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Additional Information

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32 ABSTRACT

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- 33 Background: The purpose of this study was to evaluate the effect of low-frequency self-administered
- vibration therapy into myofascial trigger points in the upper trapezius and levator scapulae on patients
- with chronic non-specific neck pain.
- 36 Methods: Twenty-eight patients with chronic non-specific neck pain were randomly assigned into a
- 37 vibration group, receiving 10 self-applied sessions of vibration therapy in the upper trapezius and levator
- 38 scapulae trigger points; or a control group, receiving no intervention. Self-reported neck pain and
- disability (Neck Disability Index) and pressure pain threshold were assessed at baseline and after the first,
- 40 fifth and 10th treatment sessions.
- 41 Findings: Significant differences were found in the vibration group when compared to the control group
- 42 after the treatment period: the vibration group reached lower Neck Disability Index scores (F=4.74, P=.033,
- 43 η^2 =0.07) and greater pressure pain threshold values (F=7.56, P=.01, η^2 =0.10) than the control group. The
- vibration group reported a significant reduction in Neck Disability Index scores (χ2=19,35, P=.00, Kendall's
- 45 W=0.28) and an increase in pressure pain threshold (χ 2=87,10, P=.00, Kendall's W=0.73) between the
- 46 assessment times over the course of the treatment. The mean increase in pressure pain threshold in the
- 47 vibration group after the 10 sessions was 8.54 N/cm2, while the mean reduction in Neck Disability Index
- 48 scores was 4.53 points.
- 49 Interpretation: Vibration therapy may be an effective intervention for reducing self-reported neck pain
- 50 and disability and pressure pain sensitivity in patients with chronic non-specific neck pain. This tool
- 51 could be recommended for people with non-specific neck pain.

52 KEYWORDS

- Neck pain; Pain threshold; Rehabilitation; Trigger points; Vibration.
- 54 ABBREVIATIONS
- 55 MTrPs: Myofascial trigger points
- VT: Vibration therapy
- 57 DOMS: Delayed onset muscle soreness
- 58 PPT: Pressure pain threshold
- 59 CG: Control group

NDI: Neck Disability Index

VG: Vibration therapy group

1. INTRODUCTION

Myofascial pain syndrome is defined as a cluster of signs and symptoms associated with active and latent myofascial trigger points (MTrPs). An MTrP is a hyperirritable focus within a taut band of skeletal muscle that is painful on compression and which, when stimulated, can evoke a characteristic pattern of referred pain and related autonomic phenomena [1].

MTrPs are a common source of regional pain in patients presenting with musculoskeletal pain. Indeed, the prevalence of MTrPs has been found to be up to 85% of the general population [2]. Sleeping posture is related to musculoskeletal disorders of the shoulder or neck [3]. Moreover, it is known that sleep disturbances are frequent among patients with neck pain [4, 5]. Specifically, poor cervical posture during sleep, which is believed to increase biomechanical stresses on the structure of the cervical spine, can produce cervical pain and stiffness, headache, and scapular or arm pain, resulting in low-quality sleep [3]. From a clinical point of view, MTrPs may be either active or latent. Active and latent MTrPs have similar physical manifestations, except that latent MTrPs do not elicit spontaneous symptoms and the local and referred pain reproduced by stimulating latent MTrPs is not familiar to the patient [6]. Active, but not latent, MTrPs have been recognized as a common cause of local musculoskeletal pain and dysfunction [6], but recent research has emphasized the importance of latent MTrPs both in diagnosis and treatment [7]. In addition, elimination of latent MTrPs is accompanied by normalization of impaired motor activation patterns [8].

Several treatment strategies have been suggested to treat MTrPs, ranging from conservative techniques such as massage [9], pressure release [10], ischemic compression [11, 12], and spray and stretch [13], to invasive interventions such as dry needling [12-15] or injections [16]. Within massage techniques, Swedish massage is probably the most commonly used among physical therapists. Massage has been claimed to promote relaxation and decrease tissue adhesion, increase intramuscular circulation [17, 18] and decrease neuromuscular excitability [17]. In addition, massage has been found to reduce myalgia symptoms by approximately 25% to 50% [19] and have preventive effects [20]. In fact, vibration massage applied for five minutes followed by kneading manoeuvres was the treatment proposed by Lindemann et al. [21] in the 1970s to reduce myogelosis, an expression synonymous with MTrPs. Despite

the extensive application of massage therapies, clinical trials investigating their efficacy in subjects with MTrPs are scarce [22].

In the last two decades, the use of mechanical vibration for rehabilitation purposes has attracted the interest of researchers [23, 24]. Vibration therapy (VT) is used to stimulate edema absorption, improve blood flow, alleviate wound healing and for its anti-inflammatory and antifibrous effects [25, 26]. In addition, the effects of VT on pain relief have also been widely demonstrated. In particular, this technique has been shown to be beneficial for patients with fibromyalgia [22], acute and chronic musculoskeletal pain [27], delayed onset muscle soreness (DOMS) [24, 28], and myotendinous injuries that involve MTrPs [29]. Although previous studies have examined the use of massage techniques on patients with MTrPs [30, 31], to our knowledge there are no studies which have evaluated the effectiveness of VT on MTrPs.

Self-management strategies are considered essential to the management of persistent musculoskeletal disorders such as neck pain [32]. Effective self-management is based on skills to encourage patients to actively participate in, and take responsibility for, common or persistent conditions [33]. These strategies may contribute to the long-term management of these conditions [34], improve adherence [35] and promote a healthy lifestyle in the patients.

The aim of this pilot study was therefore to investigate the efficacy of low-frequency self-administered VT for neck pain, disability and pressure pain thresholds (PPT) in patients with non-specific neck pain and MTrPs. We hypothesized that patients receiving VT would report lower levels of perceived neck pain and disability and present higher PPTs after receiving VT when compared with a no-treatment control group (CG).

2. METHODS

2.1. Participants

Subjects between 18 and 45 years old with a history of chronic non-specific neck pain were invited to participate in this study. Recruitment was performed by advertisement by the University of Valencia (Spain), from September 2014 to December 2019. Besides having a history of neck pain lasting three months or more over the previous year, subjects were required to have a Neck Disability Index (NDI) score of $\geq 5/50$ [36] and have active or latent MTrPs in the upper trapezius or levator scapulae muscles. Both active and latent MTrPs were considered, as latent MTrPs have been associated with the

development of sensorimotor dysfunction and can contribute to different chronic musculoskeletal pain disorders [19, 37]. Subjects were excluded if they had had previous cervical spine surgery, cervical radiculopathy as diagnosed by their primary care physician, a severe systemic disease (e.g. neurological disorders, inflammatory diseases), diagnosis of fibromyalgia, or other widespread musculoskeletal pain syndromes (e.g. chronic fatigue syndrome). Patients were also excluded if they had been regularly treated with analgesic medication or physiotherapy within the previous four weeks.

Approval for the study was granted by the Institutional Ethics Committee (University of Valencia, Spain), and the procedures were conducted according to the Declaration of Helsinki. The study was registered on the clinical trials database with number NCT02393521. Written informed consent was provided before participation.

2.2. Study Design

This study was a randomized controlled clinical trial, with parallel groups and a blinded assessor. It was undertaken in accordance with the CONSORT statement. Patients were randomly allocated to the treatments by a non-stratified block randomization with randomly varying block lengths. They were randomized into two groups: a VT group (VG) and a control group (CG), receiving no treatment.

Randomization was conducted by an external clinical assistant using a random number generator in the Statgraphics Centurion XVI software (StatPoint Technologies, Inc. Warrenton, USA). On this basis, the assistant prepared sealed, sequentially numbered envelopes containing the treatment assignments. After baseline assessment, the study physician opened the lowest numbered envelope to reveal that patient's assignment

The outcome measurements for this study were patient-reported levels of pain and disability rated by the NDI and PPT at active/latent MTrPs of the upper trapezius, and levator scapulae. They were recorded bilaterally at four assessment times: at baseline (T0), after the first (T1) and fifth (T5) sessions of treatment and after 10th and final session (T10).

2.3. Procedure

Demographic and anthropometric data of each patient were recorded. Subjects who met the study requirements completed the NDI questionnaire and were then examined to detect the presence of active/latent MTrPs in the upper trapezius and levator scapulae, and PPTs were measured at these points. The presence of MTrPs was determined using the diagnostic criteria described by Simons et al. [1]: 1) presence of a palpable taut band in the muscle; 2) presence of a hypersensitive tender spot in the taut

band; 3) palpable or visible local twitch response with snapping palpation of the taut band. Moreover, participants were evaluated to determine whether the MTrPs were active or latent, with a local compression in order to stimulate the MTrPs [38]. Active MTrPs were identified if stimulation reproduced any symptom experienced by the patient, either partially or completely, whereby the symptom was recognized as a familiar experience by the patient, even though it may not be present at the moment of the examination. Latent MTrPs were determined when stimulation did not reproduce any symptom experienced by the participant and he/she did not recognize the elicited symptom as familiar.

Patients in the VG received 10 self-applied sessions of VT. Subjects in the CG did not receive VT. They were assessed at the same points in time as the VG. Data collection was performed at the University of Valencia.

Neck Disability Index (NDI)

The NDI questionnaire is a clinical tool designed to assess perceived pain and disability in patients with neck pain [36, 39]. It consists of a total of 10 items, each with six possible choices representing everyday activities. The NDI is a valid, reliable, and sensitive tool for measuring changes in pain and disability in patients with neck pain [39]. This study used the Spanish version of the NDI validated by Andrade et al [40]. NDI scores were recorded only at T0, T5 and T10.

Pressure pain threshold (PPT) measurement

PPT measurement was conducted bilaterally for four MTrPs in each subject: active or latent MTrPs of the upper trapezius (MTrP₂) and levator scapulae (attachment MTrP) according to Simons et al. [1] (Figure 1). PPTs were measured with an analogue algometer (Force Dial model FDK 20, Wagner Instruments, Greenwich, CT, USA) with a surface area at the round tip of 1 cm². For this purpose, participants were placed in a sitting position, with their arms resting on the armrests. The algometer tip was applied perpendicularly to the skin at a rate of 0.98 N/cm² per second. This measurement was repeated three times at each point with a 30-second rest period between each measurement, and the mean of the three trials was calculated and used for further analysis [41].



Figure 1. PPT assessment and upper trapezius (A) and levator scapulae (B) MTrP locations.

A familiarization phase preceded the formal measurements, where participants were instructed on the procedure. Subjects practiced the procedure with the examiner at a remote site (forearm). Subjects were instructed to indicate the moment when pressure changed to pain, which corresponds to the definition of the PPT. They were told repeatedly that recording the first sensation of pain was the aim and not tolerance to pressure [41]. The same researcher performed the PPT measurements on all subjects and was blinded to the group assignment of the subject. Participants were not informed of their scores to prevent subject bias from influencing the results.

Pressure algometry is a valid and reliable method for PPT measurement in both healthy [42] and symptomatic subjects [43, 44], with studies showing good repeatability of measurements on the neck muscles [44]. The interrater and one-week test-retest reliability of pressure algometry in the neck has been demonstrated recently (intraclass correlation coefficient (ICC): .75-.95) [45].

Vibration therapy

VT was applied through a technical device designed for self-application in the home (Shindo®, Colchones Delax SL, L'Alcúdia, Spain). The vibration device consisted of 10 micro-electric motors, each of them equipped with an eccentric mass in order to provide an oscillatory pulse (Figure 2 left). Although the motors worked at 80 Hz, they were connected during 12 ms out of every 20 ms, thus providing a perceived frequency of 35-50 Hz, corresponding to the commonly used values used for treatment or prevention of DOMS [24, 28, 46] and to improve muscle relaxation [47]. To avoid friction with the user or the cover, the motors were enclosed in a plastic capsule with rounded surfaces. These capsules were placed inside a 32 kg high-density polyurethane mattress, with 2 cm of foam between the patient's body and the capsule. During the VT, only the cervical region (two motors) was switched on (Figure 2 right).

Subjects were able to select, through a wireless controller (Figure 2 left), one of four amplitudes of vibration (between 7 and 10G). The objective of this was to allow patient control over the intensity of the vibration in order to ensure their comfort with the treatment. The following instructions were provided to the subject: "Choose a level of intensity that is comfortable for you. You should perceive a gentle vibration sensation on your cervical area".

Subjects receiving VT (VG) were instructed to self-administer this therapy for 10 sessions, one session per day, lying on their mattress at home in the supine position for 15 minutes. [28] Participants were requested not to use any other specific treatments for their neck pain, although their usual medication was not withdrawn.

Control group

Subjects in the CG did not receive a comparable treatment, as no treatment was applied to them. They were instructed to lie on a conventional mattress without vibration effect at home, in the supine position, during the same time frame as the VG (i.e.: 15 minutes once a day during 10 days). Participants were requested not to use any other specific treatments for their neck pain, although their usual medication was not withdrawn.



Figure 2. (Left): motors used in the vibration device. (Right): wireless controller used by the subjects and location of the micro-electric motors.

2.4. Data analysis.

First, a one-way ANOVA with significance level of differences set at p<.05 was conducted to evaluate if initial differences appeared between resulting groups after the randomized assignment. The

total PPT and NDI were selected as the dependent variables and the group as the factor including two levels: VG and CG.

In order to compare the treatment evolution between VG and CG, multiple univariate ANOVA were conducted with significance levels of differences set at p<.05. A one-way ANOVA was performed at each step of the treatment (T0, T1, T5, and T10) with total PPT and NDI as dependent variables and with resulting groups as the factor. The mean values and 95% CI were also calculated. The η^2 value was calculated to measure the effect size.

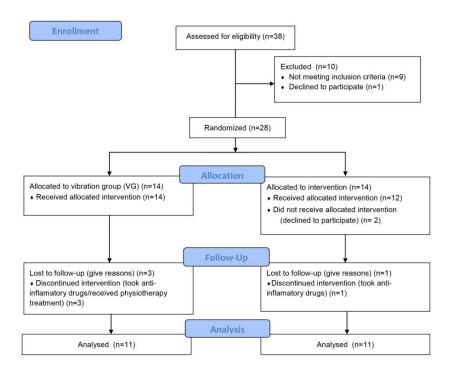
Finally, to analyse the evolution within subjects belonging to the VG, Friedman's ANOVA analysis was conducted. Total PPT for T0, T1, T5 and T10 and DNI for T0, T5 and T10 were compared with significance levels of differences set at p<.05. Post hoc Wilcoxon test were performed for each pair of variables with a Bonferroni adjustment (multiplying p-values from the Wilcoxon tests by the number of Wilcoxon tests being carried out in each case) to assure confidence level correction and identify between which pair of levels of the factor variable the differences appeared. Kendall's W was calculated to measure the effect size.

All data analyses were performed using the SPSS 16 statistical application for Windows.

3. RESULTS

Thirty-eight subjects were screened for possible eligibility criteria, and 22 subjects successfully completed the study protocol (VG n=11, CG n=11). Figure 3 shows a flow diagram representing the subject process of recruitment and dropouts. The baseline characteristics of the final sample are summarized in Table 1. No adverse effects were reported by the participants from the vibration group (VG).

CONSORT 2010 Flow Diagram



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Figure 3. CONSORT flow diagram of subject recruitment throughout the course of the study.

values than CG. Both figures also show the mean values, 95% CI, F ratio, sig. (p values), and η^2 values.

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Neck Disability Index (NDI) and pressure pain threshold (PPT)

There were no differences in NDI or in total PPT between CG and VG at T0, as shown in
Figures 4 and 5. Moreover, Figure 4 shows the results of the ANOVAs carried out to analyse the
evolution of NDI differences between CG and VG along the treatment, showing significant differences
between groups in T10, in which VG reached lower values than CG. Likewise, Figure 5 shows the results
of the ANOVAs carried out to analyse the evolution of total PPT differences between CG and VG along
the treatment, showing significant differences again between groups in T10, in which VG reached greater

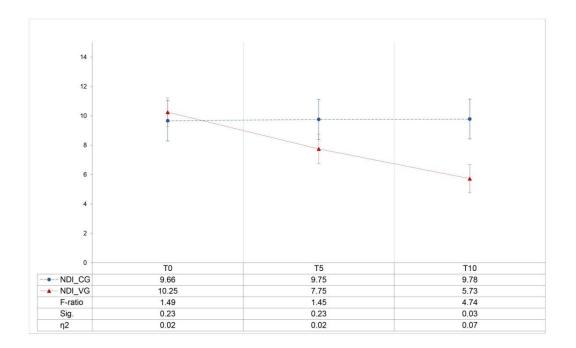


Figure 4. Comparison of NDI between CG and VG along the treatment.

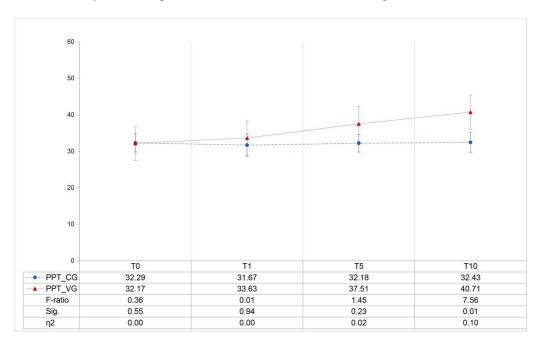


Figure 5. Comparison of total PPT (N/cm²) between CG and VG along the treatment.

Regarding analysis among subjects belonging to the VG group, Friedman's ANOVAs carried out for total PPT and NDI showed significant differences between steps of the treatment. χ^2 values, significance and Kendall's W values are shown in Table 2.

Kendall's W value for total PPT indicates a strong effect size, whereas it is moderate for NDI [48].

Post hoc Wilcoxon multiple comparison tests results are shown in Table 3. As shown in Table 3, there are significant differences between all pairs of steps for PPT, with increasing values along the treatment (as the number of sessions increased). Similarly, for NDI there were significant differences between all pairs of steps, with decreasing values along the treatment (as the number of sessions increased).

4. DISCUSSION

To our knowledge, this is the first randomized controlled study investigating the effect of VT on pressure pain sensitivity at cervical MTrPs and self-reported neck pain and disability in people with chronic non-specific neck pain. In this study, patients treated with self-applied mechanical VT showed a significant reduction in neck pain and disability and an increase in PPT at cervical MTrPs, compared to a CG, which did not receive a comparable treatment, while not receiving any intervention. Interestingly, improvements in pressure pain sensitivity and in neck pain and disability with VT increased as treatment progressed. Higher improvements in PPT and in NDI values were observed at the end of 10 sessions of VT.

Regarding the NDI results over the course of treatment, the mean reduction in NDI scores in the vibration group was 4.52 points between T10 and T0 (i.e., end of intervention) and 2.50 points between T5 and T0 (i.e., half of intervention period). The mean improvement expressed as a percentage of the initial NDI value was 44.15% and 24.39% respectively. Hence, the NDI score at the midpoint of the intervention period is well above the 10% level stated by MacDermid et al. [49] as the minimal detectable change, which demonstrates the importance of our results. The improvement observed in the NDI in this study is comparable to the improvements reported when other conservative modalities of treatment involving some form of vibration, such as cupping [50] or massage [51], were employed in people with chronic non-specific neck pain. This could suggest that vibration methods, regardless of the specific modality, may be effective for the treatment of pain and disability in patients with chronic non-specific neck pain. Further studies with larger neck pain populations should explore these promising new avenues of treatment.

Treatment effects were also observed for VT on PPT. The increase in PPT with VT was observed from the very first treatment in the VG subjects. After the first session, the increase at cervical

MTrPs was 1.46 N/cm². After five sessions, the increase reached 5.34 N/cm², and after 10 sessions 8.54 N/cm². Except for the first value, these scores exceed those proposed by Walton et al. [52] for the minimum detectable change. This means that only the increase observed between T0 and T1 could be attributed to the standard error of measurement. Furthermore, higher PPT differences were observed in the VG when compared to the CG at the end of the intervention period (1.96 N/cm² of difference at T1, 5.33 N/cm² at T5 and 8.28 N/cm² at T0). Improvements achieved with VT in the VG occurred in a continuous fashion throughout the treatment period, with stronger effects as the treatment progressed. This behaviour could be attributable to the possible cumulative effects of the VT sessions [53]. Nevertheless, caution should be taken when interpreting the differences obtained between VG and CG because, although they could be due to the specific effects of the VT, they could also be caused by 'non-specific' factors, such as placebo or patient expectations [54]. In clinical research, it is very difficult to control for all possible confounding variables, and, once these 'non-specific' factors are stripped away [54, 55], any intervention as a stand-alone treatment is of questionable efficacy [56].

Only short-term changes in PPT at MTrPs have been reported by previous studies [10, 50]. The linear trend on PPT as observed in our results seems to indicate that PPT improvement would continue to increase with a greater number of sessions. Further studies are necessary to confirm these preliminary results in order to evaluate the long-term effects of VT on PPT.

Positive effects on PPT at cervical MTrPs have been previously reported in the literature when applying different modalities of treatment. Therapies such as ischemic compression [10, 12], cupping [50], dry needling [12, 15], or spinal thrust manipulation [57] have demonstrated positive effects on PPT at MTrPs located in the cervical region. However, other self-management strategies such as therapeutic exercise have also been identified as beneficial for people with neck pain. According to the results of a recent systematic review [58], the use of specific strengthening exercises, whether isolated or combined with endurance or stretching exercises as a part of routine practice, have been shown to be an effective approach for people suffering from neck pain.

Although the underlying mechanisms of pain relief were not specifically addressed in this study, some discussion is warranted. VT may have exerted its effects by local mechanisms, such as increasing blood flow [26, 46] or normalizing the length of sarcomeres [11], which are two proposed mechanisms of action for interventions in MTrPs [11]. Besides, mechanical stimulation resulting from the application of VT may have activated A β fibres and consequently led to a segmental inhibition at the spinal cord level

via the gate control mechanism. Based on gate control hypothesis [59], it could be inferred that vibration strongly impacts upon afferent discharges from fast adapting mechanoreceptors and muscle spindles and hence acts as an effective pain reliever. As VT is a painless procedure, descending pain modulation mechanisms should not, in theory, come into action, although their effects should not be ignored. Another possible explanation with regard to pain relief mechanisms may be found in mechanotransduction theories. It is accepted that the mechanism of action of vibration treatment involves some form of mechanotransduction, which refers to the conversion of a mechanical force into a cellular and molecular response [60]. These cellular responses, in turn, promote structural change through tissue repair and remodelling [61]. However, although the adaptive ability of tissues in response to mechanical stimuli has long been established, the precise mechanisms underlying the response at the cellular and molecular levels have only recently begun to be unravelled identified and remain to be fully elucidated [60]. Muscle tissue is highly responsive to changes in functional demands through the modulation of load-induced pathways [61]. Nevertheless, the clinical application of mechanotherapy for muscle injury is based on animal studies [62], so conclusions should be reached with caution.

It is known that MTrPs in the neck and shoulder muscles may play an important role in the genesis of mechanical neck pain, or contribute to pain symptoms in individuals with mechanical neck pain [63]. Moreover, persistence of MTrPs in neck muscles can result in headache, dizziness, limited range of motion in the neck, muscle weakness, abnormal sensation, autonomic dysfunction, and disability [64]. Treatment of myofascial pain is based on inactivating the MTrPs. The most common conservative interventions for this purpose are ischemic compression and dry needling [65, 66]. However, to the best of our knowledge, VT has never been employed as a treatment alternative for MTrPs. Consequently, our results are not comparable with previous studies. Nevertheless, VT was found to be effective for treatment and prevention of DOMS [24, 28, 67]. An important overlap between the physiopathological mechanisms of eccentric contraction, which induces DOMS, and the development of MTrPs has been suggested [68], but future studies should compare the effectiveness of VT in people with DOMS and MTrPs to see if effects are comparable.

4.1. Limitations

There are some limitations to our study that should be acknowledged. First of all, the obtained findings may be somewhat limited by the sample size. While the number of subjects allowed finding significant differences between VG and CG, and within the VG along the treatment, the sample size effect is moderate in one-way ANOVAs performed at T10 (0.04 < $\eta^2 \le 0.36$). This limited sample size could reduce the generalizability of our findings to the general population. A greater sample size, which increases variability, could strengthen the magnitude of effect, as well as enable the comparison of results between different muscles or subject characteristics, such as gender or age. Further studies including more patients are therefore recommended. Secondly, since non-specific effects were not strictly controlled for this study, they should not be overlooked. Future studies should take into account confounding factors such as placebo, patient expectations or possible central sensitization patterns. Finally, as only the trapezius and levator scapulae muscles were considered in this study, our findings cannot be extrapolated to other locations. Future studies should further explore the effect of VT in other body regions/muscles. More research is also needed to determine long-term effects of VT.

5. CONCLUSIONS

This pilot study shows that 10 sessions of self-administered VT using 35-50 Hz frequency ranges improved pressure pain sensitivity over trapezius and levator scapulae MTrPs and self-reported neck pain and disability in patients with chronic non-specific neck pain. Further large population studies are needed to determine the true efficacy of VT. Thus, self-applied VT may be an effective intervention for releasing non-specific neck pain and this tool could be used as part of a comprehensive physical therapy programme.

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381		
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Table 1. Baseline demographic and clinical characteristics of trial groups

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Variable		VG values*	CG values*
		(n=11)	(n=11)
Age (years	s)	34.57 (6.21)	31.36 (10.79)
Sex (n mal	Sex (n male/n female)		3/8
NDI (0-50	NDI (0-50)		7.5 (4.58)
PPT	trapezius painful side	32.65 (16.59)	32.23 (9.92)
(N/cm ²)	trapezius non-painful side	30.00 (13.80)	29.09 (5.56)
	levator scapulae painful side	38.17 (18.60)	34.80 (10.57)
	levator scapulae non-painful side	36.40 (16.77)	32.44 (8.70)

^{*}Values are mean (SD) or as otherwise indicated.

Table 2. χ^2 values, significance and Kendall's W values for Friedman's ANOVAs

	NDI	Total PPT (N/cm ²)	
χ^2	19.35	87.10	
Sig.	0.000	0.000	
Kendall's W	0.28	0.73	

NDI		Total PPT (N/cm ²)			
Treatment Step		Z value	Treatment Step		Z value
(I)	(J)	(I) – (J)	(I)	(J)	(I) – (J)
T10	T0	-4.735***	T10	ТО	-5.425***
	T5	-2.744***		T1	-5.055***
T5	Т0	-2.218**		T5	-3.455***
			T5	Т0	-5.174***
				T1	-5.132***
			T1	Т0	-3.399***

*** p < 0.001. ** p < 0.05.