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Running head - no more than 40 letters/ spaces (this is the heading that runs across the top of each page)	Myofascial Therapies for Neck Pain
How many words are in the abstract? (approx 250 words or less)	226
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State funding sources (grants, funding sources, equipment, and supplies). Include name and number of grant if available. Clearly state here if study received direct NIH or national funding. All sources of funding should be included.	
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Contributorship	For each author, list initials for how the author contributed to this manuscript. **MRH, DRA, RMV, PRH, RLV**
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Treatment of Neck Pain with Myofascial Therapies: A Single Blind Randomized Controlled Trial.

ABSTRACT

Objective: This study aimed to investigate the effects of myofascial release therapy (MRT) versus and standard physical therapy (PT) program in patients with neck pain (NP).

Methods: This was a randomized controlled trial in which 54 participants with mechanical NP were randomly assigned into an experimental group (EG) or comparison group (CG). The EG group (n=27) received 5 therapy sessions of MRT while the CG group (n=27) received 10 sessions of massage, ultrasound therapy (US), and transcutaneous electric nerve stimulation (TENS) over a 2 week period. Outcome measures were the numerical pain rating scale (NPRS), pressure pain thresholds (PPTs) and range of motion (ROM) at the end of treatment and at one-month follow-up.

Results: At one-month follow-up, between-group differences in change scores were found in the NPRS (Mean=-1.56, 95% CI [-2.30; -0.81]; p<0.001), in the right thoracic PPT (Mean=0.35, 95% CI [0.03; 0.66]; p=0.031), and in both left (Mean=0.34, 95% CI [0.08; 0.61]; p=0.012) and right (Mean=0.29, 95% CI [0.04; 0.54]; p=0.026) suboccipital PPTs. The success rate was 63.0% in the CG and 92.6% in the EG. The number needed to treat (NNT) was 3.38 (95% CI = 1.99; 11.23).

Conclusions: MRT could be better than and standard PT Program for improving pain and suboccipital PPTs in patients with NP. However, the difference between both treatments is less than the minimum detectable change of the NPRS.

Key Indexing Terms*: Cervicalgia; fascia; physical therapy modalities; range of motion; trigger point pain.*

INTRODUCTION

Neck pain (NP) has considerable implications for health and quality of life[1] and is a well-recognized source of disability in the working population.[2] The one-year prevalence of NP in the general population is reported to range between 30 and 50 percent.[3] Every year, an episode of NP occurs in 15–20 percent of the general population, in 15–60 percent of the work force, and in 10–14 percent of those involved in traffic collisions.[4, 5] It is estimated that 70 percent of the population will experience NP throughout life, and the annual incidence ranges are between 15–50 percent of the population.[5]

At present, NP has been associated with myofascial pain syndrome (MPS),[6, 7] with a 100% prevalence of MPS in the NP population.[6] MPS can be described as the sensory, motor and autonomic symptoms caused by trigger points (TrPs).[8] A TrP is clinically defined as “a hyperirritable spot in skeletal muscle that is associated with a hypersensitive palpable nodule in a taut band. The irritable spot is painful on compression and can give rise to particular referred pain, tenderness, motor dysfunction and autonomic phenomena”.[9] Trapezius, levator scapulae, multifidi and splenius cervicis are the muscles with a high prevalence of TrPs in the NP population.[6]

Myofascial release therapy (MRT) is an effective technique for NP management.[10] There are some studies that have suggested that MRT might be better than other treatments for improving NP.[11-13] One study found improvements in pain perception in the short term in people with nonspecific spinal pain,[13] while another study showed that MRT may be better than manual therapy (MT) for improving cervical joint range of motion but not for improving

pain.[11] Another study found significant differences in NP but with a possibly insufficient sample size to detect differences in other variables.[12]

Based on this evidence, the present study aimed to analyze the effects of the MRT program in the management of patients with NP. It was hypothesized that MRT is more effective in reducing the intensity of the pain, the active cervical range of motion (ROM) and pressure pain thresholds (PPTs) compared to the effects of a standard physical therapy program.

MATERIALS AND METHODS

Design of the Study

This study was performed between June 2017 and January 2018. All participants provided written informed consent to participate in this study, which was conducted in accordance with the Declaration of Helsinki, good clinical practices, and all applicable laws and regulations. Ethical approval for the study was obtained from the Ethics Committee of Research of Cádiz (Spain) (reference number 32/16). The trial is registered with the Clinical Trials Registry (reference number NCT03184220). The current study conforms to the CONSORT statement for reporting clinical trial studies.[14]

A single-blind (assessor) randomized controlled clinical trial was designed. The patients were randomly allocated to each intervention group, using a 1:1 allocation ratio (Figure 1). The randomized sequence for allocation was created by an independent researcher using a random allocation software program (Epidat 4.0) and was concealed in sequentially numbered envelopes.

Study Populations

Participants were recruited from the Santa Maria Policlinic in the city of Cádiz, Spain. Data collection was conducted by a physician who was blinded as to which participants received experimental or comparison intervention.

In our study, mechanical NP was defined as neck and shoulder pain caused by movements or postures of the neck and palpation of the cervical muscles. The inclusion criteria for this study were as follows: patients of both sexes, aged between 20 and 60 years and diagnosed by a physician as

mechanical NP with at least a month's evolution. The exclusion criteria for this study were as follows: patients with NP due to trauma or whiplash; patients who were pregnant or who had a pacemaker; patients who had undergone surgery on the cervical spine; pharmacological treatment for pain and patients receiving myofascial therapy 1 month before the beginning of the study.

Outcome Measures

The main outcome measure was the intensity of the NP. In the morning, the presence and intensity of NP was determined in writing with an 11-point numerical pain rating scale (NPRS; 0: no pain to 10: maximum pain).[15] This scale considered a score of six or more a useful cut score for prognosis value and indicated great utility, such as a self-reported disability tool.[16] This scale has demonstrated acceptable levels of reliability and validity in individuals with NP.[15-17] NPRS had a minimal detectable change (MDC) of 2.1 points, with a minimal clinically important difference (MCID) of 1.3 points.[18]

The pressure pain threshold (PPT), defined as the minimal amount of pressure necessary to evoke pain or discomfort at the trigger point,[19] was evaluated with a pressure algometer (Pain Test FNP 100, Wagner Instruments) at cervical trigger points and followed the methodology described by Muñoz-Muñoz[20]. PPTs were measured bilaterally over the suboccipital (splenius capitis) and upper trapezius MTrPs. For the diagnosis of a PrT, compliance with the following criteria was required: (1) a hypersensitive spot in a palpable taut band, (2) palpable or visible local twitch on pincer palpation, and (3) reproduction of referred pain elicited by palpation of the sensitive spot.[21] MTrPs were located by palpating the taut band and identifying the point of maximal tenderness. The

physician localized the MTrP, placed the tip of the algometer perpendicular to the skin and applied a gradually increasing pressure by 1 kg/square cm per second. The patients were instructed to indicate whether they felt local or referred pain and to say stop at the point where the pressure became painful. The mean of three nonconsecutive measurements, with a 30 second resting interval, was chosen as the reference value. Pressure algometry is a valid and reliable tool to assess pain processing[22] and has shown a high interexaminer reliability.[23]

The cervical active range of motion (CROM) was measured by a goniometer (SP-5060 CROM cervical, Performance Attainment, St Paul, MN).[24] A high-quality review has studied CROM as an outcome measure following cervical mobilization.[24] When evaluating a patient with NP over an episode of care, clinicians should include assessments of impairments of body functions that can establish baselines and be helpful in clinical decision-making to rule in or rule out NP with mobility deficits, including CROM.[16]

All measurements were conducted by the same well-trained physician who was blinded to the group to which each patient belonged.

Treatment success was defined as an improvement of PPTs at all points evaluated of at least 30% and a decrease in NP of at least 30% from the baseline based on NPRS measurements.[25, 26]

Interventions

All patients were instructed not to perform additional treatments, which was a cause of exclusion, including other exercises, physical therapy or pharmacological treatment.

Comparison Group

The CG was treated over a two week period (five days/week) with ultrasound therapy (US), transcutaneous electric nerve stimulation (TENS) and massage, in that order. For subacute and chronic neck pain, this combination of techniques has shown improvements between pre- and post-treatment in pain and PPTs[12], as well as being as effective as neck mobilization for pain and function improvement.[4] Ultrasound was applied in pulse mode at an intensity of 1 megahertz for ten minutes in the suboccipital region and in the vicinity of the trapezius muscles. TENS was applied with a pulse duration of 250 microseconds at a frequency of 80 Hertz for 20 minutes in the suboccipital region and the trapezius bilaterally. Deep massage was applied at a slow speed for 20 minutes using sliding neutral creams. Massage therapy included gliding and kneading techniques applied over the trapezius (upper, lower, and middle fibers), splenius capitis and levator scapulae muscles, with a therapeutic intention.

Experimental Group

The EG received five treatment sessions of MRT over a two week period.[12] Each maneuver was performed once per session by slow and progressive application of a light force. The entire procedure lasted no more than 45 minutes.[11] The treatment included four basic maneuvers.[27] First, assisted induction of the cervical fascia was performed in the supine position. The therapist suspended the patient's head with one hand under the neck and the other on the parietal region until spontaneous movement was perceived, which was followed to its maximum amplitude (Figure 2). Second, the therapist proceeded to release the myofascial restrictions of the suboccipital region from

the level of the skull by flexing the metacarpophalangeal joints of the index, middle, and ring fingers to raise the atlas toward the ceiling (Figure 3). This position was maintained until the extension parameter was increased, which was detected by a descent of the skull into the therapist's hand, as well as by an elevation of the atlas. To stretch the sternocleidomastoid muscle, the therapist made a smooth rotation of the head of the patient with one hand placed over the occipital region. The other hand was placed on the belly of the sternocleidomastoid muscle, with the thumb at the point of insertion in the mastoid process. One hand then applied a rotational movement and a slight extension of the head, while the other performed a transverse sliding movement on the restriction zone in the muscle. Finally, to lengthen the myofascial structures of the posterior cervical region, the therapist held the patient's head at the occipital area and slowly bent the cervical spine. The other hand held onto the mass of the paraspinal muscles, putting the thumb on one side of the spine and just across the proximal interphalangeal joint of the index finger. While one hand held the head, the other performed a vertical slide downward.

The experimental and comparison groups were treated by a therapist who had 13 years of experience in physical therapy techniques and 9 years of experience in the MRT Technique with a certificate of completed education in this methodology.

Sample Size Calculation

Sample size was calculated with MedCalc Statistical Software version 17.8.6 (MedCalc Software bvba, Ostend, Belgium; 2014). To detect a difference of 2.1 (MDC) on an 11-point NPRS assuming a standard deviation of 2.1,[18] with

a power of 90 percent and confidence level of 95 percent, 22 patients for each group are necessary, making a total of 44 study subjects. To increase the statistical power, 54 subjects were included.

Statistical Analysis

The description of the continuous variables was carried out by the calculation of means and standard deviations (SD). Frequencies and percentages were used for the categorical variables. To test the normal distribution of continuous variables, the Kolmogorov-Smirnov test was used. To test the assumption of homoscedasticity, we used the Levene's test. To test between-group differences, change scores were obtained by subtracting baseline scores from those obtained at the end of treatment and at one-month follow-up.

The Student's t-test was used to analyze the mean differences between independent samples. To calculate the effect size (ES) in the bivariate analysis, the Cohen D, calculated as the difference of means between groups divided by the combined standard deviation, was chosen. The effect size can be interpreted as ES<0.2 reflecting a negligible effect; between ≥0.2 and ≤0.5 reflect a small effect; between 0.5 and ≤ 0.8 reflect a medium effect; and ES>0.8 reflect a large effect.[28] To test differences in clinical success, a Chi-squared test was used. Additionally, number needed to treat (NNT) was calculated. The NNT is the reciprocal of the absolute risk reduction and reflects the number of patients who must be treated to generate one more success or one less failure than would have resulted had all persons been given the comparison treatment.[29]

When any variable presented between-group differences at baseline, the differences in the change scores were analyzed by controlling the effect of said variable in the baseline. For this, Analysis of Covariance (ANCOVA) was used.

The data were analyzed with the statistical package SPSS (Statistical Package for the Social Sciences) version 19.0 for Windows (SPSS Inc., Chicago, IL, USA). We worked with a 95 percent confidence level ($p<0.05$).

RESULTS

Of the 54 subjects selected (28 men and 26 women), 27 were included in the CG (13 men and 14 women), and the other 27 were included in the EG (15 men and 12 women). The patients had pain between 1 to 6 months of evolution, which constituted a mixed sample of subacute-chronic NP. The distribution of men and women between the two groups did not differ significantly (Chi-square= 0.297, p=0.586). Descriptive data of the sample and groups can be found in Table 1. The groups did not differ significantly at baseline (pretest) for most variables, except for left cervical rotation. All subjects completed the assessments in the posttest immediately after treatment and at the follow-up 1 month after completion of treatment.

Regarding the between-group differences in change scores at the end of treatment, most of the differences were in favor of the EG except for flexion, extension, and right side-bending, where there was a small and nonsignificant effect in favor of the CG that could be classified as negligible (Table 2). Differences in favor of the EG were significant on the NPRS, left rotation and in all the PPTs except for the left thoracic point. Effect size was large for suboccipital right PPTs and medium in the rest of the significant outcomes. Success rate in immediate posttest was 40.7% (11 patients) in the CG and 70.1% (20 patients) in the EG. NNT was 3.00 (95% CI = 1.72 to 11.77). When baseline scores were entered into the ANCOVA model, the differences in posttreatment were not statistically significant for left rotation (p = 0.369) but they were for NPRS (p = 0.012).

At one-month follow-up, all differences were in favor of the EG and were significant for pain, neck rotations and PPTs except for the left thoracic point (Table 3). The effect size was large only for the NPRS and medium for the rest of the variables with significant differences. Success rate at one-month follow-up was 63.0% (17 patients) in the CG and 92.6% (25 patients) in the EG. NNT was 3.38 (95% CI = 1.99 to 11.23). When baseline scores were entered into the ANCOVA model, the differences at one-month follow-up were not statistically significant for left rotation ($p = 0.053$) and right rotation ($p=0.108$) but they were significant for NPRS ($p <0.001$).

Finally, no participants reported any adverse effects after intervention.

DISCUSSION

The main finding of the present study was that MRT was more effective than a standard PT Program at improving the NPRS and suboccipital and right trapezius PPTs in patients with NP. In our study we compared two treatment programs. The EG was treated for two weeks with a total of five sessions, which is a number similar to other studies.[11, 12, 30] The CG was treated for another two weeks with a total of 10 sessions.[31] In our study, both groups improved in both the postintervention measurement and at the one-month follow-up, however, the improvement of the EG was greater. Although between-group differences in the pain scores were statistically significant in our study, clinically, the differences cannot be considered relevant because they were less than the MDC of the NPRS. Regarding the importance of the difference between the treatments, in the immediate posttreatment period, 3 patients need to be treated with MRT to obtain clinical success in an additional patient compared to the CG. At one-month follow-up the outcome was similar.

Interest in the effect of MRT on NP is relatively recent. In fact, a recent review of the effect of MRT did not include any studies focused on pain in this body region.[32] However, MRT has been shown to improve fascial slippage and pain perception in patients with NP and back pain when compared to a sham treatment.[13]

Our results differ from those of Rodríguez-Fuentes et al.,[11] who found differences in the ROM centered on rotation and side-bending, but they noticed no differences in pain when they compared MRT to manual therapy. In our study, no differences were found in ROM, but they were found in the perceived pain.

298 We interpret that these different results are due to the different comparisons used
299 in each study. Some studies have found slight differences in pain and function
300 when comparing manipulation or mobilization with physical therapy.[26] We found
301 medium effect sizes when comparing MRT to CG.

302 To measure clinical success, we based ours on previously published
303 criteria.[25, 26] From these criteria, we measured the effect size using the NNT.
304 Under our criteria, the NNT calculation is the most suitable because it is a clinical
305 significance measure that allows us to measure a technique's clinical effects. In
306 our study, three patients should be treated with MRT to generate additional
307 clinical success if all patients had been treated with a standard PT program.
308 These results are better than those obtained with other techniques such as
309 thoracic manipulations (NNT = 5)[33] or multimodal manual therapy (NNT= 2 to
310 11)[34] for NP management.

311 The analysis of TrPs is a relevant issue since they contribute to the
312 symptoms of NP.[20] Regarding the improvement in the PPTs, our results are in
313 agreement with other studies that found an improvement at the suboccipital and
314 trapezius levels.[15, 35] Morasca et al.[35] did not find differences in PPTs in the short
315 term but did in the medium term when MRT was compared to a placebo and a
316 waiting list group. In our study, we did not find any difference in the PPTs of the
317 left trapezius in the immediate posttreatment period, but at the one-month follow-
318 up, the differences were at the limit of statistical significance when EG was
319 compared to CG.

320 The treatment carried out in the CG is based on one of the programs
321 traditionally used in Spanish private practice for the management of NP in past

decades .[36] Although the evidence suggests that therapies such as strain-counter strain, relaxation massage, electroacupuncture and some passive physical modalities (heat, cold, diathermy, hydrotherapy, and ultrasound) should not be used,[37] it is possible that the improvement observed in the comparison group could be the result of the synergy of these techniques. Local biochemical changes seemed to be produced by the massage effects, and these changes might lead to increased neural activity and affect pain perception.[38] Additionally, local biophysical and metabolic effects are attributed to the US.[39] However, the local analgesic effects of other therapies could be potentiated by central inhibition as a TENS effect.[40]

Limitations

In our study there was no control or sham group, so it is not known which part of the improvement of the patients was due to the natural evolution of the disease or the placebo effect. Regarding outcomes, other relevant results were not analyzed, including the effect on quality of life or functions measured with questionnaires, so conclusions cannot be drawn that involve these aspects. As well the therapist was not blinded to the patient groups, so it cannot be assured that the effect of the treatments was not due to the different enthusiasm of the therapist for the experimental or comparison conditions.

Future studies should analyze the effect of MRT on these variables versus groups of non-active therapy or minimal intervention. Alternatively, it is unclear whether there are differences in the trapezius PPTs. Possibly, the sample size is insufficient for analysis of this variable, so future studies could focus on this variable when performing the sample size calculation.

CONCLUSION

In conclusion, the treatment of NP by MRT seems to be more effective than a standard PT program including massage, US, and TENS for reducing pain and PTTs in TrPs on the neck. However, the difference between the two treatment programs could be clinically irrelevant because it is less than the MDC of the NPRS.

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Figure legends.

Figure 1. Flow diagram of the progress through the phases of the study.

Figure 2. Assisted induction of the cervical fascia.

Figure 3. Release to the myofascial restrictions of the suboccipital region.

Table 1. Descriptive data of the sample and treatment groups, and differences in baseline.

	TOTAL	N=54	CG	n=27	EG	n=27	t-Student
	Mean	SD	Mean	SD	Mean	SD	p-value
Height	1.71	0.09	1.71	0.09	1.71	0.09	0.964
Weight	74.83	14.83	75.85	15.69	73.82	14.13	0.618
BMI	25.26	4.31	25.80	4.29	24.71	4.34	0.358
NPRS	6.93	1.08	6.70	1.14	7.15	0.99	0.131
Flexion	50.96	7.66	50.04	7.84	51.89	7.50	0.379
Extension	46.28	10.17	45.44	10.62	47.11	9.83	0.552
Left side-bending	37.44	6.89	37.78	7.15	37.11	6.73	0.726
Right side-bending	42.04	6.18	41.93	7.24	42.15	5.04	0.896
Left Rotation	62.96	9.95	66.44	10.50	59.48	8.15	0.009†
Right Rotation	63.94	9.17	65.89	9.46	62.00	8.61	0.120
Left S PPT	1.20	0.55	1.19	0.48	1.22	0.63	0.827
Right S PPT	1.24	0.57	1.22	0.42	1.26	0.69	0.767
Left T PPT	1.52	0.59	1.46	0.52	1.58	0.66	0.454
Right T PPT	1.58	0.57	1.53	0.51	1.62	0.64	0.533

*p<0.05. †p<0.01. ‡p<0.001. CG: Comparison Group. EG: Experimental Group SD: Standard Deviation. BMI: Body Mass Index. PPT: Pressure pain threshold. S: Sub-occipital. T: Thoracic

Table 2. Between-Group differences in change scores on immediate post-treatment.

	CG Post-treatment		CG Change-Scores		EG Post-treatment		EG Change-Scores		Difference (95% CI)			T Student	Effect Size	
POST-TEST	Mean	SD	**Mean**	**SD**	Mean	SD	**Mean**	**SD**	**Difference**	**Lower**	**Upper**	**p-value**	**D Cohen§**	**ES**
NPRS	2.93	1.24	-3.78	1.50	2.33	0.96	-4.82	0.88	-1.04	-1.71	-0.36	0.003†	0.69	Medium
Flexion	62.15	8.12	12.11	8.41	63.15	7.92	11.26	7.78	-0.85	-5.28	3.57	0.701	-0.10	Negligible
Extension	58.30	7.38	12.85	9.02	58.81	9.27	11.70	7.76	-1.15	-5.74	3.45	0.618	-0.13	Negligible
S-B Left	48.11	7.53	10.33	6.97	47.96	7.00	10.85	6.23	0.52	-3.09	4.13	0.774	0.07	Negligible
S-B Right	48.93	8.32	7.00	7.11	48.63	7.78	6.48	6.96	-0.52	-4.36	3.33	0.788	-0.07	Negligible
Rotation Left	71.78	8.00	5.33	6.56	68.63	9.60	9.15	6.93	3.81	0.13	7.50	0.043*	0.58	Medium
Rotation Right	71.15	6.22	5.26	7.36	70.63	8.54	8.63	5.90	3.37	-0.27	7.01	0.069	0.46	Small
PPT S Left	1.59	0.40	0.41	0.34	1.84	0.62	0.62	0.33	0.21	0.03	0.40	0.021*	0.62	Medium
PPT S Right	1.62	0.39	0.41	0.35	1.99	0.73	0.72	0.36	0.32	0.12	0.51	0.002†	0.89	Large
PPT T Left	1.95	0.55	0.49	0.46	2.21	0.74	0.63	0.39	0.14	-0.09	0.37	0.223	0.30	Small
PPT T Right	1.94	0.55	0.41	0.44	2.35	0.75	0.72	0.49	0.31	0.06	0.56	0.018*	0.70	Medium

*p<0.05. †p<0.01. ‡p<0.001.

CG: Comparison Group; EG: Experimental Group; SD: Standard Deviation; NPRS: Numerical Pain Rating Scale; S-B: Side-Bending; PPT: Pressure Pain Thresholds; S: Sub-occipital; T: Thoracic; CI: Confidence Interval.

§ Negative sign means Effect Size in favour of PT Group.

Table 3. Between-Group differences in change scores at one-month follow-up.

	CG Follow-up		CG Change-Scores		EG Follow-up		EG Change-Scores		Difference (95% CI)			T Student	Effect Size	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Difference	Lower	Upper	p-value	D Cohen	ES
NPRS	2.26	1.77	-4.44	1.60	1.15	0.77	-6.00	1.07	-1.56	-2.30	-0.81	<0.001‡	0.98	Large
Flexion	63.74	9.25	13.70	11.81	67.85	6.54	15.96	6.59	2.26	-2.96	7.48	0.389	0.19	Negligible
Extension	61.26	10.93	15.82	13.53	63.89	9.65	16.78	9.20	0.96	-5.36	7.28	0.761	0.07	Negligible
S-B Left	50.96	9.27	13.19	9.19	54.81	9.94	17.70	9.78	4.52	-0.67	9.70	0.086	0.49	Small
S-B Right	52.78	8.91	10.85	9.75	55.52	6.25	13.37	5.73	2.52	-1.85	6.88	0.252	0.26	Small
Rotation Left	71.52	8.01	5.07	9.60	71.93	8.19	12.44	6.39	7.37	2.92	11.82	0.002†	0.77	Medium
Rotation Right	72.37	6.46	6.48	9.23	73.63	7.64	11.63	6.96	5.15	0.68	9.61	0.025*	0.56	Medium
PPT S Left	1.86	0.56	0.68	0.55	2.24	0.69	1.02	0.40	0.34	0.08	0.61	0.012*	0.62	Medium
PPT S Right	1.95	0.60	0.73	0.53	2.28	0.68	1.02	0.38	0.29	0.04	0.54	0.026*	0.55	Medium
PPT T Left	2.18	0.69	0.72	0.62	2.59	0.89	1.00	0.49	0.29	-0.02	0.59	0.066	0.45	Small
PPT T Right	2.26	0.67	0.73	0.64	2.70	0.77	1.08	0.51	0.35	0.03	0.66	0.031*	0.55	Medium

*p<0.05. †p<0.01. ‡p<0.001.

CG: Comparison Group; EG: Experimental Group; SD: Standard Deviation; NPRS: Numerical Pain Rating Scale; S-B: Side-Bending; PPT: Pressure Pain Thresholds; S: Sub-occipital; T: Thoracic; CI: Confidence Interval.