

# Effects of upper cervical translatoric mobilization on headache, quality of life, cervical mobility and pressure pain threshold in patients with cervicogenic headache: A randomized controlled trial.

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## Research article

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# Abstract

## Objective

The purpose of this study was to evaluate the effects of upper cervical translatoric spinal mobilization (UC-TSM) on headache, quality of life, cervical mobility and pressure pain threshold in subjects with cervicogenic headache (CEH).

## Methods

Eighty-two volunteers ( $41.5 \pm 15.3$  years; 20 males and 62 females) with CEH participated in the study and were randomly assigned to control or treatment group. The treatment group received 3 sessions of UC-TSM and the control group remained the same sessions, in the same position and time but received no treatment. Primary outcomes were Headache Impact Test for headache-related quality of life and flexion-rotation test for upper cervical mobility. Secondary outcomes included intensity, frequency and duration of headache, general cervical mobility and pressure pain thresholds over cervical spine. They were measured at baseline, at the end of the treatment and one month after the intervention.

## Results

UC-TSM group increased significantly headache-related quality of life ( $p < .001$ ;  $d = .857$ ). Headache intensity, frequency and duration improved in UC-TSM group ( $p = .000-.013$ ), in contrast to control group which did not obtain significant changes ( $p = .234-.965$ ). UC-TSM group presented significant increases in upper cervical mobility ( $p < .001$ ). Between-group effect sizes were considered large at T1 ( $d = 0.90-1.21$ ) and moderate to large at T2 ( $d = 0.78-1.17$ ).

## Conclusions

Three sessions of UC-TSM increased headache-related quality of life and upper cervical mobility in subjects with CEH. Intensity, duration and frequency of headache, cervical mobility and PPT also improved. Further research considering the limitations of the present clinical trial is required to confirm this tendency.

## 1. Introduction

Cervicogenic headache (CEH) is a secondary headache arising from disorders of the cervical spine (International Headache Society, 2013). The anatomical basis for CEH is the convergence of the upper cervical spine (C1-C3) and trigeminal afferent tracts in the trigeminocervical nucleus. This convergence results in cervical spine nociceptive input being expressed particularly in the sensory distribution of the ophthalmic branch of the trigeminal nerve, referring symptoms to the forehead, temple, and orbit (Bogduk,

2001). Therefore, any structure innervated by C1, C2, or C3 spinal nerves can be the source of CEH (Biondi, 2000).

CEH is characterized by unilateral headache with symptoms and signs of neck involvement, including reduction in cervical range of motion and pain on palpation of the neck, especially on the upper cervical spine (Sjaastad et al., 1998). Restoration of the upper cervical mobility is therefore considered essential for the treatment of CEH. Manual therapy interventions seek to restore upper cervical mobility through a wide range of therapeutic procedures including mobilization or manipulation techniques. Previous clinical trials and systematic reviews reported preliminary evidence for the application of upper cervical manual therapy techniques for the management of CEH (Vernon et al., 1989; Chaibi and Russell, 2012).

Although severe harm of the patient after cervical manual therapy procedures are extremely rare (Ernst, 2007; Cassidy et al., 2008), there is an international discussion regarding the adoption of safety measures for manual techniques in the cervical spine. In order to guide clinical reasoning for the assessment and intervention of the cervical spine region focusing on mobilization and manipulation techniques, the International Federation of Orthopaedic Manipulative Physical Therapists (IFOMPT) developed a consensus clinical reasoning framework for best practice, through an iterative consultative process with experts and manual physical therapy organisations (Rushton et al., 2014). The aim of the framework development was to guide clinical reasoning for the assessment and treatment of the cervical spine region focussing on techniques occurring in end range positions, notably during passive joint mobilization, exercise, and high velocity thrust manipulation interventions. Considerations for manual therapy practice of the cervical spine region presented in the framework include minimising end-range cervical techniques, force minimisation, and monitoring for adverse effects (Rushton et al., 2014).

Upper cervical translatoric spinal mobilization (UC-TSM) techniques have been suggested as a safe alternative that meets the criteria proposed by IFOMPT. Translatoric Spinal Mobilization (TSM) is defined as a system of manual techniques using straight-line forces delivered in a parallel or perpendicular direction to an individual vertebral joint or motion segment (Krauss et al., 2006). An increasing body of evidence supporting the clinical effectiveness (Creighton et al., 2005; Kondratek et al., 2006; Krauss et al., 2008) and safety (Kondratek et al., 2006; Maher et al., 2010; Creighton et al., 2011) of TSM in the management of patients with cervical impairments has appeared during the last years. Nevertheless, to the best of the authors' knowledge, no study to date has investigated the long-term effects of UC-TSM in patients with CEH. Therefore, the purpose of this randomized controlled trial was to determine effects of UC-TSM on headache, quality of life, cervical mobility and cervical pressure pain thresholds (PPT) in patients with CEH.

## 2. Methods

The study design was a two-group (parallel) randomized controlled trial with pre- and post-intervention measurements (clinical trial registration number NCT02422862). Concealed allocation was performed using a computer-generated randomized table of numbers created prior to start of data collection by a

researcher not involved in the recruitment or intervention. The allocation ratio was 1:1. The study was conducted in accordance with the Declaration of Helsinki and approved by the local ethics committee (Comité Ético de Investigación Clínica de Aragón). All participants provided informed consent before their enrolment in the study. This clinical trial was carried out in the facilities of the Faculty of Health Sciences (University of Zaragoza, Spain).

## 2.1. Participants

Eighty-two volunteers (20 male, 62 female), aged 18–80 participated in the clinical trial (Fig. 1). The inclusion criteria were: age over 18 years old and present a diagnosis of CEH according to Sjaastad et al. (1998): subjects had to fulfil both parts I and III of the major criteria (pain aggravated by neck movement, sustained position or external pressure, restricted cervical range of motion and unilateral pain starting in the neck and radiating to the frontotemporal region) (Sjaastad et al., 1998). These criteria have demonstrated moderate to good reliability (van Suijlekom et al., 1999). Anaesthetic blockades were not used as a criterion for CEH, as the procedure was considered too invasive and is not readily accessible to most clinicians. Potential participants were excluded if they had received cervical treatment in the previous month, presented red flags for headache or any contraindications to manual therapy, or were currently involved in compensations.

## 2.2. Sample size calculation

The sample size was calculated using Minitab 13.0 for the primary outcome measures. The calculations were based on detecting differences of 4.63 units in Headache Impact Test (HIT-6) (De Hertogh et al., 2009) and 10.0° in FRT (Hall and Robinson, 2004; Ogince et al., 2007; pilot data) at post data, assuming a standard deviation (SD) of 7.52 units and 7.74° respectively, a 2-tailed test, an  $\alpha$  level of 0.05 and a desired power ( $\beta$ ) of 90%. These assumptions generated a sample size of 41 subjects per group.

## 2.3. Procedure / Study protocol

Participants were randomly allocated to the control ( $n = 41$ ) and treatment (UC-TSM) ( $n = 41$ ) groups using a computer generated sequence of numbers (simple randomization) performed by an independent blinded investigator. A second researcher assigned an intervention group to each number. To implement the random allocation sequence, sequentially numbered opaque sealed envelopes (SNOSE) was used. Participants were recruited by a different researcher who was blinded to the number sequence and intervention assignment. The researcher who had to apply the manual treatment opened the opaque sealed envelope.

## 2.4. Outcome measures

The primary outcome measures reported in this study were headache-related quality of life and upper cervical mobility using flexion-rotation test (FRT). Secondary outcomes included general cervical mobility, intensity, frequency and duration of headache and cervical pressure pain thresholds (PPTs).

First, headache-related quality of life was assessed using HIT-6, a validated survey developed to provide a quantification of impact of headache on sufferers' lives (Martin et al., 2004). HIT-6 has demonstrated good reliability in headache patients (Cronbach's  $\alpha$ : 0.75–0.92; intraclass correlation coefficient: 0.76–0.80) (Rendas-Baum et al., 2014).

Physical tests of the cervical spine included active cervical movements in all cardinal planes for the assessment of general cervical mobility and the flexion-rotation test (FRT) for the assessment of upper cervical mobility. For active tests, subjects were asked to move their head as far as they could without pain (Edmondston et al., 2005). The FRT, which has been reported to be a valid and reliable measurement of upper cervical movement, predominantly at C1-C2, was performed with the patient supine according to a method previously described by Hall et al. (2008) and Takasaki et al (2011). The CROM device (Pastimo Airguide, Buffalo Grove, Illinois) was used to measure the cervical mobility. The CROM device is a reliable and valid method for measuring active and passive cervical mobility (Williams et al., 2010). Three measurements of each movement were performed and the mean was used for further analysis.

Intensity, frequency and duration of headache were reported by the patient in relation to the previous month. Headache intensity was rated on a visual analogue scale (VAS), a valid and reliable tool for measuring pain intensity widely used for pain-related research (Conti et al., 2001; Lundeberg et al., 2001). A continuous vertical line of 10 cm, anchored by 2 verbal descriptors ("no pain" and "worst imaginable pain"), one for each extreme, was used. It has been reported that, for patients with neck pain, the minimal detectable change and the minimal clinically important difference (MCID) is 1.3 and 2.1 points respectively (Cleland et al., 2008). However, there are no available data for the minimal detectable change and MCID in patients with headache. The frequency and duration of headache were reported as the number of headache episodes and their average duration during the previous month.

Finally, cervical PPT was measured using a digital algometer (Somedic AB Farsta) with a round surface area of 1 cm<sup>2</sup>, with pressure applied at a rate of 1 kg/cm<sup>2</sup>/s perpendicular to the skin. With the subject supine, PPT was assessed over 3 points bilaterally: upper trapezius muscle, C2-C3 zygapophyseal joint and suboccipital muscles. Participants were instructed to press the button of the digital algometer at the precise moment that pressure sensation changed to pain. A 30-second resting period was allowed between each measure. The mean of 3 trials was calculated over each point and used for analysis. The reliability of PPT measurement has been found to be high (intraclass correlation coefficient = 0.91–0.97) (Chesterton et al., 2007; Jones et al., 2007) and minimal detectable change (MDC) for PPT over the cervical spine in patients with neck pain was 47.2 kPa (Walton et al., 2011).

Two investigators with orthopaedic manual therapy specialized training and more than 5 years of experience, performed the outcome measures at baseline (T0), immediately after the intervention (T1) and one month after the intervention (T2). They were blinded to the allocation group of each subject throughout the process. Participants were not informed of the assignment group.

## 2.5. Intervention

The UC-TSM group received 3 non-consecutive sessions of treatment during 5 days. Each treatment session consisted of 30-seconds series of translatoric mobilizations of the upper cervical spine with 10-seconds rest between sets, during 30 minutes. For that purpose, the patient was positioned in supine, with the cervical spine in neutral position. The therapist placed a hand dorsally at the level of the vertebral arch of C1 with the metacarpophalangeal and radial border of the index finger. The other hand was placed posteriorly under the occiput, with the shoulder positioned anteriorly on the patient's forehead. The mobilization force was directed dorsally from the shoulder until the therapist felt a marked resistance and then slightly more pressure was applied in order to perform a stretching mobilization. No pain was reported by the subjects during the intervention. Nevertheless, participants were asked to report any adverse event that they experienced after the intervention and during a 1-month follow-up. The control group received no treatment intervention, remaining in supine lying for 30 minutes (a position and time similar to those for the UC-TSM group).

The treatment was applied by one therapist with orthopaedic manual therapy specialized training and more than 5 years of manual therapy experience.

## 2.6. Statistical analysis

Statistical analysis was conducted with the SPSS 15.0 package (IBM, Armonk, New York). The mean and standard deviation were calculated for each variable. The Kolmogorov-Smirnov test was used to determine a normal distribution of quantitative data ( $p > .05$ ). Intra-group and inter-group differences were analyzed using Student  $t$  test. For the variables that did not follow a Gaussian distribution, nonparametric analysis was carried out for statistical evaluation using the Mann-Whitney  $U$  test and Wilcoxon signed-rank test. Effect sizes were calculated using Cohen's  $d$  coefficient (Cohen, 1988). An effect size  $> 0.8$  was considered large; around 0.5, moderate; and  $< 0.2$ , small (Cohen, 1988). All subjects enrolled originally were included in the final analysis as planned (no participant was excluded or dropped out). Thus, participants were analyzed as per protocol (i.e., by intention-to-treat). The level of significance was set at  $p < .05$ .

## 3. Results

One hundred and sixty-two volunteers with headache were recruited. Eighty-two participants (20 male and 62 female; 41.5 years, SD = 15.3 years) satisfied all the eligibility criteria and agreed to participate. Forty-one subjects were randomly assigned to each group, received the intended treatment and were analyzed with respect to outcome. The patients' demographic characteristics are summarized in Table 1. There were no significant differences between the two groups ( $p > .05$ ) at baseline, so it could be assumed that both groups were comparable in all variables (Table 1).

Table 1  
Baseline features for both groups.

	Control Group (n = 41)	UC-TSM Group (n = 41)	P
Clinical Features	40.59 ± 15.10	42.49 ± 15.61	.498
Age (years)	10 M: 31 F	10 M: 31 F	.999
Sex (M/F)	1.65 ± 0.08	1.65 ± 0.09	.905
Height (m)	67.71 ± 14.88	68.76 ± 15.25	.754
Weight (kg)			
Quality of Life (HIT-6)	59.49 ± 7.53	60.51 ± 6.65	.465
Headache Characteristics	2.85 ± 1.96	3.41 ± 2.24	.269
Headache Intensity (0–10 VAS)	8.38 ± 1.45	8.28 ± 1.88	.830
Average	.26 ± .71	.15 ± .41	.773
Maximum	13.73 ± 11.06	13.56 ± 10.20	.933
Minimum	20.09 ± 22.06	24.07 ± 34.14	.647
Headache Frequency (episodes/month)			
Headache Duration (hours/episode)			
PPTs (kPa)	415.93 ± 172.71	447.34 ± 269.87	.989
Thenar eminence (R)	469.23 ± 167.30	462.46 ± 233.57	.481
Thenar eminence (L)	224.54 ± 172.48	229.10 ± 129.01	.478
Upper trapezius (R)	250.39 ± 163.37	235.76 ± 111.48	.878
Upper trapezius (L)	207.12 ± 108.90	216.44 ± 100.97	.409
C2-C3 (R)	209.68 ± 113.20	213.12 ± 87.49	.578
C2-C3 (L)	240.98 ± 128.03	253.41 ± 98.63	.252
Suboccipital (R)	237.20 ± 131.27	259.71 ± 117.20	.206
Suboccipital (L)			
Upper cervical ROM (°)	32.67 ± 9.61	30.06 ± 8.60	.199
FRT (R)	36.22 ± 8.06	37.20 ± 8.90	.602
FRT (L)			
General cervical ROM (°)	52.98 ± 52.67	52.38 ± 12.27	.832
Flexion	57.48 ± 11.68	57.14 ± 13.19	.846
Extension	35.88 ± 9.06	38.19 ± 9.14	.253
Side-bending (R)	37.30 ± 9.59	38.16 ± 9.79	.688
Side-bending (L)	62.90 ± 9.24	64.18 ± 11.20	.574
Rotation (R)	62.40 ± 12.94	64.46 ± 12.43	.462
Rotation (L)	308.39 ± 54.19	314.51 ± 59.23	.627
Total			
Values are expressed as mean ± SD. F: female; FRT: flexion-rotation test; L: left; M: male; ROM: range of motion; R: right; UC: upper cervical; UC-TSM: upper cervical translatoric spinal mobilization.			

One month after the intervention, UC-TSM group improved significantly headache-related quality of life ( $p < .001$ ) with a large effect size ( $d = .857$ ) (Table 2). In the other hand, no significant differences were found in the control group ( $p = .839$ ) (Table 2). Comparison between groups one month after the intervention showed a significant improvement in UC-TSM group compared to the control group ( $p = .0001$ ;  $d = .994$ ) (Table 2).

Table 2  
Pre-treatment and Follow-up measurements and differences for pain-related outcomes.

Outcome / Group	T0 (Pre-treatment)	T2 (Follow-up)	Within-group ( <i>p</i> )	Between-group ( <i>p</i> )
Quality of Life ( <i>HIT-6</i> )	59.49 ± 7.57	59.27 ± 8.39	.839	.001*
Control Group	60.51 ± 6.65	50.54 ± 10.94	<i>d</i> = .000	<i>d</i> = .994
UC-TSM Group			< .001*	
			<i>d</i> = .857	
Headache Characteristics	2.85 ± 1.96	2.96 ± 2.08	.234	.020*
<i>Headache Intensity (0–10 VAS)</i>	3.41 ± 2.24	1.95 ± 2.12	<i>d</i> = .000	<i>d</i> = .500
<i>Average</i>	8.38 ± 1.45	8.32 ± 1.33	< .001*	< .001*
Control Group	8.28 ± 1.88	5.23 ± 3.68	<i>d</i> = .707	<i>d</i> = 1.34
UC-TSM Group	.26 ± .72	.27 ± .92	.569	.095
<i>Maximum</i>	.15 ± .42	.06 ± .31	<i>d</i> = .000	<i>d</i> = .306
Control Group	13.73 ± 11.06	14.00 ± 10.97	< .001*	< .001*
UC-TSM Group	13.56 ± 10.20	7.32 ± 10.22	<i>d</i> = .949	<i>d</i> = .701
<i>Minimum</i>	20.09 ± 22.06	17.70 ± 18.64	.635	< .001*
Control Group	24.07 ± 34.14	7.95 ± 10.62	<i>d</i> = .000	<i>d</i> = .687
UC-TSM Group			.013*	
<i>Headache Frequency (episodes/month)</i>			<i>d</i> = .172	
			.965	
Control Group			<i>d</i> = .000	
UC-TSM Group			< .001*	
<i>Headache Duration (hours/episode)</i>			<i>d</i> = .424	
Control Group			.139	
UC-TSM Group			<i>d</i> = .105	
			< .001*	
			<i>d</i> = .480	

Values are expressed as mean ± SD. HIT-6: headache impact test; UC-TSM: upper cervical translatoric spinal mobilization; VAS: visual analogue scale.

## Headache

One month after the intervention, average, maximum and minimum headache intensity improved significantly in UC-TSM group ( $p = .000-0.013$ ), in contrast to control group which did not obtain significant changes ( $p = .234-.635$ ). Regarding headache frequency, UC-TSM group passed from 13.56 episodes per month ( $SD = 10.20$ ) to 7.32 ( $SD = 10.22$ ) ( $p < .001$ ) with a moderate effect size ( $d = .424$ ). Control group did not change the frequency of headache ( $p = .965$ ), with significant differences between groups ( $p < .001$ ) and moderate effect size ( $d = .701$ ). Duration of headache in UC-TSM group reduced significantly from 24.07 hours per episode ( $SD = 34 - 14$ ) to 7.95 ( $SD = 10.62$ ) ( $p < .001$ ;  $d = .480$ ). Table 2 shows pain-related outcomes in both groups.

## Upper Cervical range of motion

A significant increase in upper cervical range of motion was observed after the intervention for the UC-TSM group in FRT ( $p < .001$ ) (Table 3). Pre-post effect sizes varied from moderate to large ( $d = 0.399-1.000$ ) for the UC-TSM group. These differences remained after one month follow-up for total FRT and right FRT, however did not reach statistical signification for left FRT. For the control group, there were no statistically significant differences between pre- and post-treatment and 1 month follow up except for right FRT ( $p < .003$ ), with a reduction in ROM at 1 month follow up (Table 3). UC-TSM group experienced significant increases in upper cervical range of motion as compared with the control group in the FRT to the right ( $p < .001$  at T1 and T2) and left ( $p < .001$  at T1 and  $p < .003$  at T2) (Table 3). Between-group effect sizes were considered large at T1 ( $d = 0.90-1.21$ ) and moderate to large at T2 ( $d = 0.78-1.17$ ).

Table 3

Pre-treatment, Post-treatment and Follow-up measurements and differences for upper cervical mobility outcomes.

Outcome / Group	T0 (Pre-treatment)	T1 (Post-treatment)	T2 (1 month Follow-up)	Within-group (T1) ( <i>p</i> )	Within-group (T2) ( <i>p</i> )	Between-group ( <i>p</i> )
FRT (R)	32.67 ± 9.61	30.55 ± 10.14	26.74 ± 9.66	.081	.003*	< .001* (T1)
Control Group			35.76 ± 6.77	<i>d</i> = .149	<i>d</i> = .471	<i>d</i> = 1.213
UC-TSM Group	30.06 ± 8.60	40.71 ± 6.65		< .001*	.003*	< .001* (T2)
				<i>d</i> = 1.000	<i>d</i> = .500	<i>d</i> = 1.177
FRT (L)	36.22 ± 8.06	34.50 ± 11.31	33.73 ± 9.72	.717	.084	.001* (T1)
Control Group			39.74 ± 6.51	<i>d</i> = .147	<i>d</i> = .249	<i>d</i> = .903
UC-TSM Group	37.20 ± 8.90	42.60 ± 6.13		< .001*	.077	< .003* (T2)
				<i>d</i> = .399	<i>d</i> = .236	<i>d</i> = .784
Total	68.91 ± 14.62	65.29 ± 20.17	60.47 ± 17.63	.105	.002*	< .001* (T1)
Control Group			75.50 ± 12.10	<i>d</i> = .123	<i>d</i> = .363	<i>d</i> = 1.115
UC-TSM Group	67.27 ± 15.08	83.31 ± 11.92		< .001*	< .001*	< .001* (T2)
				<i>d</i> = .721	<i>d</i> = .416	<i>d</i> = 1.019
Values are expressed as mean ± SD. FRT: flexion-rotation test; L: left; R: right; UC-TSM: upper cervical translatoric spinal mobilization.						

### Cervical range of motion

In contrast with the control group, a statistical significant increase of ROM in all planes of movement in the cervical spine was observed at the end of the treatment and 1 month follow up for the UC-TSM group (flexion ( $p < .001$  at T1;  $p = .002$  at T2); extension ( $p = .008$  at T1;  $p < .001$  at T2); right sidebending ( $p = .002$  at T1;  $p = .005$  at T2); left side-bending ( $p < .001$  at T1;  $p = .003$  at T2), right rotation ( $p < .001$  at T1;  $p = 0.04$  at T2), left rotation ( $p < .001$  at T1;  $p = .002$  at T2)); however pre-post effect sizes were small to moderate (Table 4).

Table 4  
Pre-treatment, Post-treatment and Follow-up measurements and differences for cervical mobility outcomes.

Outcome / Group	T0 (Pre-treatment)	T1 (Post-treatment)	T2 (1 month Follow-up)	Within-group (T1) ( <i>p</i> )	Within-group (T2) ( <i>p</i> )	Between-group ( <i>p</i> )
Cervical Flexion	52.98 ± 13.12	48.45 ± 12.99	52.06 ± 14.93	.005*	.594	<.001* (T1)
Control Group			57.61 ± 11.96	<i>d</i> = .225	<i>d</i> = .000	<i>d</i> = 1.037
UC-TSM Group	52.38 ± 12.27	59.81 ± 9.47		<.001* <i>d</i> = .467	.002* <i>d</i> = .307	.067 (T2) <i>d</i> = .397
Cervical Extension	57.48 ± 11.68	54.63 ± 12.44	55.50 ± 13.14	.077	.877	.020* (T1)
Control Group	57.14 ± 13.19	61.35 ± 13.23	61.85 ± 12.64	<i>d</i> = .184	<i>d</i> = .117	<i>d</i> = .560
UC-TSM Group				.008* <i>d</i> = .218	<.001* <i>d</i> = 0,226	.029* (T2) <i>d</i> = .480
Cervical Side-bending (R)	35.88 ± 9.06	35.91 ± 9.85	37.08 ± 10.89	.975	.264	.021* (T1)
Control Group	38.19 ± 9.14	40.84 ± 9.16	40.29 ± 8.85	<i>d</i> = .000	<i>d</i> = .149	<i>d</i> = .649
UC-TSM Group				.002* <i>d</i> = .157	.005* <i>d</i> = .166	.066 (T2) <i>d</i> = .344
Cervical Side-bending (L)	37.30 ± 9.59	37.65 ± 10.82	37.45 ± 11.19	.679	.873	.030* (T1)
Control Group	38.16 ± 9.79	42.42 ± 8.55	40.59 ± 8.61	<i>d</i> = .000	<i>d</i> = .000	<i>d</i> = .552
UC-TSM Group				<.001* <i>d</i> = .332	.003* <i>d</i> = .166	.159 (T2) <i>d</i> = .312

Values are expressed as mean ± SD. L: left; R: right; UC-TSM: upper cervical translatoric spinal mobilization.

Outcome / Group	T0 (Pre-treatment)	T1 (Post-treatment)	T2 (1 month Follow-up)	Within-group (T1) ( <i>p</i> )	Within-group (T2) ( <i>p</i> )	Between-group ( <i>p</i> )
Cervical Rotation (R)	62.90 ± 9.24	62.11 ± 10.93	62.94 ± 11.22	.456	.965	.001* (T1)
Control Group	64.18 ± 11.20	69.77 ± 9.84	68.24 ± 9.29	<i>d</i> = .000	<i>d</i> = .000	<i>d</i> = .736
UC-TSM Group				< .001*	.004*	.022* (T2)
				<i>d</i> = 0,352	<i>d</i> = .281	<i>d</i> = .597
Cervical Rotation (L)	62.39 ± 12.94	61.95 ± 12.40	63.39 ± 13.63	.741	.320	.002* (T1)
Control Group	64.46 ± 12.43	69.93 ± 10.06	68.50 ± 11.14	<i>d</i> = .059	<i>d</i> = .057	<i>d</i> = .724
UC-TSM Group				< .001*	.002*	.098 (T2)
				<i>d</i> = .320	<i>d</i> = .244	<i>d</i> = .415
Total	308.39 ± 54.19	301.28 ± 60.23	307.88 ± 64.38	.145	.893	.001* (T1)
Control Group				<i>d</i> = .087	<i>d</i> = .012	<i>d</i> = .772
UC-TSM Group	314.51 ± 59.23	344.07 ± 51.38	336.83 ± 53.42	< .001*	< .001*	.029* (T2)
				<i>d</i> = .385	<i>d</i> = .278	<i>d</i> = .494
Values are expressed as mean ± SD. L: left; R: right; UC-TSM: upper cervical translatoric spinal mobilization.						

In the between-group comparison, the UC-TSM group experienced significant increases in cervical range of movement as compared with the control group in all movements in T1 and in extension, right rotation and total cervical ROM in T2 (Table 4). Between-group effect sizes were moderate to large in T1 ( $0.552 < d < 1.037$ ) and in T2 ( $0.312 < d < 0.597$ ).

#### Pressure pain threshold

There were statistically significant increases in PPT between pre- and post-intervention measurements in the UC-TSM group in T1 (Right thenar eminence ( $p = .023$ ); right upper trapezius ( $p = .033$ ); left upper trapezius ( $p = .023$ ); left C2-C3 ( $p = .04$ ); right suboccipital ( $p = .034$ ) and left suboccipital ( $p = .017$ ) and T2 (Right thenar eminence ( $p = .05$ )) with small size effects ( $d < .2$ ). In the control group, there were statistically significant reductions in PPT in T1 (Left thenar eminence ( $p = .042$ ); left upper trapezius ( $p = .04$ )) with between pre- and post-intervention measurements ( $d < .2$ ).

At T1, there were only statistically significant differences between groups in PPT of the right and left suboccipital and upper trapezius with moderate side effects ( $p = .292-.465$ ) (Table 5). However, there were no statistical significant differences between groups at T2 (1 month follow up). (Table 5)

Table 5

Pre-treatment, Post-treatment and Follow-up measurements and differences for pressure pain threshold outcomes.

Outcome / Group	T0 (Pre-treatment)	T1 (Post-treatment)	T2 (1 month Follow-up)	Within-group (T1) ( <i>p</i> )	Within-group (T2) ( <i>p</i> )	Between-group ( <i>p</i> )
PPT Thenar eminence (R)	415.93 ± 172.71	414.00 ± 166.37	446.07 ± 196.48	.941 <i>d</i> = .004	.162 <i>d</i> = .119	.066 (T1) <i>d</i> = .341
Control Group	447.34 ± 269.87	484.22 ± 238.90	487.41 ± 239.96	.023*	.050*	.428 (T2)
UC-TSM Group				<i>d</i> = .102	<i>d</i> = .111	<i>d</i> = .188
PPT Thenar eminence (L)	469.23 ± 167.30	413.37 ± 174.27	440.80 ± 176.21	.042* <i>d</i> = .231	.243 <i>d</i> = .117	.256 (T1) <i>d</i> = .239
Control Group	462.46 ± 233.57	460.76 ± 217.62	489.17 ± 261.15	.776	.306	.693 (T2)
UC-TSM Group				<i>d</i> = .005	<i>d</i> = .076	<i>d</i> = .220
PPT Upper Trapezius (R)	224.54 ± 172.48	214.12 ± 119.41	230.73 ± 137.26	.877 <i>d</i> = .050	.468 <i>d</i> = .028	.045* (T1) <i>d</i> = .292
Control Group	229.10 ± 129.01	248.56 ± 114.50	249.78 ± 142.51	.033*	.231	.295 (T2)
UC-TSM Group				<i>d</i> = .113	<i>d</i> = .108	<i>d</i> = .136
PPT Upper Trapezius (L)	250.39 ± 163.37	217.80 ± 117.70	238.66 ± 126.88	.040* <i>d</i> = .162	.174 <i>d</i> = .057	.022* (T1) <i>d</i> = .349
Control Group	235.76 ± 111.48	257.63 ± 112.86	254.24 ± 114.93	.023*	.136	.211 (T2)
UC-TSM Group				<i>d</i> = .138	<i>d</i> = .115	<i>d</i> = .133
PPT C2-C3 (R)	207.12 ± 108.90	195.88 ± 89.39	215.02 ± 92.74	.408 <i>d</i> = .080	.510 <i>d</i> = .055	.053 (T1) <i>d</i> = .390
Control Group	216.44 ± 100.97	236.85 ± 119.62	221.98 ± 114.76	.133	.604	.937 (T2)
UC-TSM Group				<i>d</i> = .130	<i>d</i> = .036	<i>d</i> = .254

Values are expressed as mean ± SD. L: left; PPT: pressure pain threshold; R: right; UC-TSM: upper cervical translatoric spinal mobilization.

Outcome / Group	T0 (Pre-treatment)	T1 (Post-treatment)	T2 (1 month Follow-up)	Within-group (T1) ( <i>p</i> )	Within-group (T2) ( <i>p</i> )	Between-group ( <i>p</i> )
PPT C2-C3 (L)	209.68 ± 113.20	198.15 ± 99.09	209.07 ± 95.74	.279	.904	.056 (post)
Control Group				<i>d</i> = .077	<i>d</i> = .004	<i>d</i> = .313
UC-TSM Group	213.12 ± 87.49	229.12 ± 99.69	226.34 ± 102.76	.040*	.191	.366 (FU)
				<i>d</i> = .121	<i>d</i> = .098	<i>d</i> = .172
PPT Suboccipital (R)	240.98 ± 128.03	228.88 ± 131.10	255.51 ± 134.99	.506	.204	.007* (T1)
Control Group				<i>d</i> = .066	<i>d</i> = .078	<i>d</i> = .420
UC-TSM Group	253.41 ± 98.63	283.78 ± 131.21	265.51 ± 149.11	.034*	.762	.745 (T2)
				<i>d</i> = .185	<i>d</i> = .068	<i>d</i> = .071
PPT Suboccipital (L)	237.20 ± 131.27	229.78 ± 132.54	243.59 ± 140.22	.206	.814	.003* (T1)
Control Group				<i>d</i> = .040	<i>d</i> = .033	<i>d</i> = .465
UC-TSM Group	259.71 ± 117.20	294.34 ± 147.63	269.37 ± 159.16	.017*	.761	.640 (T2)
				<i>d</i> = .184	<i>d</i> = .049	<i>d</i> = .174
Values are expressed as mean ± SD. L: left; PPT: pressure pain threshold; R: right; UC-TSM: upper cervical translatoric spinal mobilization.						

No harm or unintended effect derived from the intervention was reported.

## 4. Discussion

This study showed that three sessions of UC-TSM resulted in a short-term increase of headache-related quality of life and upper cervical range in patients with CEH.

Evidence for headache-related quality of life changes following cervical manual therapy interventions

The present study demonstrated that UC-TSM may be effective for an improvement of short term headache-related quality of life in subjects with CEH. One month after the intervention, UC-TSM group showed a statistically significant reduction in HIT-6 score compared to the control group (10.0 (SD 10.6) in UC-TSM vs. 0.2 (SD 2.9) in the control group), with large effect size and superior to the MDC of 8 points (Castien et al., 2012). HIT-6 comprises 6 items (Kosinski et al., 2003): severe pain during headache, the limitations in daily activities, the need to lie down during headaches, tiredness due to headaches, irritation

from headaches, and difficulty concentrating during headaches. By that reason, the improvements of the UC-TSM group in HIT-6 score may involve benefits in all these aspects of headache-related quality of life. The impact in the headache-related quality of life was reinforced by the statistically significant reduction in the headache intensity, frequency and duration produced by the UC-TSM group compared to the control group at one month follow-up. Nevertheless, only reduction in the maximum headache overcame the recommended minimal clinically important difference (MCID) on the VAS of 1–2 points (McCormack et al., 1988; Kelly, 2001). In any case, the results of the present study in terms of headache intensity and MCID should be interpreted and compared with caution. Some have argued that the MCID value varies depending on baseline pain score, with the MCID increasing for higher baseline pain score (Hawker et al., 2011).. In case of low baseline scores as in the current study (mean baseline headache intensity of about 1.5), a difference of 0.5 may be considered a clinically relevant change (Rowbotham, 2001). Considering this aspect and the different methodologies, our study supports the effects of manual therapy in the cervical spine without and within a multimodal approach for the reduction of headache intensity, duration and frequency (Nisson et al., 1995; von Piekartz et al., 2011; Bodes-Pardo et al., 2013).

#### Evidence for cervical mobility changes following cervical manual therapy interventions

The present study demonstrated that UC-TSM may be effective for an improvement of cervical mobility in subjects with CEH with small to moderate effect sizes. The improvements in each plane overcame the lower bound of the standard error of measurement established between 2° and 7° (Sterling et al., 2002). These increases in cervical ROM were superior to the studies of Hidalgo et al. (2016) and Lluch et al. (2013), that used our same technique but with a lower dosage (1 session of 10 minutes and 3 minutes respectively). Our sample presented a total cervical ROM lower than what is considered normal for an asymptomatic sample of similar age (353° (SD = 46)) (Prushansky et al., 2006). In T1, the UC-TSM group almost achieved the normal total cervical ROM (344.07° (SD = 51.38)) from the value in T0 (314.51° (SD = 59.23)) and reduced the total cervical ROM to 336.83 (SD = 53.42) in T2, with statistical signification compared to the control group in both T1 and T2.

In spite of the shown cervical ROM effects, the indication of the translatory mobilization of the occipital-C1 segment is mainly to restore upper cervical dysfunction (Hidalgo et al., 2016). Due to the involvement of the upper cervical spine in CEH, especially the C1-C2 segment (Bogduk, 2001), quantification of the upper cervical mobility is considered more important in the assessment of CEH patients. FRT suppose a valid and reliable tool for testing C1-C2 mobility (Hall et al., 2008; Takasaki et al., 2011). In the present study, increases of FRT in UC-TSM group exceeded the minimal detectable change (Hall et al., 2010) reaching the clinically relevant improvement for patients with CEH (Hall et al., 2004), in right FRT at T1 unlike left FRT (whose increase in FRT was more reduced from an almost normal FRT at baseline ( $37.2 \pm 8.90$ )). At T1, both right and left FRT achieved a ROM in the considered values as normal for asymptomatic subjects (39°-45°) (Amiri et al., 2003; Hall y Robinson, 2004; Ogince et al., 2007). At T2, UC-TSM group showed a statistically significant increase in FRT mobility compared to the control group, however not reaching the MDC. The improvement of FRT mobility obtained in the present study, applying UC-TSM with the cervical spine in neutral position, are comparable to those of previous studies using

different cervical manual techniques applied at the end of the cervical rotation, in asymptomatic subjects (Clements et al., 2001) and patients with neck pain (Dunning et al., 2012) or CEH (Hall et al., 2007). These findings support the efficacy of UC-TSM to increase upper cervical mobility, suggested as a technique in neutral cervical position meeting the international recommendations (Rushton et al., 2014). Based on the available evidence, these results can be explained by a model in which a mechanical input generated by the UC-TSM triggers a cascade of biomechanical and neurophysiological events, leading to an increase of cervical mobility (Bialosky et al., 2009).

### Evidence for hypoalgesic changes following cervical manual therapy interventions

The present study showed that UC-TSM group exhibited statistically significant increases in PPT but with small size effects in T1 and these differences were not maintained in T2. These results are similar to studies using UC-TSM in patients with cervical<sup>43</sup> and craniofacial pain<sup>44</sup>. On the other hand, control group demonstrated a statistically significant reduction of cervical PPT in right thenar eminence in T1. One potential explanation for the reduction in the control group is the possibility that evaluation tests used (especially the use of algometry for PPTs) may have irritated participants (Mansilla-Ferragut et al., 2009), increasing their pain and reducing their cervical mobility.

Current evidence suggest that immediate hypoalgesic effects of manual therapy are possibly due to neurophysiological mechanisms activated, in this case, by the mechanical stimulus of the UC-TSM (Schmid et al., 2010). Possible neurophysiological mechanisms include the activation of descendent pain inhibitory systems via corticospinal projections from the periaqueductal gray matter (PAG) (Paungmali et al., 2003; Skyba et al., 2003). Further studies are needed to determine the mechanisms of hypoalgesic effects of manual therapy interventions in CEH patients.

### Limitations

Although a potential strength of the current controlled clinical trial was the inclusion of a control group without receiving any intervention, we should recognize potential limitations that should be considered. First, headache intensity during the procedure was low in both groups (VAS = 1.31 and 1.58), hindering to make meaningful interpretations of headache intensity results because of the occurrence of a floor effect. For this reason, headache intensity was not used as a main study variable. Additionally, this study presents immediate post-treatment and 1 month follow-up effects of UC-TSM, so mid and long term effects should not be inferred. Third, control group did not receive any type of intervention, so placebo effect cannot be ruled. On the other hand, one therapist provided the treatment in the current study, which may limit the generalization of the results. Finally, CEH subject selection was based on clinical criteria; however anaesthetic blockades were not used as a criterion. Further studies should address these issues.

## 5. Conclusion

Three sessions of UC-TSM showed an improvement of headache-related quality of life and upper cervical mobility in patients with CEH. Intensity, duration and frequency of headache during a month were reduced

in UC-TSM group, with moderate to large effect sizes. General cervical mobility and PPT also improved in UC-TSM group compared to control group, however differences were small and likely of limited clinical value. Further research considering the limitations of the present clinical trial is required to confirm the tendency to an improvement of headache-related quality of life and increase of cervical mobility in patients with CEH.

## Abbreviations

CEH: Cervicogenic headache; FRT: Flexion-rotation test; HIT-6: Headache Impact Test; IFOMPT: International Federation of Orthopaedic Manipulative Physical Therapy; MCID: Minimal clinically important difference; MDC: Minimal detectable change; PPT: Pressure pain threshold; T0: baseline; T1: immediately after the intervention; T2: one month after the intervention; TSM: Translatory spinal mobilization; UC-TSM: Upper cervical translatory spinal mobilization; VAS: Visual analogue scale.

## Declarations

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### Authors' contributions

- MMU: responsible for project, drafting initial manuscript, manuscript revision and study design; JMTM: study design and manuscript revision; EEdM: data analysis and manuscript revision; EBG: data acquisition and manuscript revision; PFM: data acquisition and manuscript revision; CHG: data acquisition and manuscript revision. The authors read and approved the final manuscript.

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### Availability of data and materials

- Anonymized and statistical information of all the participants was made available to and shared only among qualified investigators.

### Ethics approval and consent to participate

- The study was conducted in accordance with the Declaration of Helsinki and approved by the local ethics committee (Comité Ético de Investigación Clínica de Aragón). All participants provided informed consent before their enrolment in the study. This clinical trial was carried out in the facilities of the Faculty of Health Sciences (University of Zaragoza, Spain).

### Consent for publication

- Not applicable.

## Competing interests

- Authors have no conflict of interest to declare.

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## Figures

## CONSORT Flow Diagram

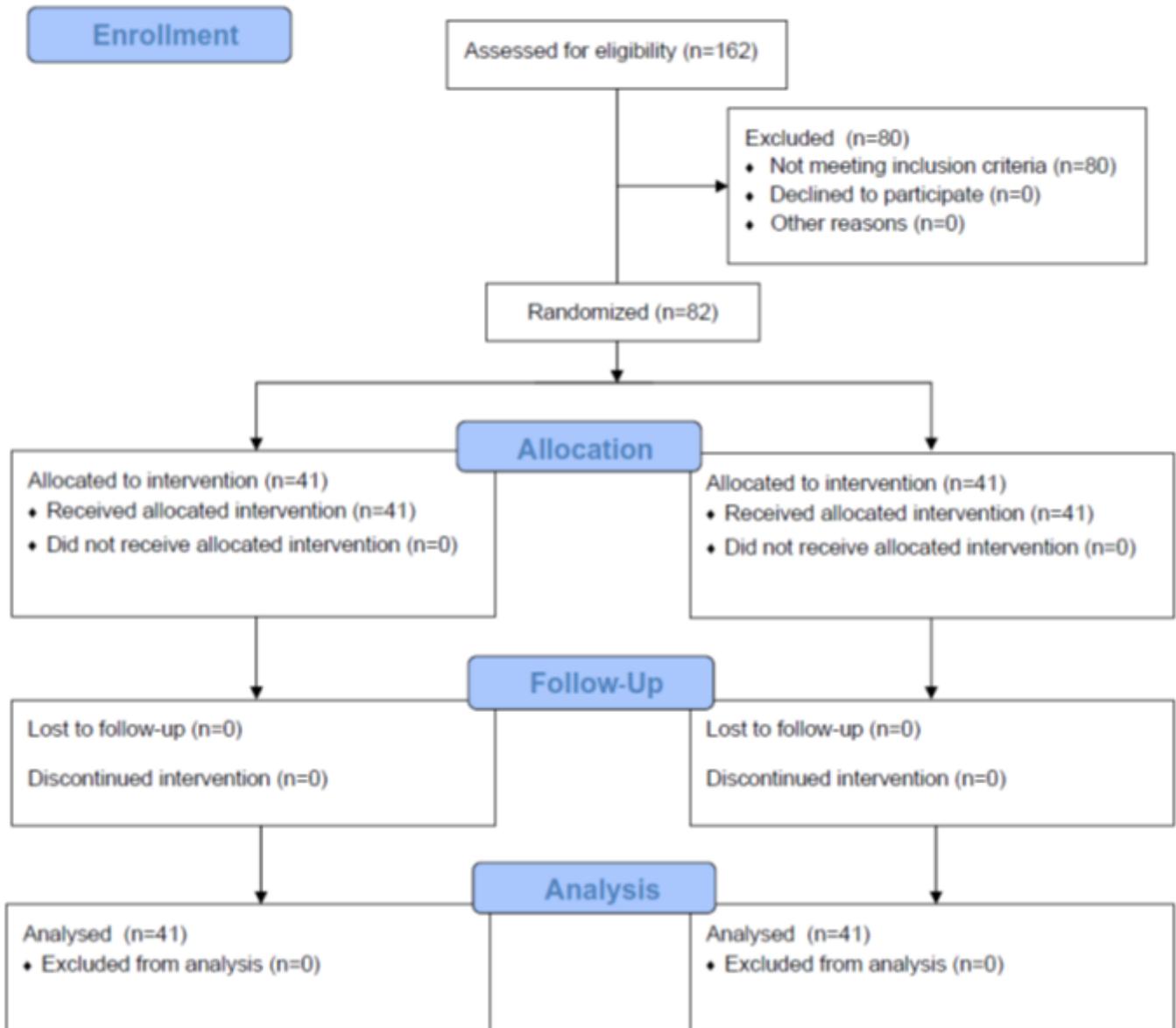


Figure 2

CONSORT (Consolidated Standards of Reporting Trial) flow diagram.