

cardiopulmonary parameters and rate of perceived exertion was done before treatment and end of 4 weeks.

Procedure for neck stabilization exercise: Tucking in of chin, extending the neck, shrugging of shoulder, rolling of shoulder, retraction of scapular. [13] Protocol for isometric neck exercise: Isometric neck flexion, Isometric neck extension, Isometric lateral flexion.[11]

Assessment of cardiovascular parameters: The researcher ensured that the subjects were well rested before commencing the assessment. The subjects were instructed to rest their arm comfortably on a surface to ensure uniformity of readings. The heart rate and blood pressure were evaluated using the protocol of Holocomb et al.[22] The rate pressure product (RPP) was measured by calculation. The researcher multiplied the value of heart rate (HR) and systolic blood pressure (SBP). RPP=HR×SBP (mmHg.bpm).

Assessment of pulmonary parameters: Respiratory rate was taken as the blood pressure was being measured in sitting position, subjects were not aware that their respiratory rates were being taken. The lung function assessment was done using the protocol of Coates et al.[23] The subjects' rate of perceived exertion was assessed using the Borg scale of perceived exertion.[24]

DATA ANALYSIS: Data were analyzed using Statistical Package for Social Science (SPSS) 21.0 version and was summarized using descriptive statistics of mean and standard deviation. Analysis of variance (ANOVA) and Kruska wallis test were used to establish the statistically significant difference across the 3 groups. Wilcoxon rank test and paired t-test was used to determine significance difference within each group at p≤0.05.

Results

The result of this research revealed that therapeutic exercise is efficacious in the reduction of pain-related disability, improvement of quality of sleep, depression, anxiety and cardiopulmonary parameters in individuals with NSCNP. There was clinical improvement in outcome parameters in the two intervention groups (neck stabilization and neck stabilization combined with isometric exercise groups) after 4 weeks post treatment.

Eighteen patients with NSCNP were involved in this research, however only 14 subjects (6 males and 8 females) completed the study. The three groups were comparable (Table I). The sex distribution of the participants is shown in figure 2.

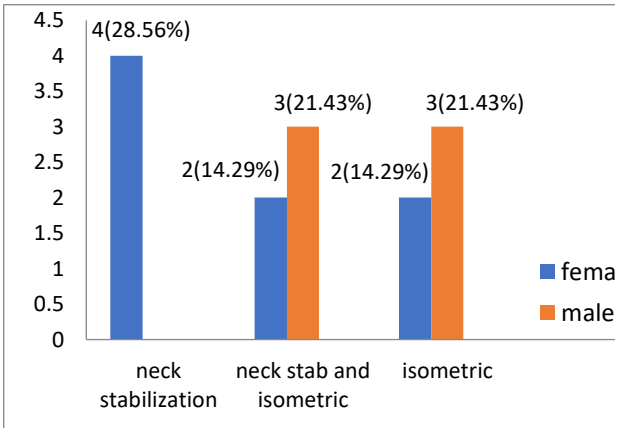

Figure 2: Sex Distribution of Subjects

Table II showed the mean scores of pain-related disability, anxiety, depression and sleep disturbance before intervention and 4 weeks post intervention. Wilcoxon test established no significant difference but clinical changes in pain-related disability, anxiety, depression and sleep disturbance in groups A and C, while there was significant differences in pain-related disability (p=0.04), anxiety (p=0.04) and depression (p=0.04) in group B.

Table III showed the mean scores of cardiopulmonary variables before intervention and end of 4th week. Paired t-test demonstrated that there was significant differences in FVC (p=0.05), FEV1 (p=0.05) and RPE (p=0.03) in group A, while FVC (p=0.02), FEV1 (p=0.00) and PEFR (p=0.02) in group B, and FEV1

Table I: Demographic Characteristics of the participants

	All subjects X±SD(N=14)	Group A X±SD (N=4)	Group B X±SD (N=5)	Group C X±SD (N=5)	f-test	p-value
Age(years)	44.07±17.95	50.00±20.05	40.40±19.28	43.00±17.90	0.30	0.75
Weight (Kg)	72.50±11.44	80.00±13.49	71.20±10.16	67.80±9.99	1.39	0.29
Height(m)	1.71±0.07	1.67±0.03	1.74±0.06	1.70±0.10	1.34	0.30
BMI(Kg/m^2)	24.90±3.87	28.82±5.09	23.32±2.34	23.34±1.50	4.36	0.04*

Significant at p≤0.05

(p=0.01) and PEFR (p=0.01) in group C.

Table IV demonstrated the comparison of the mean scores of neck pain-related disability, anxiety, depression and sleep disturbance before treatment and 4 weeks after treatment in all the groups. Analysis demonstrated no significant difference before and after intervention evaluation of pain-related disability, anxiety and depression across the groups. There was a significant difference in sleep disturbance (p=0.03) in all the groups.

Table II: Outcome measure parameters within each group at baseline and end of 4th week

	Outcome Measures	Pre-Rx(Baseline) Mean±SD	POST-RX(END OF 4TH) Mean±SD	z-test	p-value
Group A (N=4)	NPRD	39.56±11.82	18.33±6.57	1.83	0.07
	Anxiety	5.50±1.91	2.75±1.71	1.89	0.06
	Depression	5.75±1.26	2.00±1.83	1.83	0.07
	Sleep disturbance	10.50±3.87	4.50±0.58	1.83	0.07
Group B (N=5)	NPRD	26.84±13.46	13.47±8.44	2.03	0.04*
	Anxiety	5.80±4.21	2.80±2.28	2.03	0.04*
	Depression	5.00±2.24	3.60±2.07	2.03	0.04*
	Sleep Disturbance	2.40±2.61	0.80±1.30	1.63	0.10
Group C (N=5)	NPRD	20.18±11.87	14.45±8.23	1.75	0.08
	Anxiety	3.80±1.92	1.80±1.10	1.86	0.06
	Depression	2.20±2.39	1.00±0.71	1.29	0.20
	Sleep Disturbance	4.60±3.58	2.00±1.87	1.84	0.07

*Significant at p≤0.05` Z-test= Wilcoxon sign rank test

Table III: Cardiopulmonary parameters within each group at baseline and end of 4th week

	Parameters	PRE-RX (BASELINE) Mean± SD	POST-RX (end of 4th week) Mean ±SD	t-test	p-test
GROUP A(N=4)	SBP(mmHg)	121.00±13.64	118.25±10.21	0.55	0.62
	DBP(mmHg)	82.25±10.15	74.75±5.50	1.70	0.19
	HR(b/m)	66.00±12.96	78.75±12.42	1.04	0.38
	RR(c/m)	20.75±5.74	25.00±8.87	0.98	0.40
	RPP (mmHg)	7953±1658.90	9353.00±1919.25	1.02	0.38
	MAP (mmHg)	95.42±9.92	90.00±6.45	1.74	0.18
	FVC(L)	1.96±0.08	2.53±0.36	3.13	0.05*
	FEV1(L)	1.49±0.69	2.10±0.69	3.22	0.05*
	PEFR(L/s)	3.14±0.89	3.97±0.36	2.02	0.14
	RPE	10.50±2.52	6.25±0.50	3.83	0.03*
GROUP B (N=5)	SBP(mmHg)	118.00±11.83	114.60±8.41	2.13	0.10
	DBP(mmHg)	82.20±15.60	75.00±11.05	2.09	0.11
	HR(b/m)	72.20±7.95	73.20±6.42	0.37	0.73
	RR(c/m)	17.40±2.97	19.60±2.97	0.92	0.41
	RPP(mmHg)	8479.20±887.28	8399.60±532.75	0.21	0.85
	MAP(mmHg)	94.13±14.28	87.67±7.85	2.23	0.09
	FEV1(L)	1.93±0.41	2.53±0.35	6.74	0.00*
	FVC(L)	2.21±0.49	2.65±0.34	3.69	0.02*
	PEFR(L/s)	3.87±1.20	4.72±1.22	3.80	0.02*
	RPE	9.60±3.58	6.20±0.45	2.37	0.08
GROUP C(N=5)	SBP(mmHg)	118.00±7.07	117.40±7.60	0.21	0.85
	DBP (mmHg)	72.60±5.55	76.00±5.83	0.94	0.40
	HR (b/m)	59.40±21.26	65.60±7.80	0.90	0.42
	RR (c/m)	20.80±4.15	19.00±4.24	0.82	0.46
	RPP (mmHg)	7039.20±2598.51	7703.60±1041.82	0.78	0.48
	MAP(mmHg)	108.53±50.18	89.80±5.35	0.83	0.45
	FEV1(L)	1.97±0.31	2.26±0.30	4.66	0.01*
	FVC(L)	2.34±0.44	2.61±0.36	1.44	0.22
	PEFR(L/s)	3.38±1.30	4.49±1.01	4.82	0.01*
	RPE	6.20±0.45	6.00±0.00	1.00	0.37

***Significant at p≤0.05**

Table IV: Comparison of outcome variables at baseline and end of 4th week across the three groups

Outcome Measures	GROUP A mean±SD	GROUP B mean±SD	GROUP C mean±SD	H-test	p-value
NPRD	39.56±11.82	26.84±13.46	20.18±11.87	3.46	0.18
Anxiety	5.50±1.91	5.80±4.21	3.80±1.92	1.05	0.59
Depression	5.75±1.26	5.00±2.24	2.20±2.39	4.98	0.08
Sleep disturbance	10.50±3.87	2.40±2.61	4.60±3.58	6.89	0.03*
NPRD	18.33±6.57	13.47±8.44	14.45±8.23	2.28	0.32
Anxiety	2.75±1.71	2.80±2.28	1.80±1.10	0.79	0.68
Depression	2.00±1.83	2.60±1.52	1.00±0.71	2.65	0.27
Sleep disturbance	4.50±0.58	0.80±1.30	2.00±1.87	7.17	0.03*

***Significant difference≤0.05**

Table V: Comparison of cardiopulmonary parameters at baseline and end of 4th week across the three groups

	PARAMETERS	GROUP A Mean±SD	GROUP B Mean±SD	GROUP C Mean±SD	f-value	p-value
BASELINE	SBP(mmHg)	121.00±13.64	118.00±11.83	118.00±7.07	0.11	0.90
	DBP(mmHg)	82.25±10.15	82.20±15.60	72.60±5.55	1.17	0.35
	HR(b/m)	66.00±12.96	72.20±7.95	59.40±21.26	0.88	0.44
	RR(c/m)	20.75±5.74	17.40±2.97	20.80±4.15	1.00	0.40
	RPP(mmHg/m)	7953±1658.90	8479.20±887.28	7039.20±2598.51	0.76	0.49
	MAP(mmHg/m)	95.42±9.92	94.13±14.28	108.53±50.18	0.30	0.74
	FVC(L)	1.96±0.08	2.21±0.49	2.34±0.44	1.00	0.40
	FEV1(L)	1.49±0.69	1.93±0.41	1.97±0.31	1.32	0.31
	PEFR(L/s)	3.14±0.89	3.87±1.20	3.38±1.30	0.47	0.64
	RPE	10.50±2.52	9.60±3.58	6.20±0.45	3.74	0.06
END OF 4TH WEEK	SBP(mmHg)	118.25±10.21	114.60±8.41	117.40±7.60	0.23	0.80
	DBP(mmHg)	74.75±5.50	74.60±7.60	76.00±5.83	0.07	0.93
	HR(b/m)	78.75±12.42	73.20±6.42	65.60±7.80	2.49	0.13
	RR(c/m)	25.00±8.87	19.60±2.97	19.00±4.24	1.50	0.27
	RPP(mmHg)	9353.00±1919.25	8399.60±532.75	7703.60±1041.82	2.02	0.18
	MAP(mmHg)	90.00±6.45	87.67±7.85	89.80±5.35	0.18	0.84
	FVC(L)	2.53±0.36	2.65±0.34	2.61±0.36	0.14	0.87
	FEV1(L)	2.10±0.69	2.53±0.35	2.26±0.30	1.02	0.39
	PEFR(L/s)	3.97±0.36	4.72±1.22	4.49±1.01	0.68	0.53
	RPE	6.25±0.50	6.20±0.45	6.00±0.00	0.58	0.58

Significant at p≤0.05

KEY

X±SD = Mean± standard deviation
GROUPA = Neck stabilization exercises only
GROUP B= Neck stabilization and isometric neck exercises
GROUP C= Isometric neck exercises only
SBP = Systolic blood pressure
DBP = Diastolic blood pressure
HR = Heart rate
RR = Respiratory rate
RPP = Rate pressure product
MAP = Mean arterial pressure
FVC = forced vital capacity
FEV1 = forced expiratory volume in one second
PEFR = peak expiratory flow rate
RPE = rate of perceived exertion
F-value = ANOVA (analysis of variance)

Table V demonstrated the comparison of mean scores of cardiopulmonary variables before treatment and 4 weeks after treatment across all the groups. ANOVA test demonstrated no significant difference across the three groups.

Discussion

This randomized controlled study was embarked on to examine the effects of neck stabilization and isometric neck exercises on neck pain-related disability, psychological status, sleep disturbance and selected cardiopulmonary parameters in individuals with non-specific chronic neck pain (NSCNP).

This research demonstrated that there was significant improvement in neck stabilization combined with isometric exercise group but clinical improvement in

neck stabilization exercise only group and isometric exercise group. This is in accordant with the outcome of the research of Kaka *et al* [13] on the effects of stabilization and dynamic exercises in patients with NSCNP. The mode of which neck stabilization exercise reliefs' pain is on the premise that activity is increased in the motor pathways due to intense exercise. It is also believed that exercise slows down its impact on pain centres in the brain and spinal cord. It also has a stimulating effect on mechanoreceptors, stimulating the sensory nerve which slows down the effect on mediating pain pathways.[13, 15] This result confirms the assertion of

Dusuncelli *et al* [14] which showed the superiority of neck stabilization exercise when compared with isometric exercise and physical therapy agents.

Chung *et al*[25] in their study reported an improvement in pain-related disability with the craniocervical flexion exercise showing greater improvement than the isometric exercise. Isometric contraction against a resistance for about 6 seconds leads to increase in strength and endurance of muscles. This allows the development of peak tension for the occurrence of metabolic changes for each muscle contraction.[16] Pain reduction could be due to increased endorphins which are released from the pituitary gland after isometric contractions activate muscle stretch receptors.[26] The improvement in pain-related disability observed in neck stabilization combined with isometric group may be due to the combination of the therapeutic effects of both exercises on the neck muscles.

According to this study, Isometric neck exercises only show no significant improvement in pain-related disability in individuals with non-specific neck pain. This is probably because of fewer loads placed on the muscles when compared to neck stabilization exercise combined with isometric.

This may be due to the positive change in pain and functional capacity level of patients post treatment. Neck pain affects the neurotransmitters in the brain, altering the manner in which pain is perceived. This causes patients to be depressed and anxious.[1] Though there was clinical improvement in the neck stabilization exercise group and isometric exercise group post intervention, the improvement was not enough to obtain a significant difference and this may simply be due to low turnout of subjects for this study.

There is a scarcity of literature on the assessment of the effect of isometric neck exercise on the level of anxiety and depression. The outcome of this the research demonstrated that the combination of both exercises have been found to have significant effect on anxiety and depression.

Dusunceli *et al*[14] while evaluating the effectiveness of neck stabilization exercises on neck pain, reported a positive change in the depression level of neck pain patients after undergoing neck stabilization exercises compared with isometric exercises and physical agents. This outcome is in congruence with the statement of Kaka *et al* [13] on reduction in depression level of neck pain patients after treatment for eight weeks while comparing the efficacy of neck stabilization and dynamic neck exercises on patients with non-specific neck pain. Zibiri *et* al [15] and Akodu et al [27] affirmed that neck stabilization was valuable in the improvement of anxiety and depression in persons with NSCNP. It was also discovered that stabilization exercises had the ability to decrease hormonal and muscle stress, thereby decreasing anxiety levels. [28]

This research discovered a clinical improvement in sleep quality in patients with NSCNP in all the groups but there was no significant difference, this may be due the low turnout of subjects for this research. The study of Zibiri *et al*[15] also showed an improvement in sleep disturbance after treatment with neck stabilization exercises. The improvement may be due to decrease in pain of the neck muscles at night which leads to reduced interruption of patients' sleep. There was no significant difference in sleep disturbance value in the neck stabilization combined with isometric neck exercise group. There is an insufficient literature on the impact of isometric neck exercises on sleep disturbance in patients with NSCNP.

The results of this study showed no significant difference in all cardiovascular parameters in the three groups. This may be due to the low turnout and dropout of participants in this research. Blood pressure has been shown to be high in individuals with chronic pain with a

proportion of less than 10% hypertension.[7, 8] There is a significant rise in blood pressure and heart rate following exercise but this elevation tends to reduce after exercise.[28] This occurs due to the ability of blood vessels to dilate and supply oxygen to the muscles post exercise.[29] This effect is experienced in isometric exercise by the stimulation of motor units which cause excitation of the central nervous system which increases sympathetic outflow and reduces parasympathetic outflow.[29]

Pulmonary function in chronic neck patients has been found to be reduced. According to Dimitriadis *et al* [30], patients with chronic neck pain were found to have decreased FVC with FEV1 and peak expiratory flow rate remaining unaffected. In this study, a significant improvement was found in some pulmonary parameters (FEV1, FVC, RPE) in neck stabilization exercise group and in PEFR for both neck stabilization combined with isometric and isometric neck exercise group alone. Neck stabilization exercise helps to improve pulmonary function by correcting the altered biomechanics of the cervical and thoracic spine which in turn improves the thoracoabdominal mobility and efficacy of diaphragm.[31]

It is recommended that further studies should be done with a larger population and longer period/follow-up since this is a pilot study.

Conclusion

This study revealed that all interventions have been found to have clinical/significant improvement of pain-related disability, anxiety, depression, sleep disturbance and some pulmonary parameters (FEV1, FVC) in all the groups. It is encouraged that all of the interventions can be used in the treatment of individuals with NSCNP. Therefore, Physiotherapist should consider the use of neck stabilization combined with isometric neck exercise, neck stabilization exercise alone in the management of individuals with NSCNP. Physiotherapist should also consider the assessment of patients with NSCNP for cardiopulmonary compromise to know the specific intervention that will be suitable for their management.

Recommendations: It is recommended that further studies should be done with a larger population and longer period/follow-up since this is a pilot study.

Limitations: This pilot study involved small sample size with drop-outs. There was also a short period of follow-up to determine consistency. Several outcomes were assessed, so the chance of a Type 1 error is reasonably high. Therefore, the results of the study should be viewed with caution.

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