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A randomized clinical trial

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# Short-term effects of manipulative treatment versus a therapeutic home exercise protocol for chronic cervical pain: A randomized clinical trial

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#### Abstract.

**BACKGROUND:** While both manipulative treatment and physical exercises are used to treat cervical pain, it remains unclear which is most effective.

**OBJECTIVE:** To compare the short-term effect of high-velocity, low-amplitude manipulation techniques (MT) with those of home-exercise (HE) with stretching and low intensity (10% of max) isometric contractions on pain and function.

**METHODS:** Single-blind randomized clinical trial was performed. A total of 27 asymptomatic subjects were randomly assigned to 2 groups: manipulation techniques (VT, n = 13) and home exercise (HE, n = 14). The visual analogue scale (VAS); neck disability index (NDI); pressure pain bresholds; cervical spine range of motion and electromyography during the cranio-cervical flexion test was measured before and one week after the intervention.

**RESULTS:** After the interven ion, both groups showed improved (P < 0.05) NDI and VAS scores and flexion in both rotation ranges compared with the precintervention values. For the NDI, pain intensity, and neck flexion, the effects sizes were large; for the majority of the other measurements, the effect sizes were small to moderate. The MT group showed significantly better results than the HE group for 2 out of 17 tests.

CONCLUSIONS: Both interventions improved function and pain after one week, with only marginal between-group differences in favor of MT.

Keywords: Spinal manipulation, neck pain, cervical vertebrae, thoracic vertebrae, electromyography

#### 1. Introduction

\*Corresponding author: Mikel Izquierdo, Department of Health Sciences, Public University of Navarra (Navarra), Spain. Campus of Tudela Av. de Tarazona s/n. 31500 Tudela (Navarra), Spain. Tel.: +34 948 417876; E-mail: mikel.izquierdo@gmail.com. Neck pain is defined as pain experienced from the base of the skull (the occiput) to the upper part of the back and extending laterally to the outer and superior bounds of the shoulder blade (scapula) [1]. Neck pain

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is one of the most prevalent complaints in the general population and is a major cause of disability [2]. In the United States of America, neck pain is the third most common chronic pain condition [3], and its prevalence is higher among young female adults [4]. In the general population, the prevalence has been reported to be greater than 70% [5], while in young adults, the prevalence of neck pain is reported to be between 12 and 34% [6]. It is important to consider the public health and financial implications of neck pain as neck pain patients use the health care system twice as often as the rest of the population [1].

A wide variety of treatment protocols for neck pain are available. However, the most effective management remains an area of debate. Manipulation techniques (MT) and home exercises are commonly used to manage neck pain, and spinal manipulative therapy plus home exercise and advice have yielded better clinical outcomes and lower total societal costs compared with other treatments [7]. In the literature, at least one study has found that a multi-segmental approach to spinal manipulation improved neck pain more than articular manipulation alone [8]. The biomechanical relationship between the TMJ and the cervical complex and the most recent research results recommend the inclusion of that segment in the management of neck pain [9–12]. Considering this findings, in our study manipulations were performed on the upper the acic spine, the cervical spine and the temporomancibular joint (TMJ).

There are different exercise protocclo that can be performed to reduce neck pain, a high-quality randomized clinical trial found that at intervention consisting of several elements, including strength training and stretching, produced results that were superior to those of an intervention that focused mostly on stretching [13], for this reason, the studied protocol included the performance of specific cervical flexor exercises, stretching, isometric exercises, general mobilizations and cranio-cervical flexion endurance exercises [14–18]. In the present study, we did not include nonspecific aerobic exercise because although some authors have found an association between such exercise and a moderate decrease in pain [19], this improvement was not as important because it could be achieved through analytical strength exercise of the muscles involved in neck pain [20].

In our study, young adult women with chronic neck pain who volunteered to participate were included, both because they comprise the most common population with neck pain [4] and because compared with elderly people, young people have shown lower levels of sternocleidomastoid (SCM) activity in the cranio-cervical flexion test (CCFT) [21]. This test relates the activation of superficial neck flexors during the CCFT with neck pain [22].

There is lack of evidence to support any conclusions regarding the effectiveness of MT versus HE for relieving mechanical neck pain. Therefore, this study will add to the growing body of knowledge regarding whether these two techniques yield comparable outcomes or one technique is superior to the other and which should be the therapy of choice. This study was performed to compare the short-term effects of an MT protocol and an HE protocol on the neck disability index (NDI), the visual analogue scale (VAS), pressure pain thresholds (PPT), coval spine ROM and EMG activation of the sternogle domastoid muscle (SCM) during the cranio-(ervical flexion test (CCFT) in young adult women with chaonic neck pain.

#### 2. Nethods

### 2. Study design

A single-blind randomized clinical trial was performed. One research spinal physical therapist registered in Spain conducted patient recruitment and screening at the Osteopathic Clinic and the Sports Medicine Investigation Center of Pamplona. The study was performed in accordance with the Declaration of Helsinki (2000) and was approved by the local office for Medical Research Ethics Committee of The Public University of Navarra. A written consent form was signed by the participants, and the procedure was explained by the investigator. No formal sample size calculation was performed.

#### 2.2. Participants

Social networks and word-of-mouth were used to recruit twenty-seven women with chronic idiopathic neck pain. The participants were enrolled between April and August 2016 and were randomly allocated to either the manipulation group (MT, n = 13) group or the home exercise group (HE, n = 14) (Fig. 1).

Women were included if they were between 18 and 50 years old with a history of neck pain for 3 months during the last year and a pain intensity at rest in the week before the study of 30/100 on a VAS and somatic dysfunction in temporo-mandibular joint, cervi-

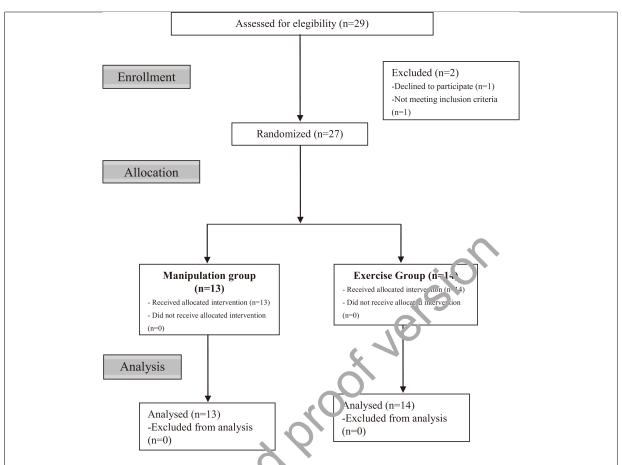


Fig. 1. Flow of participants through the study.

cal spine and upper thoracic spine. The exclusion criteria were any type of cranio-cervical traima during the last two years, including whiplast, pain radiating to the limbs; neurological alterations in the upper limbs; neurological alterations of the testral nervous system; diagnosed vertebral discinium, degenerative, rheumatologic and/or inflammatory pathologies; pregnancy; previous cervical spine surgery; psychiatric pathologies; spine fractures; dislocation; or positive vertebral artery test [18]. The risks were minimized by ruling out contraindications to the testing protocols via a health history and a thorough physical examination prior to the manipulation session.

#### 2.3. Procedure

The individuals who met the inclusion criteria were randomly allocated to the MT group or the HT group using a computer-generated method (www.randomizer. org) without replacement. The allocation was conducted by the primary investigator prior to the base-

line assessment. At each visit, after entering informed consent was given and prior to the start of data collection, an external researcher who was blinded to the study researchers opened the two sealed envelopes and put two index cards inside them, and the participants choose one of them. In this manner, the risk of bias was reduced, and randomization was ensured.

#### 2.4. Data collection and outcome measures

A physical therapist with five years of experience in osteopathic medicine and ten in manual therapies performed the measurement protocol. Each group followed the same measurement protocol. The order of assessments was NDI, VAS at rest, CROM, PPT and EMG during the CCFT before the intervention and one week later.

#### 2.4.1. Neck disability index

This questionnaire evaluates pain intensity, personal care, lifting weights, reading, headache, concentration,

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hard work, driving, sleep and leisure activities [23]. A Spanish version of the NDI validated by Andrade et al. was used [24].

#### 2.4.2. VAS at rest

Neck pain at rest was measured using a VAS both before and one week post intervention. The patient placed a vertical mark on a continuous 10-cm line to indicate her pain levels, ranging from no pain (0) to the worst pain possible [10]. The reliability and validity of the VAS as a measure of pain has been established previously [25,26].

#### 2.4.3. Cervical spine ROM

All of the patients were evaluated for cervical mobility using a CROM goniometer (Performance Attainment Associates, St. Paul, MN, USA). This device has been validated in several studies and offers a moderate intra-examiner intraclass correlation coefficient (> 0.69) and a good inter-examiner intraclass correlation coefficient (> 0.75) [27,28]. The CROM goniometer has three inclinometers whose scales range from two to two degrees. These inclinometers are attached to a frame similar to eyeglasses. The CROM device was mounted over the subject's nose bridge and ears and secured to the head with a strap. The frontal and lateral gravity-dependent inclinometers measured side bending and flexion/extension, respectively... hile a third, magnetic-dependent inclinometer required he use of a magnetic necklace to measure rotation. At the start of the measurement, the participants were seated and relaxed with their feet flat on the floor their knees and ankles at 90° of flexion, and the hands supported on their thighs. The researcher instructed each subject to move her head correctly of the test. The measurement protocol study included active cervical ROM flexion, extension, right side bending, left side bending, right rotation and left rotation. Three consecutive measurements were obtained, and the mean of these 3 trials was used for data analysis.

#### 2.4.4. Pressure pain thresholds (PPT)

The pressure pain threshold is defined as the minimal amount of pressure at which the sensation of pressure changes to a sensation of pain [29]. A mechanical pressure algometer (Force Dial FDK 20, Wagner Instruments, Greenwich, CT, USA) was used in this study. This device consists of a round metal disk (area, 1 cm<sup>2</sup>) attached to a pressure (force) gauge. The gauge displays values in kilograms. Because the surface of the device is 1 cm<sup>2</sup>, the readings are expressed in kilo-

grams per square centimeter. The range of the algometer is 0 to 10 kg in 0.1 kg increments. Previous articles have reported good inter-examiner reliability with a mean intra-class correlation coefficient (ICC) of 0.75; furthermore, intra-examiner reproducibility was excellent (mean ICC = 0.84) [30–32].

Before the PPT measurement, the patients were instructed to say "stop" when the sensation changed from pressure to pain. The PPT was measured posterolaterally, between the lower border of the occiput and the horizontal level of the spinous process of C2, over the C5/6 zygapophyseal joint, and the middle of the front edge of the upper trapezius fibers). We also used a trigger point within the gluteus medius muscle as a regional control point, given is regmental distance from the manipulated segment [52]. The PPT was assessed on the most painful side indicated by the patient. When both sides were reported as equally painful, the right side was selected. Three measurements were recorded for each PPT and the mean was used for the statistical analyses

## 2.4.5 Measurement of the efficiency of the cervical deep flexor muscles (cranio-cervical flexion test)

An EMG-USB Multichannel Bioelectrical Amplifier (Bioelecttronica, Torino, Italy) device, which displayed information in real time and stored it on a personal computer, was used. The surface EMG was recorded with 24-mm-diameter round adhesive bipolar connector electrodes (Spes Medica, Battipaglia, Italy). The participant's skin was cleaned with water before electrode placement.

The sEMG signals were recorded at a sample rate of 2048 Hz and were post-processed offline using MAT-LAB (Mathworks, Inc.). The sEMG signals were bandpass filtered between 10 Hz and 500 Hz, and the amplitude RMS value was obtained for each muscle.

To measure of the efficiency of the cervical deep flexor muscles, SCM activity was assessed by performing the cranio-cervical flexion standard clinical protocol described in previous studies [22,34,35]. These studies showed the relationship between neck pain, the inhibition of cervical deep flexor muscles (the longus capitis and longus colli muscles) and the increased EMG activity of the SCM. During this protocol, the patient was in the supine position with the neck in a neutral position, such that the line of the face was horizontal and a line bisecting the neck longitudinally was horizontal to the testing surface. The layers of a pressure sensor were inflated to 20 mmHg and placed

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below the neck (Stabilizer, Chattanooga Group Inc., USA). First, the operator instructed the patient to perform five incremental contractions of 10 seconds each. The participants practiced targeting the five test levels between 22 and 30 mmHg in two practice trials before the electrodes were applied. During the first contraction, the patient was asked to produce enough pressure to raise the pressure device to 22 mmHg; in the second, the device was to reach 24 mmHg; in the third, the target was 26 mmHg; in the fourth, it was 28 mmHg; and in the fifth, the target was 30 mmHg. Between contractions, the patient rested for 30 seconds. After training, the operator placed the electrodes on the sternal portion of the SCM [36] to assess its activity. To obtain the activation value of the SCM during the cranio-cervical flexion test, an average between the maximum and the five sub-maximum values was determined. Following the application of the electrodes, the participants performed a standardized maneuver for EMG normalization (reference voluntary contraction). This reference voluntary contraction involved a head lift (cervical and cranio-cervical flexion) just clear of the bed that was maintained for 10 s, during which EMG data were recorded. A one-minute rest period was allowed before the participants performed the experimental CCFT measurement during which the EMG data were recorded.

#### 2.5. Interventions

#### 2.5.1. Manipulation group (MT)

In the MT group, after the measurement protocol assessment, joint dysfunction was evaluated. The method chosen for the evaluation was exclusively manual, based on a study by Jul in 1998 that showed high reliability for assessing dysfunctions using manual methods [37]. In our study, we used passive mobility tests and tests of anterior-posterior and lateral pressure. These tests have been validated with radiographic studies of the cervical spine and have shown high inter- and intra-examiner reliability as well as a good relationship between manual diagnosis and hypomobility [38,39]. For the upper thoracic spine, the operators used anterior-posterior pressure tests and passive mobility tests [40]. Also tenderness, tissue texture changes and asymmetry were assessed [41]. The patient was evaluated in the flexion, extension and neutral positions to find a FRS, ERS or NSR dysfunctions [40–42]. To correct the cervical dysfunction a HVLA manipulation was performed, the patients were positioned in supine, however to manipulate the upper thoracic spine the subjects were positioned in prone, these techniques have been commonly used in research studies and were safe and effective [43,44]. The operator adapted the technique to the diagnosed dysfunction; all of them are perfectly detailed in Greenman, Ward and Gibbons textbooks [40–42]. After manipulation, the operator repeated the measurement protocol.

To correct the TMJ dysfunctions, TMJ mobilizations (caudal and ventro-caudal traction, ventral and mediolateral translation) were used [41], these techniques achieved a successful effects in the management of temporo-mandibular joint disorders [45].

The participants were instructed to contact the principal researcher if adverse events such as pain, headache, dizziness or other symptom occurred in the week after the study.

#### 2.5.2. Home exercise group (HE)

On the first day, the patients in the HE group received personal instruction and supervision by an experienced physiotherapist to ensure that they performed the exercises correctly. All of the subjects were given an exercise diary and a telephone and email contract. The exercise lasted no longer than 10–20 minutes once per day. The exercises were to be performed without provoking neck pain.

The HE protocol consisted of a general range of motion movements, specific stretching of the bilateral upper trapezius and cervical extensor muscles, CCF and submaximal isometric exercises.

First, while the participant was in a sitting position, general range of motion movements of the neck (flexion, rotation and side bending) were achieved 10 times in each direction. The movements were performed gently, with the goal of trying to go a little further during each repetition.

The stretching exercises were performed with the participant in a sitting position. To stretch the right upper trapezius, the subjects fixed the right shoulder with the left hand and then performed a left lateral flexion, right rotation and slight anterior flexion of the head and neck. The left trapezius was then stretched in the same manner. The cervical extensor muscles were stretched using neck and head flexion; to aid the stretch, the hands were placed at the occipital bone. The stretch position was maintained for 30 seconds. Each exercise was repeated 3 times [14,15].

In the supine position, the subjects performed a CCF exercise for 10 repetitions of 10 seconds' duration, with a 10-second rest interval between each contraction (total contraction time: 100 seconds, to-

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tal time of session: 190 seconds). The correct movement was first guided by a physical therapist to activate the deep cervical flexor muscles with minimal activity of the superficial cervical flexors. To monitor the correct movement and contraction intensity, a pressure biofeedback device (Stabilizer; Chattanooga Group, Inc., Chattanooga, TN, USA) was used. The participants were instructed to maintain pressure sensor levels between 22 and 30 mmHg comfortably and with no pain during contraction [16,17]. When performing the exercises at home, the patients placed a towel under the neck and then placed one hand gently on the front of the neck to feel the superficial muscles during the cranio-cervical flexion movement. The patients were instructed to stop the contraction if they felt that the muscles were beginning to harden.

Finally, submaximal isometric contractions were performed. In sitting position, the patients achieved a five-second contraction using only 10% effort. The contractions were performed 5 times in each direction (rotation, flexion, extension and lateral flexion in both directions) [18].

Additional outcomes of this study were participant adverse events (such as: pain, headache, dizziness or other symptoms) occurred in the next week after the study.

#### 3. Statistical analysis

The statistical analysis was performed by a statistician who was blinded to the rando vization, measurement and intervention protocol. Staustical analyses were conducted using SPSS Statistics 20 for Windows (SPSS, Inc., Chicago, IL. USA) The demographic data and initial assessment resuls were compared using ttests. The statistical distribution of the data was analyzed using the Shapiro Wilks W test. For parametric data, the t-test for paired samples was used to compare the results of the assessment before and after treatment; for nonparametric data, the Wilcoxon signed-rank test was used. The independent t-test for parametric data or the Mann-Whitney U Test for non-parametric data was used to compare the difference (change score) from pre to post treatment between groups. Finally, to calculate the effect size, Cohen's d was used. A small effect was identified by a Cohen's d score of approximately 0.2, a moderate effect was defined as a Cohen's d score of approximately 0.5, and a score of approximately 0.8 identified a large effect. The alpha level was set at 0.05.

Table 1	
Baseline characteristics of the subjects incl	uded in the study

	MT group	HE group	P value
Sex (% females)	100% (13/13)	100% (14/14)	_
Age (years) (mean $\pm$ SD)	32.15 (1.87)	34.35 (1.71)	0.393
Weight (kg) (mean $\pm$ SD)	64.71 (5.99)	67.10 (4.72)	0.756
Height (cm) (mean $\pm$ SD)	1.64 (0.01)	1.65 (0.01)	0.779
BMI (mean $\pm$ SD)	23.91 (2.05)	24.58 (1.62)	0.802

Pre and post values were expressed as mean (SE) two groups and all variables. Significant group interaction (P < 0.05).

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#### 4. Results

#### 4.1. Subjects

Of the 28 parients deemed eligible for inclusion, 96% (27 of 20) were enrolled and randomly divided into 2 group. The MT group (n=13) and the HE group (n=4); (Fig. 1). There were no significant differences in the subjects' baseline characteristics (Table 1) between the two groups. No adverse events were reported, and all of the participants who were randomly assigned to a group completed the study.

#### 4.2. Neck disability index

After one week, both interventions (manipulation and home exercises), showed significant ant differences (p=0.000 in both cases), and the changes were not significantly better in the manipulation group ( $-43.4\% \pm 21.82$ ) than in the home exercise group ( $-39.72 \pm 22.68$ ). Additionally, the Cohen's d showed large effects (d=1.36; 0.61-2.03) in both the manipulation and the exercise group (d=1.43; 0.70-2.09); however, no differences were observed between the groups (p=0.909) (Table 2) (Figs 2 and 3).

#### 4.3. Visual analogue scale

Significant changes were observed in both groups between the pre- and post-intervention measurements (p = 0.001 in both cases), and the effect size was large  $(d = 1.11; 0.39-1.77 \text{ in the manipulation group and } 1.52; 0.77-2.17 \text{ in the home exercise group), but no differences were observed between the groups <math>(p = 0.908)$  (Table 2) (Figs 2 and 3).

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Table 2 Summary neck disability and VAS results					
	Baseline	Post intervention	Cohen's d effect size 95% CI	Within-group p value	Between-group p value
NDI					
MT group $(n = 13)$	13.07 (1.09)	7.46 (1.19)	1.36 (0.61 to 2.03)	0.000	0.909
HE group $(n = 14)$	14.14 (1.15)	8.35 (0.99)	1.43 (0.70 to 2.09)	0.000	_
VAS					
MT group $(n = 13)$	48.23 (4.30)	25.84 (6.61)	1.11 (0.39 to 1.77)	0.001	0.958
HE group $(n = 14)$	53.85 (3.64)	31.85 (4.10)	1.52 (0.77 to 2.17)	0.001	_

Pre and post values were expressed as mean (SE) two groups and all variables. Significant group interaction (P < 0.05). Effect sizes were expressed as Cohen's d (95% Confidence Interval), and an effect size greater than 0.8 was considered large, an effect size of approximately 0.5 was considered moderate, and an effect size of less than 0.2 was considered small.

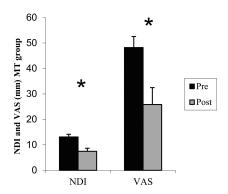


Fig. 2. NDI and VAS results, MT group. Pre and post values were expressed as mean (SE) two groups and all variables. \* denotes p value < 0.05 within – group interaction.

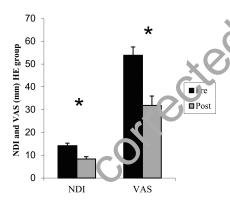


Fig. 3. NDI and VAS results, HE group. Pre and post values were expressed as mean (SE) two groups and all variables. \* denotes p value < 0.05 within – group interaction.

#### 4.4. Cervical range of motion data

One week after the interventions, no significance differences were observed in extension or left and right side bending range between the two intervention groups. However, the changes in flexion, right rotation and left rotation range in the MT and HE groups were significant (p = 0.004, p = 0.006 and p = 0.000, respectively, in the MT group and p = 0.016, p = 0.016

and p=0.006, respectively, in the HE group). Furthermore, in the MT group, the effect size was considered large for flexion (d=1.25; 0.51–1.91), right rotation (d=0.94; 0.25–1.58), and left rotation (d=0.99; 0.27–1.64); however, in the HE group, only the flexion effect size was large (d=1.25; 0.51–1.91). Regarding the between group interaction, only the extension range differences were considered significant (p=0.037) (Table 3) (Figs 4 and 5).

#### 4.5. ressure pain thresholds

No significant changes were observed in any of the measured PPTs from pre to post intervention or between groups; however, the effect size in the MT group was considered moderate for the upper trapezius PPT (d = 0.48; -0.19-1.12), which had a decrease of 11.24%. No differences were observed between the two groups (Table 4).

#### 4.6. Cranio-cervical flexion test

No significant differences were observed between the pre- and post-intervention RMS of the SCM during the five stages of the cranio-cervical flexion test for the two groups. However, the statistical analysis showed a tendency toward a decreased SCM signal in the first stage of CCFT in the exercise-group interaction (p = 0.062), with a moderate effect size (d = 0.57, -0.12-1.22). Additionally, in the MT group, the SCM signal decreased 29% and 34% in the first and fifth stage, respectively, showing a moderate effect size in both stages (d = 0.40, -0.31-1.08 and 0.46; -0.23-1.13, respectively). No significant differences were observed between the groups (Table 5).

#### 5. Discussion

To our knowledge, our study is the first to compare

Table 3 Summary cervical range of motion results					
	Baseline	Post intervention	Cohen's d effect size 95% CI	Within-group p value	Between-group p value
Flexion					
MT group $(n = 13)$	34.02 (3.47)	47.69 (2.53)	1.25 (0.51 to 1.91)	0.004	0.700
HE group $(n = 14)$	35.07 (2.54)	46.52 (3.31)	1.04 (0.35 to 1.66)	0.016	_
Extension					
MT group $(n = 13)$	56.46 (3.38)	60.30 (2.65)	0.35 (-0.31  to  0.99)	0.092	0.037
HE group $(n = 14)$	64.66 (3.60)	61.85 (2.41)	0.24 (-0.39  to  0.86)	0.214	-
Right side bending					
MT group $(n = 13)$	39.38 (1.79)	40.50 (1.94)	0.17 (-0.51  to  0.84)	0.324	0.965
HE group $(n = 14)$	39.71 (1.64)	40.80 (2.06)	0.16 (-0.47  to  0.77)	0.463*	_
Left side bending					
MT group $(n = 13)$	37.84 (1.90)	38.10 (1.72)	0.04 (-0.61  to  0.68)	0.899	0.974
HE group $(n = 14)$	39.38 (1.90)	39.57 (1.71)	0.03 (-0.59  to  0.65)	0.789*	_
Right rotation					
MT group $(n = 13)$	56.30 (1.84)	63.02 (2.11)	0.94 (0.25 to 1.58)	0.006	0.488*
HE group $(n = 14)$	59.90 (3.37)	65.80 (2.04)	0.57 (-0.09  to  1.20)	0.016*	_
Left rotation				•. ( ) •	
MT group $(n = 13)$	53.89 (2.31)	62.25 (2.38)	0.99 (0.27 to 1.64)	0.700	0.189
HE group $(n = 14)$	56.38 (2.40)	61.66 (1.90)	0.65 (0.00 to 1.27)	v 906	_

Pre and post values were expressed as mean (SE) two groups and all variables. Significant order interaction (P < 0.05). Effect sizes were expressed as Cohen's d (95% Confidence Interval), and an effect size greater than 0.8 was considered large, an effect size of approximately 0.5 was considered moderate, and an effect size of less than 0.2 was considered small. \*p-values were drawn from nonparametrical tests.

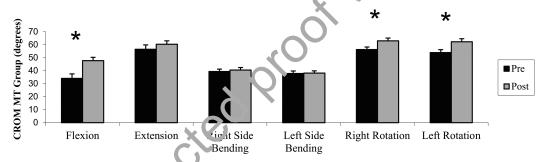


Fig. 4. CROM results, MT Group. Pre and pc st values were expressed as mean (SE) two groups and all variables. \* denotes p value < 0.05 within – group interaction.

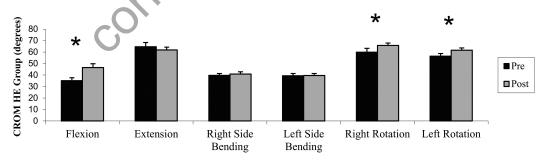


Fig. 5. CROM results, HE Group. Pre and post values were expressed as mean (SE) two groups and all variables. \* denotes p value < 0.05 within – group interaction.

the short-term effects of an MT protocol with those of an HE protocol in women with chronic neck pain. The main finding was that both interventions improved function and pain, with only marginal between-group.

differences in favor of MT group, manipulation was more effective than exercise for only 2 out of 17 measures

After one week, both interventions showed an im-

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Table 4 Summary pressure pain thresholds results					
	Baseline	Post intervention	Cohen's d effect size 95% CI	Within-group p value	Between-group $p$ value
PPT C1					
MT group $(n = 13)$	1.33 (0.04)	1.30 (0.06)	0.11 (-0.54  to  0.75)	0.759	0.863
HE group $(n = 14)$	1.24 (0.06)	1.23 (0.07)	0.03 (-0.60  to  0.65)	0.885	_
PPT C5					
MT group $(n = 13)$	1.30 (0.06)	1.43 (0.12)	0.38 (-0.29  to  1.01)	0.231	0.818
HE group $(n = 14)$	1.28 (0.06)	1.38 (0.10)	0.31 (-0.32  to  0.93)	0.236	_
PPT upper trapezius					
MT group $(n = 13)$	1.24 (0.05)	1.34 (0.05)	0.48 (-0.19  to  1.12)	0.162	0.737
HE group $(n = 14)$	1.23 (0.06)	1.30 (0.05)	0.28 (-0.35 to 0.90)	0.315	_
PPT gluteus medius					
MT group $(n = 13)$	2.22 (0.16)	2.27 (0.16)	0.08 (-0.60  to  0.75)	0.937*	0.487
HE group $(n = 14)$	2.25 (0.17)	2.40 (0.13)	0.26 (-0.37  to  0.88)	0.150	

Pre and post values were expressed as mean (SE) two groups and all variables. Significant group interaction (P < 0.05). Effect sizes were expressed as Cohen's d (95% Confidence Interval), and an effect size greater than 0.8 was considered large, a refect size of approximately 0.5 was considered moderate, and an effect size of less than 0.2 was considered small. \*p-values were drawn from nonparametrical tests.

Table 5
Summary SCM activation during TFCC results

	Baseline	Post intervention	Cohen's d effect size 95% CI	Wn'in-group p value	Between-group $p$ value
First stage		-	18		
MT group $(n = 13)$	11.59 (2.78)	10.30 (3.15)	0.12 (-0.57  to  0.78)	0.935	0.376
HE group $(n = 14)$	15.38 (3.58)	9.49 (2.20)	0.57 (-0.12 to 1 22)	0.62	_
Second stage					
MT group $(n = 13)$	22.61 (6.01)	14.33 (6.22)	0.40 (-0.31  to  1.08)	0.488	0.346
HE group $(n = 14)$	12.36 (2.56)	13.21 (3.84)	0.07 (- 0.6c to 0.74)	0.848	-
Third stage			<b>40</b>		
MT group $(n = 13)$	24.96 (6.56)	20.63 (6.66)	(.1c (- 9.82 to 0.47)	0.461	0.583*
HE group $(n = 14)$	19.00 (2.23)	23.75 (5.89)	6.29 (-0.35  to  0.90)	0.380	_
Fourth stage					
MT group $(n = 13)$	30.64 (7.57)	25.29 (7.97)	0.20 (-0.48  to  0.87)	0.379	0.566
HE group $(n = 14)$	21.94 (3.18)	19.20 (4.6 )	0.18 (-0.46 to 0.81)	0.299	_
Fifth stage					
MT group $(n = 13)$	36.91 (5.14)	25.0 (9.12)	0.46 (-0.23  to  1.13)	0.151	0.362
HE group $(n = 14)$	28.35 (3.98)	24 /3 (7.08)	0.17 (-0.49  to  0.81)	0.508	_

Pre and post values were expressed as a can (3E) two groups and all variables. Significant group interaction (P < 0.05). Effect sizes were expressed as Cohen's d (95% Confide. to Interval), and an effect size greater than 0.8 was considered large, an effect size of approximately 0.5 was considered moderate, and an effect size of less than 0.2 was considered small. \*p-values were drawn from nonparametrical tests.

portant decrease in NDI and VAS scores. The manipulation protocol decreased the NDI 43.48% (6.05) and the VAS 50% (6.06). The NDI changes in the MT group may be similar to those found in previous studies. For example, Saavedra and cols [8] found patients with chronic mechanical neck pain showed greater reduction in NDI scores after manipulations of the cervical and thoracic spine than after manipulation of the cervical spine alone. The short-term effects on pain could be different if, like Pires and cols [46], these authors did not find significant differences in VAS scores 48–72 hours before manipulating T1. These conclusions seem to reinforce the belief that multisegment manipulation treatment improves the effects on neck pain more than isolated manipulation. Our protocol

also included the temporo-mandibular joint; because of its relationships with the neck and cervical pain and biomechanics [9,10,47], including the TMJ in treatment yields more effective results. The physiological mechanism by which CSM produces analgesic effects is still unknown. Some authors studied a chemical response, while others examined biomechanical effects or neurophysiological relationships [48–50]. More studies investigating the mechanism behind these effects are needed.

In our study, the HE group showed decreases of 39.72% (6.06) in the NDI value and 37.37% (10.72) in the VAS score. These results are similar to those of other authors, such as Karlsson [16,51]; however, our study differs in that it investigated the short-term

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effects of the treatments and that our HE protocol was a combined strength and stretching program. The analgesic effect of the home exercise protocol studied seems to be related to various aspects; on the one hand, the motor unit recruitment during isometric contractions elicits a significant hypoalgesic response [19], while on the other hand, cranio-cervical flexion exercise improves the motor control activation of the deep flexors [17].

Regarding ROM, significant changes were found in flexion and in both directions of rotations in the MT group. The HE group also showed similar changes, but only the flexion effect size was considered large in this group (d = 1.25; 0.51–0.91). The results in the MT group were similar to other studies [52,53]. A study by Saavedra and cols of a manipulation protocol also concluded that MT resulted in significant improvement in ROM and functional status. For the HE group, our results are in accordance with the Freimann and cols study [54]. While no significant changes were observed in either group in side-bending range, the non-improvement may be due to the pre-intervention measures (39.38 (1.79) and 37.84 (1.90) for right and left, respectively, in the MT group and 39.71 (1.64) and 39.38 (1.90) for right and left, respectively, in the HE group), which were already similar to normal [55]. At any rate, the between-groups differences observed in these movements were not significant.

Regarding the PPT investigation, no significant differences between the pre- and post-intervation results were found in any of the measured P.T. between groups. In the MT group, these results d ffer from those of another study of the short-term e're its of manipulation [52]; however, in that study the chort-term effect was measured 20 minutes post intervention. Similarly, for the HE group, Lluch an (co's [16,56] found immediate effects on the subscienced and C5/6 PPTs, but it is possible that in that study the immediate effects did not persist over time because the last home exercise protocol repetition was performed several hours before assessment. Regardless, although the performance of cranio-cervical flexion exercise for 6 weeks demonstrated reductions in pain and the NDI, no changes in the PPTs over the upper trapezius and at other locations were found [57].

Among the studied subjects, only those in the MT group showed a moderate effect size (d=0.48; -0.19-1.12) for the upper trapezius PPT was found. This is consistent with the findings of Camargo and cols [58], who also found a moderate effect size for upper trapezius PPT change after C5/6 manipulation. No differences were observed between the two groups.

Patients with chronic cervical pain often present a significant correlation between pain intensity and superficial muscle activity during cranio-cervical flexion tests, a finding that could explain altered neuromuscular function [16]. In the exercise group, after one week, statistical analysis showed a decreasing trend in the SCM signal during the first stage of the CCFT with a moderate effect size (d = 0.57; -0.12–1.22). This result was not consistent with those of previous studies [56], which showed immediate, significant changes during the third and fifth stage; however, our findings were in the same line as those of Gallego and cols [59], who found significant changes in the long term but not immediately or one month after the intervention. In the MT group, at the first and fifth stages, the SCM signals decreased by 29% and 34%, respectively, showing modera'e effect sizes for both stages  $(d = 0.40; -0.31 \cdot 1^{-0})$  and  $0.46; -0.23 \cdot 1.13$ , respectively). These findings were in with those of other studies [60,61], 'w' while Sterling and cols found significant changes in the first, second and third stage after grad III C5/6 mobilization, Moraleida and cols only found significant differences in the first stage based on ul rasonography results. Other authors, such as Pi es and cols [46], did not find significant short-term changes in motor control of the neck; however, a different motor control test was used. In the authors' opinion, the SCM signal decrease in the fifth stage could be explained because the temporomandibular joint manipulation had an effect on cranio-cervical biomechanics [9,11,12]; however, this conclusion should be affirmed by an exhaustive investigation.

These findings did not explain the excellent results on the NDI and VAS; however, in the authors' opinion and in agreement with other investigators, multiple factors could contribute to altered motor function in individuals with chronic mechanical neck pain [16].

Some limitations of this study should be considered. First, the investigator who performed the measurement protocol was not blinded to the intervention. Second, although we attempted to control for adherence to the home exercises through telephone contact, it was impossible to determine whether the exercises were being performed correctly. Third, the VAS and NDI are self-reported measures of pain, not objective measures. Fourth, the study did not have a control group. Fifth, there may have been an interaction between the treatment effects of the HE and MT protocols; therefore, the results may have demonstrated only the relative effectiveness of the two protocols. Another limitation is that the present HE protocol did not include strength train-

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ing, only stretching and low-intensity isometric contractions. Additionally, the statistical analyses were not adjusted for multiple comparisons; because the significance level was set at 5%, some of the significant differences may have occurred by chance (statistical type I error). Conversely, a number of potentially significant differences may not have been significant because the sample size was small (statistical type II error). Lastly, the outcome assessor was not blinded, which might have led to measurement bias. More studies with larger sample sizes comparing the short-term effects of an HVLA manipulation protocol and a home exercise protocol are needed. We suggest a longer duration of treatment with more sessions to maximize the treatment effect. Only female with chronic neck pain were included in this study, this fact limited the findings to the female population.

#### 6. Conclusions

Both interventions decreased the NDI and VAS in patients with chronic neck pain; additionally, flexion and both rotation directions improved after one week. The between-group differences were marginal, and MT showed significantly better results than HE in only 2 out of 17 tests.

The effect size in the MT group was considered moderate for the C5 and upper trapezius PTT similarly, the manipulation protocol group show 17 moderate decrease in the first and fifth stage of CCFT in the SCM signal. A moderate decrease during the first stage was also found for the HE 510.70

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#### Conflict of interest

None declared.

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