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ORIGINAL ARTICLE

The effect of manipulation plus massage therapy *versus* massage therapy alone in people with tension-type headache. A randomized controlled clinical trial

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ABSTRACT

BACKGROUND: Manipulative techniques have shown promising results for relief of tension-type headache (TTH), however prior studies either lacked a control group, or suffered from poor methodological quality. The aim of this study was to compare the effect of spinal manipulation combined with massage *versus* massage alone on range of motion of the cervical spine, headache frequency, intensity and disability in patients with TTH.
DESIGN: Randomized, single-blinded, controlled clinical trial.
SETTING: University clinic.
POPULATION: We enrolled 105 subjects with TTH.
METHODS: Participants were divided into two groups: 1) manipulation and massage; 2) massage only (control). Four treatment sessions were applied over four weeks. The Headache Disability Inventory (HDI) and range of upper cervical and cervical motion were evaluated at baseline, immediately after the intervention and at a follow-up, 8 weeks after completing the intervention.
RESULTS: Both groups demonstrated a large (f=1.22) improvement on their HDI scores. Those that received manipulation reported a medium-sized reduction (f=0.33) in headache frequency across all data points (P<0.05) compared to the control group. Both groups showed a large within-subject effect for upper cervical extension (f=0.62), a medium-sized effect for cervical extension (f=0.39), and large effects for upper cervical (f=1.00) and cervical (f=0.27) flexion. The addition of manipulation resulted in larger gains of upper cervical flexion range of motion, and this difference remained stable at the follow-up.
CONCLUSIONS: These findings support the benefit of treating TTH with either massage or massage combined with a manipulative technique. However, the addition of manipulative technique was more effective for increasing range of motion of the upper cervical spine and for reducing the impact of headache.
CLINICAL REHABILITATION IMPACT: Although massage provided relief of headache in TTH sufferers, when combined with cervical manipulation, there was a stronger effect on range of upper cervical spine motion.

(*Cite this article as*: Espí-López GV, Zurriaga-Llorens R, Monzani L, Falla D. The effect of manipulation plus massage therapy *versus* massage therapy alone in people with tension-type headache. A randomized controlled clinical trial. Eur J Phys Rehabil Med 2016;52:606-17)

Key words: Tension-type headache - Physical therapy modalities - Manipulation, spinal - Disabled persons.

Tension-type headache (TTH) is the most common primary headache.[1, 2] TTH is classified as either episodic tension-type headache (ETTH) or chronic tension-type headache (CTTH) and is often accompanied by tenderness of the pericranial structures.[3] In particular, ETTH is the most common headache disorder,

with one year prevalence reports indicating that 42% of adults are affected, women more so than men. In contrast, CTTH affects 1-3% of adults.[4] Although the disease burden due to TTH is higher in CTTH compared to ETTH, ETTH still has a significant impact on quality of life.[2, 5]

A number of studies have evaluated the effects of physical therapy on TTH. Studies show that massage combined with either exercise, myofascial techniques, postural techniques, cervical mobilization, cervical relaxation exercises, gentle and progressive stretching or trigger point therapy, are effective at reducing the intensity, frequency and duration of headache, as well as increasing cervical range of motion. The use of manipulation has also shown promising results, however the studies conducted either did not have a control group or their methodological quality was considered too low.[6]

A systematic review of the effectiveness of spinal manipulation for the treatment of headache disorders identified six trials with only three involving people with TTH. No conclusive results regarding the effectiveness of spinal manipulation could be drawn since the studies were limited by not having a control group or being a single-blinded study.[7] In a subsequent review,[8] the effectiveness of manual therapy techniques for reducing pain in TTH was evaluated. Only six studies were identified and overall, the results did not provide convincing evidence that manual therapy had a positive effect at reducing TTH. More specifically, soft tissue techniques showed limited evidence (level 3) and spinal manipulation showed some evidence of effectiveness (level 4). However, more recent clinical trials concluded that manipulation of the suboccipital region may address other factors such as the level of disability caused by TTH.[9-13] It is apparent that further well designed clinical trials are necessary to appreciate the value of manipulation for the management of TTH.

This study evaluated the effectiveness of combining a manipulative technique and massage *versus* a control treatment of massage only in people with TTH. To assess treatment effectiveness, we evaluated changes in the frequency and severity of headache, changes in disability caused by headache, changes in various functional and emotional dimensions of headache, and change in cervical range of motion. Measurements were taken immediately after four weeks of treatment and at a medium term follow-up. We hypothesized that manipulation of the suboccipital region would have a positive effect on headache severity and frequency as well as the functional and emotional disability associated with TTH, as compared to a control treatment of massage in people with TTH. Moreover, compared to massage, the addition of manipulation would improve cervical range of motion.

Materials and methods

Participants

The sample consisted of 105 people diagnosed with frequent (47.6%) and chronic (52.4%) TTH derived from two primary care centers in Valencia (Spain), selected according to the criteria of the IHS.[3] Participants were included if they had suffered from TTH for more than three months. The patients included were aged between 18 and 65 years (mean±SD: 38.9±10.9 years), which included 23 men (21.9%) and 82 women (78.1%). Patients were excluded if they had suspected malignant disease, rheumatoid arthritis, pregnancy, vertigo, continuous intake of prescribed medication or those who received physical therapy over the past three months for headache or neck pain. Detailed inclusion and exclusion criteria are presented in Table I. Finally, 102 subjects completed the study (2 from the treatment group dropped out due to work problems and one from the control due to lack of improvement) (Figure 1).

The software G*power [14] was used to calculate the required sample size, using data from previous studies to estimate the effect sizes to be expected. Our review of the literature showed that across studies, large effect sizes were obtained with a sample size of ~44 (Cohen's d=0.40).[15-19] We accepted a 5% alpha risk (α=0.05) and 10% beta risk (β=0.1) as study parameters which showed that 51 subjects were required in each group to achieve a medium-to-large effect size (f=0.35). We predicted a 5% dropout rate in the follow-up period.

Study design

The study was a randomized, single-blinded, controlled clinical trial conducted from January to November, 2014. After the initial clinical interview, an external assistant randomly allocated the patients to either the

TABLE I.—*Inclusion and exclusion criteria.*

Inclusion criteria	Exclusion criteria

– Subjects aged between 18 and 65 years
– Diagnosis of frequent ETTH and CTTH
– At least 10 episodes occurring on ≥1 day per month for at least 3 months
– Headache episodes lasting from 30 minutes to 7 days
– Headaches has at least two of the following c:
  – Bilateral location of pain
  – Pressing tightening (non-pulsating) quality
  – Mild or moderate intensity
  – Not aggravated by routine physical activity such as walking or climbing stairs
– No nausea or vomiting in ETTH
– No more than one of photophobia or phonophobia in CTTH
– No more than one of photophobia or mild nausea in CTTH.Headache may be associated with pericranial tenderness
– Not attributed to another disorder
– Subjects being under pharmacological control
	– Patients with infrequent ETTH (≤1 day per month for at least 3 months), and patients with probable TTH
	– Headache that is aggravated by head movements.
	– Metabolic or musculoskeletal disorders with symptoms similar to headache (rheumatoid arthritis)
	– Previous neck trauma
	– Vertigo, dizziness, arterial hypertension.
	– Joint stiffness, arteriosclerosis or advanced degenerative osteoarthritis
	– Patients with heart devices
	– Patients in process of pharmacological adaptation
	– Excessive emotional tension
	– Other neurological disorders
	– Laxity of neck soft tissues
	– Radiological alterations
	– General hypermobility or hyperlaxity
	– Joint instability
	– Pregnancy
	– Received physical therapy treatment for headache or neck pain in the previous 3 months
	– Suspicion of malignancy

TTH. tension-type headache; ETTH. episodic tension-type headache; CTTH. chronic tension-type headache.

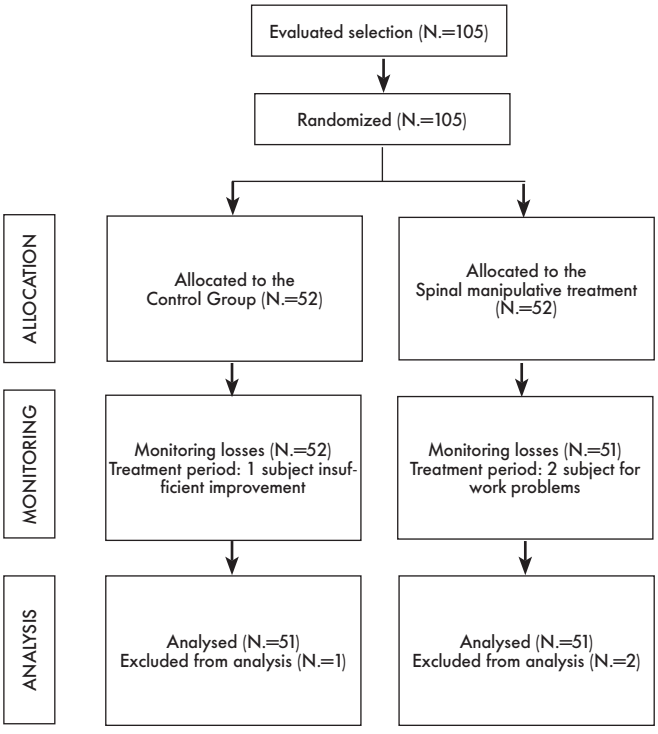

Figure 1.—Flowchart according to the CONSORT Statement for reporting randomized trials.

control or treatment group using a computer-generated random sequence (randomized.com). Thus different people performed the randomization of the participants and the eligibility check for inclusion into the trial. The external assistant, therapist and examiner were blinded to the study's objective.

The treatment group received occiput-atlas-axis manipulation (OAA) and soft tissue treatment by massage. The control group received massage only. The exposure times were the same for each group, thus the difference between groups was the inclusion of a manipulative OAA technique which only the treatment group received. Four sessions were conducted (once per week) and the assessment was carried out in 3 stages: at baseline, end of treatment (at 4 weeks) and follow-up at 8 weeks following the completion of treatment. All patients in both groups were assessed under the same conditions before and after the treatment by an examiner blinded to their group allocation. The participants were advised in both the information sheet and consent form not to make changes to their activities, medication or other treatments over the course of the study. The study assistant maintained contact with the participants regularly throughout the follow-up period to encourage their commitment to the study.

The study was conducted at the University of Valencia (Spain) and was approved by the University's Ethics Committee (H1380701837435). Prior to data collection, informed written consent stating that there were two types of treatments and that participants would be randomly assigned to one group, was obtained from all

patients. All procedures were conducted according to the Declaration of Helsinki. This study was registered in Clinical Trials as NCT02450955.

Intervention

Vertebral artery tests were initially conducted on all patients in both groups during the first session in order to minimize risk. The exclusion criteria of the study also ensured a very low risk of an incident due to cervical spinal manipulation.[20] Each treatment was applied individually, with the participant positioned on a treatment table. During each treatment session the control group received 10 minutes of massage followed by 10 minutes of rest thus resulting in a total treatment time of approximately 20 minutes. The treatment group received an OAA manipulative technique, followed by 10 minutes of massage and 10 minutes of rest thus lasting approximately 20 minutes. Therefore the duration of treatment for each group was similar and all treatments were performed by the same therapist. The therapist participating in this study had the necessary training and over 15 years of experience in spinal manipulation.

Massage

A superficial massage was performed for 10 minutes in the cervical region consisting of gentle rubbing and kneading, five minutes prone and five minutes supine with a focus on cervical and suboccipital muscles.[21-23]

Occiput-atlas-axis technique

This technique was applied as described previously [9, 10, 12] with the aim of restoring joint mobility between the occiput, atlas and axis. It is a structural technique applied bilaterally, performed on a vertical axis passing through the dens process of the axis without extension or flexion and very little side-bending. The technique is applied in two stages: in the first stage, a light decompression is performed and then small circumductions are made with the aim of increasing viscoelasticity of tissues. Subsequently the appropriate joint barrier is sought by selective tension and high-velocity rotation manipulation is performed in a cranial helical motion without raising the subjects head.

Resting position

After the treatment, both groups rested for 10 minutes in a supine position with neutral ranges of neck flexion, extension, lateral flexion, and rotation.[10, 12, 24]

Assessment

A preliminary assessment was conducted one month before the baseline measurement to obtain preliminary data about the participant's headache characteristics. Subsequently, the disability caused by headache and cervical range of motion was evaluated on three occasions; at baseline, end of treatment (at 4 weeks) and at a follow-up, 8 weeks following completion of treatment.

Headache disability

We used the Headache Disability Inventory (HDI) developed by Jacobson *et al*.[25, 26] as our main measure of headache disability. The purpose of the scale is to identify the difficulties the patient may experience due to headache. It includes two items: headache severity (mild, moderate and severe) and frequency (once a month, more than once and less than 4 times a month, and once a week) and 25 items that assess two subscales (E=emotional with 13 items and F=functional with 12 items). Subjects answer each question (yes=4 points, sometimes =2 points or no =0 points). The maximum disability score in this inventory is 100 points. The Spanish adaptation was performed by Rodríguez *et al*.[27] in 2000, and provides a good index of internal consistency (Cronbach 0.94).

Cervical range of motion

The instrument used in this study was the CROM goniometer (Performance Attainment Associates, MN, USA) device was used to assess range of motion of the cervical spine.[28, 29] The CROM is a system that combines inclinometers and magnets arranged on a head support with support on the bridge of the nose to measure the degrees in cervical flexion, extension, tilt, and rotation. High inter-tester reliability for the CROM is reported for measures of the upper cervical spine (ICC>=0.89).[30] To assess upper cervical flexion and extension, the patient was standing with their back against the wall, looking forward horizontally and performed upper cervical flexion and extension guided by the examiner. For the assessment of

cervical flexion and extension, the patient was seated and performed the movements whilst the examiner placed one hand on the sternum and the other over the upper thoracic region to minimize compensatory movements.

Statistical analysis

Group differences of demographic data were assessed using Student's *t* for continuous variables and Pearson's χ^2 difference test for nominal or ordinal variables. Statistical significance was set at $\alpha<0.05$. The Kolmogorov-Smirnov Test was used to evaluate data for normal distribution. A repeated-measures multivariate analysis of variance (RM-MANOVA) was used to determine if mean scores of the criteria differed significantly and statistically between time points within subjects. Violations of the assumption of Sphericity we tested using Mauchly's [31] *W* statistic. Whenever this assumption was violated, following Girden,[32] Huynh-Feldt's correction was applied if $\varepsilon>0.75$ in both Greenhouse-Geisser [33] and Huynh-Feldt [34] tests. If assumption of Sphericity was confirmed and RM MANOVA showed significance, pairwise comparison of estimated marginal means scores were performed using Bonferroni's method to adjust for multiple comparisons. All statistical analyses were performed with IBM SPSS 22©.

Results

Table II presents the baseline descriptive statistics for both groups. No significant mean differences were found for any of the baseline variables. Table III shows Means, SD and Mann-Whitney's *U* values for both groups for range of motion and HDI scores. Tables IV-V show Wilks' Λ, *F*-values and estimated marginal means, *SE* and 95% *CI* of the two RM-ANOVAS models. Neither RM-ANOVAS violated the homogeneity of variance assumption. Further, Mauchly's *W* was non-significant in all analyses, with the exception of upper cervical extension (W=0.79, χ^2=23.46, P<*0*.001), upper cervical flexion (W=0.84, χ^2=17.62, P<*0*.001), cervical flexion (W=0.90, χ^2=9.85, P<*0*.01), and the HDI emotional (W=0.94, χ^2=6.29, P<*0*.05) and functional (W=0.91, χ^2=9.58, P<*0*.01) dimensions. Since ε was >0.75, the Huynh-Feldt's correction was used in these cases. No adverse effects were reported.

Headache Disability Inventory

Model 1 shows that patients in both groups demonstrated a large (f=1.22) improvement in all four subscales of the HDI (frequency, severity, emotional, functional). Further, as compared to the control group (I), patients that received the additional articulatory technique (J) reported a medium-sized reduction (f=0.33) in headache frequency across all data points (I-J=-0.25, ±0.10, P<0.05, [-0.44, -0.05]). However, for the remaining HDI subscales, large (f=0.51) interactive effects were found (Table V and Figure 2). Although patients in the treatment group which included the articulatory technique showed higher initial scores in the three remaining HDI subscales (emotional, functional and severity), the difference from the control group was non-significant (Table III). Thus, lower post-test and follow-up scores in these subscales of patients in the treatment group indicates these between-within subject interactive effects (Table V and Figure 2). It is to be noted that differences in significance between Tables III, V for the emotional subscale can be explained because the RM-MANOVA technique adequately addresses the shared variance that results from a high correlation between the emotional and functional subscales at all three data points (τ=0.62*** for protest, τ=0.73*** for post-test and τ=0.73*** for follow-up).

Range of motion

Model 2 shows that in both treatment groups we observed a large-sized within-subjects effect on upper cervical extension (f=0.62), a medium-sized effect on cervical extension (f=0.39), and large-sized effects on upper cervical (f=1.00) and cervical (f=0.27) flexion. For upper cervical extension, a pairwise comparison of estimated means showed that post-test ($I\text{-}J_1$=-5.42,±0.77, P<*0*.001, [-7.29, -3.55]) and follow up ($I\text{-}J_2$=-4.97±1.12 P<0.001 [-7.69, -2.25]) scores differed significantly from pre-test (I) scores. Similarly, for cervical extension, for both groups, post-test ($I\text{-}J_1$=-6.00,±1.07, P<0.001, [-8.61, -3.39]) or follow-up ($I\text{-}J_2$=-5.20±1.32 P<0.001 [-8.40, -1.99]) scores significantly differed from pre-test scores. However, non-significant differences were found between post-test and follow-up scores for upper cervical extension ($J_1\text{-}J_2$=-.45±0.86 P<1.00 [-1.65, 2.55]) or cervical extension ($J_1\text{-}J_2$ =0.80,±1.23 P<1.00

TABLE II.—*Demographic data and clinical characteristics.*

Treatment type	Massage (N.=51)	Massage plus manipulation (N.=51)	Test of basal differences between conditions
Age, years, (mean±SD)	40.47±11.33	37.69±10.64	t (2,100)=1.28; P=0.20
Sex, F/M	38/13	41/10	χ^2 (1)=0.50; P=0.48
History			
Evolution of headache, years (mean±SD)	10.46±10.46	11.10±10.64	t (2,100)=-0.30; P=0.76
ETTH/CTTH	27/24	26/25	χ^2 (1)=0.03; P=0.84
Severity of disorder: mild/moderate/severe	4/38/8	6/32/13	χ^2 (1)=2.281; P=0.32
Pain profile (triggers)			
Location of pain: front/parietal/occipital pain	18/20/13	14/18/19	χ^2 (2)=1.96; P=0.38
Location bilateral pain: no/yes	0/51	2/49	χ^2 (1)=2.04; P=0.15
Pressure throbbing pain: no/yes	10/41	6/45	χ^2 (1)=1.19; P=0.28
NO pain increases with physical activity: no/yes	10/41	14/37	χ^2 (1)=0.87; P=0.35
Time when the pain begins: morning/day/night/indifferent	14/21/2/14	5/19/4/23	χ^2 (1)=7.22; P=0.06

P-values were calculated using Student's *t* for continuous variables and Pearsons χ^2 difference test for nominal or ordinal variables.

TABLE III.—*Mean±standard deviation of upper cervical and cervical range of motion and the Headache Disability Inventory score for the intervention groups across data points (N.=102).*

	Headache disability inventory (HDI)				Upper cervical		Cervical	
	Frequency	Intensity	Functional	Emotional	Flexion	Extension	Flexion	Extension
Pre-test								
Massage	2.65±0.56	2.16±0.64	23.65±11.96	19.86±12.69	8.31±4.41	15.00±7.95	48.18±10.45	45.53±16.66
Massage + Manipulation	2.55±0.54	2.24±0.59	24.43±12.69	21.41±11.15	7.82±3.27	16.22±8.58	52.57±10.98	46.12±14.67
	U=1161.50	U=1224.50	U=1264.50	U=1187.50	U=1261.50	U=1234.50	U=1022.00	U=1287.50
	z=-1.10, NS	z=-0.58, NS	z=-0.24, NS	z=-0.76, NS	z=-0.27, NS	z=0.33, NS	z=-1.87†	z=-0.09, NS
Post-test								
Massage	2.47±0.61	1.98±0.76	21.29±11.94	17.45±12.48	11.16±4.42	18.80±8.87	55.22±11.26	51.37±14.21
Massage + Manipulation	2.25±0.63	1.71±0.64	16.57±12.00	16.20±12.19	13.16±4.75	23.25±9.74	54.31±11.28	52.27±15.38
	U=1060.50	U=1046.00	U=981.00	U=1219.00	U=994.50	U=938.00	U=1225.50	U=1279.50
	z=-1.79†	z=-1.85†	z=-2.14*	z=-0.55, NS	z=-2.06*	z=-2.44*	z=-0.50, NS	z=-0.14, NS
Follow-up								
Massage	2.29±0.67	1.76±0.68	17.29±11.66	14.59±12.04	11.06±4.78	18.96±11.03	53.88±11.42	51.31±13.87
Massage + Manipulation	1.86±0.69	1.57±0.64	14.47±10.23	12.63±9.76	11.67±4.97	22.20±11.22	52.59±12.84	50.73±13.98
	U=880.50	U=1098.50	U=1114.00	U=1207.50	U=1173.00	U=1041.00	U=1242.00	t (2, 100)=0.21, NS
	z=-3.05**	z=-1.49, NS	z=-1.25, NS	z=-0.62, NS	z=-0.86, NS	z=-1.75†	z=-0.86, NS	

Note: †P<0.10; *P<0.05; **P<0.01; P-values were calculated using Student's *t* for normally distributed variables and Mann-Whitney's U for non-normally distributed variables.

[-2.20, 3.80]). For upper cervical flexion, in both treatment groups, post-test ($I\text{-}J_1$= -4.09,±0.48, P<0.001, [-5.26, -2.92]) and follow up ($I\text{-}J_2$=-3.29±0.57 P<.001 [-4.68, -1.91]) scores differed significantly from pre-test scores, but non-significant differences existed between post-test and follow-up ($J_1\text{-}J_2$ =0.79±0.40 P<0.14 [-.17, 1.76]) scores.

Similarly, in both treatments, cervical and upper cervical flexion differed significantly between pre-test (I) and post-test ($I\text{-}J_1$=-4.39,±0.97, P<0.001, [-6.76, -2.02]) scores, but there were no significant differences between pre-test and follow-up ($I\text{-}J_2$=-2.86±0.57 P<0.08 [-5.95, 0.23]) scores, nor between post-test and the follow-up ($J_1\text{-}J_2$=1.53±1.10 P<0.50 [-1.15, 4.21]) scores (Figure 3). Significant medium-sized effects were found across groups that varied in time, for upper cervical (*f*=0.39) and cervical flexion (*f*=0.20). Table IV and Figure 3 show that the treatment which included manipulation was a more effective than a soft tissue technique alone for increasing upper cervical flexion, and this difference remained stable at the follow-up. However, although initial pre-test differences in cervical flexion

TABLE IV.—*Model 1. RM-ANOVA's estimated marginal means, standard errors (se±) and 95% confidence intervals for the intervention groups across data points (N.=102).*

Measure	Treatment (Between-subject effects)		Data point (Within-subjects effects)	
HDI	Group	Est. Marg. Means,±SE, [95% CI]	Measurement	Est. Marg. Means,±SE, [95% CI]
Frequency	Massage	2.47 (.07), [2.33, 2.61]	Pre-test	2.60,±0.05; [2.49, 2.71]
			Post-test	2.36,±0.06; [2.24, 2.48]
			Follow-up	2.08,±0.07; [1.94, 2.21]
	Massage +manipulation	2.22 (.07), [2.08, 2.36]	*F*-value	*F* (1.97, 196.85)=34.70***, η²=0.26
	F-value	*F* (1, 100)=4.72*, η²=0.06		
Intensity	Massage	-	Pre-test	2.20,±0.06; [2.07, 2.32]
			Post-test	1.84,±0.07; [1.70, 1.98]
			Follow-up	1.67,±0.06; [1.54, 1.80]
	Massage +manipulation	-	*F*-value	*F* (2, 200)=34.14***, η² =0.25
	F-value	-		
Functional	Massage		Pre-test	24.04,±1.22; [21.62, 26.46]
			Post-test	18.93,±1.18; [16.58, 21.28]
			Follow-up	15.88,±1.09; [13.73, 18.04]
	Massage +manipulation		*F*-value	*F* (1.88, 188.22)=60.18***, η²=0.38
Emotional	Massage	-	Pre-test	20.64,±1.20; [18.26, 23.01]
			Post-test	16.82,±1.22; [14.40, 19.25]
			Follow-up	13.61,±1.08; [11.45, 15.76]
	Massage +manipulation	-	*F*-value	*F* (1.94, 188.40)=46.37***, η²=0.32
	F-value	-		
	Wilks' Λ=0.90; *F* (4, 97)=2.81*, η²=0.10		Wilks' Λ=0.40; *F* (8, 93)=17.42***, η²=0.60	

***P<0.001; **P<0.01, *P<0.05; A Bonferroni's correction has been applied for multiple comparisons. For parsimony, only estimated marginal means of statistically significant effects are shown. *F*-values were corrected using the Huynh-Feldt correction when necessary.

were in favor of the treatment group which included the articulatory technique, this difference was non-significant (Mann-Whitney *U*=1022.00 P<.06), post-test and follow-up scores show no differences across groups for cervical flexion.

Discussion

In this randomized, controlled study, the overall results for the entire sample showed the efficacy derived from the application of treatment focused on the suboccipital and cervical region. The results were positive when the treatment consisted of soft tissue massage, but the effect was greater when spinal manipulation was included. These results confirm the hypothesis and objectives addressed.

The treatment including manipulation was more effective for increasing mobility of the upper cervical region (flexion and extension). However, after statistically controlling for a possible systemic variation (correlation) between cervical and upper cervical mobility, only differences between flexion in both the cervical and upper cervical region remained significant. More precisely, the addition of the manipulative technique was more effective at improving upper cervical and cervical flexion, but there was no statistically significant difference in treatment efficacy for upper cervical or cervical extension. On the other hand, Table IV and Figure 2 show that when the same statistical controls are conducted for all HDI dimensions, post-treatment scores show that the manipulative treatment combined with massage was more effective than massage alone, a pattern which remained stable at the subsequent evaluation (follow-up).

Several studies have shown that TTH is closely re-

Treatment group x data point (Between-within subject effects)		
Group	Measurement	Est. Marg. Means,±*SE*, [95% *CI*]
Massage	Pre-test	2.65,±0.08; [2.49, 2.80]
	Post-test	2.47,±0.09; [2.30, 2.64]
	Follow-up	2.29,±0.10; [2.10, 2.48]
Massage +manipulation	Pre-test	2.55,±0.08; [2.40, 2.70]
	Post-test	1.98,±0.10; [1.78, 2.18]
	Follow-up	1.86,±0.10; [1.67, 2.05]
F-value	*F* (1.97, 196.85)=3.64*, η^2=0.04	
Massage	Pre-test	2.16,±0.09; [1.99, 2.33]
	Post-test	1.98,±0.10; [1.78, 2.18]
	Follow-up	1.76,±0.09; [1.38, 1.75]
Massage +manipulation	Pre-test	2.23,±0.09; [2.06, 2.41]
	Post-test	1.71,±0.10; [1.51, 1.90]
	Follow-up	1.57,±0.09; [1.38, 1.75]
F-value	*F* (2, 200.22)=4.03*, η^2=0.04	
Massage	Pre-test	19.86,±1.69; [16.50, 23.22]
	Post-test	17.45,±1.73; [14.02, 20.88]
	Follow-up	14.59,±1.53; [11.54, 17.63]
Massage +manipulation	Pre-test	21.41,±(1.69; [18.05, 24.77]
	Post-test	16.20,±1.73; [12.77, 19.62]
	Follow-up	12.63,±1.53; [9.58, 15.67]
F-value	*F* (1.88, 188.22)=6.94***, η^2=0.06	
Massage	Pre-test	23.65,±1.73; [20.22, 27.02]
	Post-test	21.29,±1.68; [17.97, 24.62]
	Follow-up	17.29,±1.54; [14.25, 20.34]
Massage +manipulation	Pre-test	24.43,±1.73; [21.01, 27.86]
	Post-test	16.57,±1.68; [13.24, 19.89]
	Follow-up	14.47,±1.54; [11.42, 17.52]
F-value	F (1.94, 188.40)=3.23*, η^2=0.03	
Wilks' Λ=0.79; *F* (8, 93)=3.08**, η^2=0.21		

lated to muscle tension which improves with gentle soft tissue treatment.[9, 19] In this study we show that the addition of spinal manipulation was, in general, more effective than treatment with massage alone. In agreement with suggestions from other authors [35] the clinical treatment of patients with TTH must go beyond the local treatment of pain, and rather, should aim to normalize the overall sensitivity of the central nervous system. In this regard, manipulation may positively influence the perpetuation of pain. Moreover, manual therapy applied to this region may improve vascularization and the technique applied in this study, and used in other pathologies, has been shown to enhance circulation.[36, 37]

The functional and emotional aspects of headache disability also play an important role in the subjects' quality of life. This study has taken into account the overall improvement and the functional and emotional aspect in detail with a medium term follow-up. The review by Lante´ri-Minet *et al*., 2011 [38] reports that 17 of the 34 studies reviewed showed a loss of work productivity due to headache. At the functional level, the patient may feel restricted when performing occupational and recreational or social activities, physical symptoms such as pain and functional impairment in his or her daily life, but the treatment applied in this study showed that it had the potential to reduce these drawbacks. At the emotional level, the patient feels disabled, misunderstood, moody, angry, confused and frustrated. Their worldview changes with a significant effect on their family and social situation. Many people-suffering with headache have psychological distress. For example, many patients with recurrent headache have somatization of emotions as a component of their problems. In addition, some headache sufferers have been shown to have alexithymia, problems identifying and feel-

TABLE V.—*Model 2. RM-ANOVA's estimated marginal means, standard errors (SE±) and 95% confidence intervals for the intervention groups across data points (N.=102).*

Measure	Area	Data point (within-subjects effects)		Treatment group x data point (between x within subjects effects)		
		Measurement	Est. Marg. Means,±*SE*, [95% *CI*]	Group	Measurement	Est. Marg. Means,±*SE*, [95% *CI*]
Extension	Upper cervical	Pre-test	15.61,±0.82; [13.98, 17.23]	-	-	-
		Post-test	21.03,±0.92; [19.20, 22.86]			
		Follow-up	20.58,±1.10; [18.39, 22.76]			
	F-value	*F* (1.69, 165.15)=21.03***, η^2=0.17				
	Cervical	Pre-test	45.82,±1.55; [42.74, 48.91]	-	-	-
		Post-test	51.82,±1.46; [48.92, 54.72]			
		Follow-up	51.02,±1.38; [48.28, 53.75]			
	F-value	*F* (1.95, 195.13)=14.47***, η^2=0.13				
		Wilks' Λ=0.60; F (4, 97)=15.94 P<0.001 η^2=0.40				
Flexion	Upper cervical	Pre-test	8.07,±0.38; [7.31, 8.83]	Massage	Pre-test	8.31,±0.54; [7.23, 9.39]
		Post-test	12.16,±0.45; [11.25, 13.06]		Post-test	11.16,±0.64; [9.88, 12.43]
		Follow-up	11.36,±0.48; [10.41, 12.32]		Follow-up	11.06,±0.68; [9.70, 12.41]
	F-value	*F* (1.76, 176.43)=39.66***, η^2=0.28		Massage +manipulation	Pre-test	7.82,±0.54; [6.74, 8.90]
					Post-test	13.16,±0.64; [11.88, 14.43]
					Follow-up	11.67,±0.68; [10.31, 13.02]
				F-value	*F* (1.76, 176.43)=3.29***, η^2=0.03	
	Cervical	Pre-test	50.37,±1.06; [48.27, 52.48]	Massage	Pre-test	48.18,±1.50; [45.20, 51.15]
		Post-test	54.76,±1.07; [52.65, 56.88]		Post-test	55.22,±1.51; [52.22, 58.21]
		Follow-up	53.23,±1.20; [50.85, 55.62]		Follow-up	53.88,±1.70; [50.51, 57.26]
	F-value	*F* (1.88, 188.22)=7.92***, η^2=0.07		Massage +manipulation	Pre-test	52.57,±1.50; [49.59, 55.55]
					Post-test	54.31,±1.51; [51.32, 57.31]
					Follow-up	52.59,±1.70; [49.21, 55.96]
				F-value	*F* (1.88, 176.43)=4.02*, η^2=0.04	
	Multivariate test	Wilks' Λ=0.50; F (4, 97)=23.26***, η^2=0.13		Wilks' Λ=0.87; F (4, 97)=3.65**, η^2=0.13		

***P<0.001; **P<0.01, *P<0.05; A Bonferroni's correction has been applied for multiple comparisons. For parsimony, only estimated marginal means of statistically significant effects are shown. *F*-values were corrected using the Huynh-Feldt correction when necessary.

ing emotions or difficulty regulating emotions such as anger.[39] The emotional aspect of disability caused by headache may be unnoticed for professionals treating these patients. In this sense, Abbass *et al*.[39] suggests to address these aspects through emotion-focused interviews in order to determine the emotional processes that are relevant for each patient.

Other evaluated treatments in patients with CTTH include cervical or thoracic spinal mobilization, which were shown to be effective for pain impact, although they were combined treatments which also included cranio-cervical exercises and postural correction. Although manipulation showed positive effects in this study and may be effective cost-wise, clinically suitable exercise and psychological support can be critical, especially when the headache is chronic.

Limitations and strengths of the study

There are few published randomized controlled trials analyzing the effectiveness of spinal manipulation and/or mobilization for TTH, and there is a need for high-quality randomized controlled trials assessing the effectiveness of these interventions in headache disorders.[36, 40] In this regard, our aim was to perform a clinical trial that met all the requirements to achieve adequate methodological quality. The study adheres to the PEDro checklist for quality assessment of randomized clinical trials in relation to the specified eligibility criteria, random allocation of participants, allocation concealment, similar baseline characteristics of the groups, blinding of the assessors, sufficient data acquirement, report of between-group statistical comparisons, and

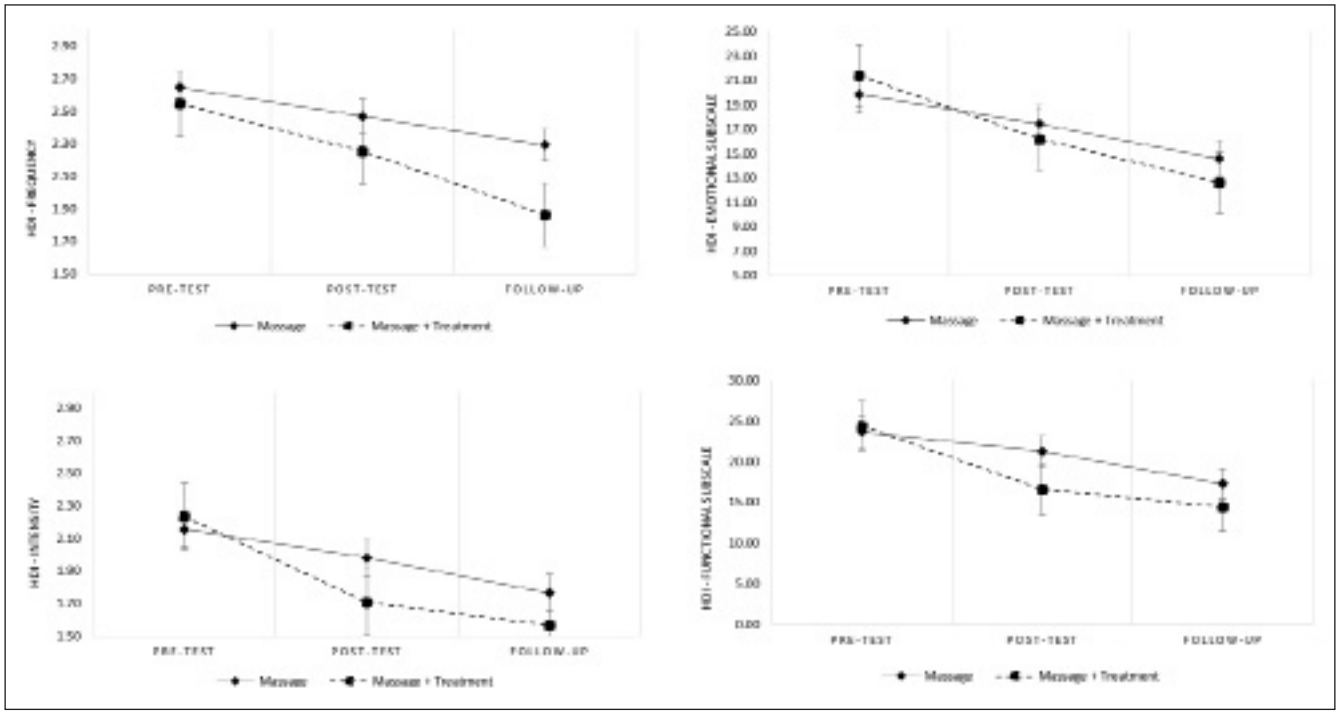

Figure 2.—Estimated marginal means for the intervention groups across data points for scores on the Headache Disability Inventory.

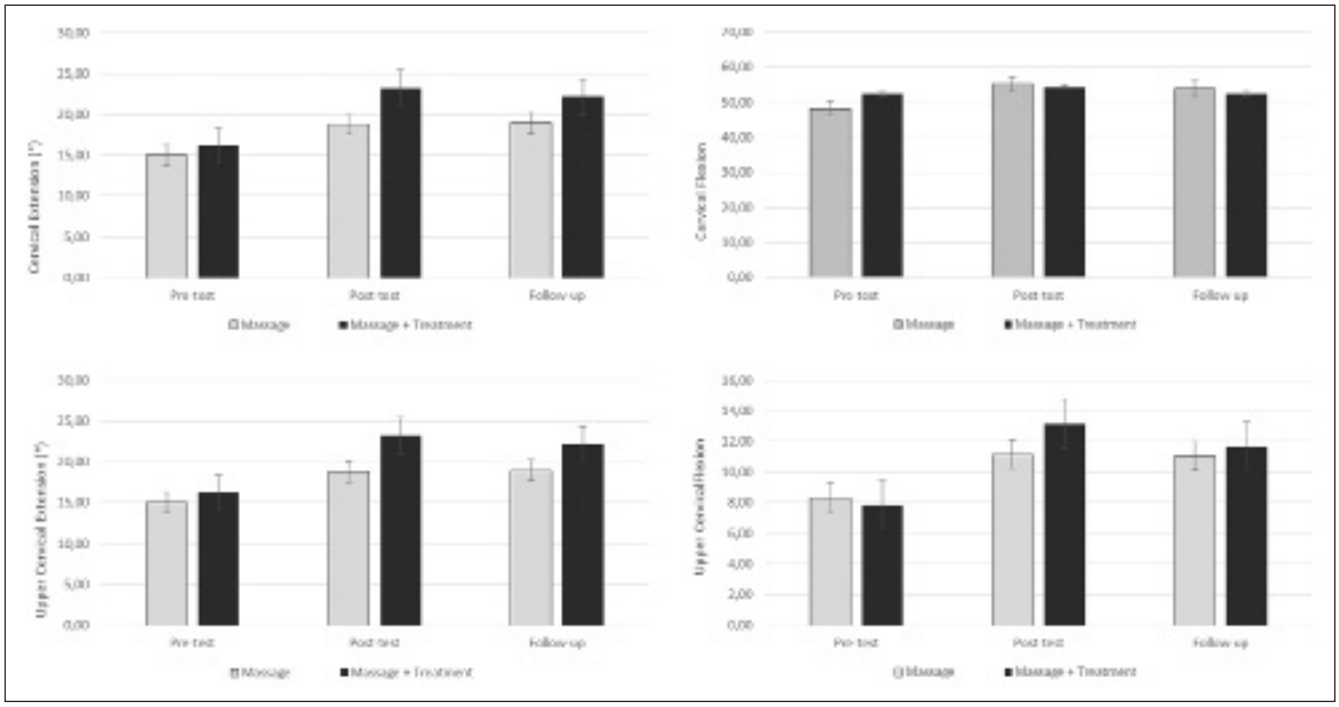

Figure 3.—Estimated marginal means for the intervention groups across data points for cervical and upper cervical flexion and extension range of motion (°).

the report of point measures and measures of variability. However, the participants were not blinded as they were aware that the treatment may or may not include manipulation when providing consents to participate in the study. Moreover, although the therapist was blinded to the study's objective, the therapist was obviously aware of the treatment applied.

Our study is unique because it is one of the few that has demonstrated the effectiveness of manipulative therapy in the treatment of TTH treatment in terms of both headache disability and physical measures (*i.e.* range of motion). In addition, the sample is sufficiently representative, the study is methodologically rigorous, a potentially beneficial treatment for both groups of patients was provided, and its reproducibility by specialized therapists in manual therapy is possible. However, although this study validates treatment focused on the suboccipital region as an important component of TTH treatment, it should be made clear that application of spinal manipulative techniques requires therapeutic specialization. It is possible that mobilization of the suboccipital region without the audible pop[41] could have achieved the same results without the need for actual manipulation and this needs to be tested in future studies.

A possible limitation of this study is that it failed to consider muscle response to treatment and, although this was not an objective of the study, the authors suggest that future studies should account for this aspect and include measures of muscle activity (*i.e.* electromyography). A second limitation is the absence of a long-term follow-up. In this regard, we suggest future longitudinal studies with a longer follow-up. We also recommend a multidisciplinary approach that not only includes physical techniques, but also psychological support when needed. As known, there can be many emotional aspects to headache[39] which may need to be specifically addressed.

Conclusions

This study confirms the efficacy derived from the application of treatment focused on the upper cervical region for TTH. Both interventions, massage alone or massage combined with manipulation, showed positive results for headache relief. However, the addition of manipulation was more effective at improving upper cervical and cervical flexion range of motion. Moreover, the addition of manipulation was more effective than massage alone for reducing the impact of headache on the four sub-dimensions of the HDI.

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Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Article first published online: March 18, 2016. - Manuscript accepted: March 16, 2016. - Manuscript revised: March 8, 2016. - Manuscript received: August 25, 2015.