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DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED CLINICAL TRIAL

# Treatment of tension-type headache with articulatory and suboccipital soft tissue therapy: A double-blind, randomized, placebo-controlled clinical trial

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## KEYWORDS

Effectiveness;  
Tension-type  
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**Summary** This study researches the effectiveness of two manual therapy treatments focused on the suboccipital region for tension-type headache.

A randomized double-blind clinical trial was conducted over a period of four weeks with a follow-up at one month. Eighty-four patients with a mean age of 39.7 years (SD 11.4) with tension-type headache were assigned to 4 groups which included the following manual therapy treatment: suboccipital soft tissue inhibition; occiput-atlas-axis global manipulation; combination of both techniques; and a control group.

The primary assessment consisted of collecting socio-demographic data and headache characteristics in a one-month base period, data such as age, gender, severity of pain, intensity and frequency of headache, among other. Outcome secondary assessment were: impact of headache, disability, ranges of motion of the craniocervical junction, frequency and intensity of headache, and pericranial tenderness.

In the month prior to the study, average pain intensity, was rated at 6.49 (SD 1.69), and 66.7% subjects suffered headaches of moderate intensity. After 8 weeks, statistically

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significant improvements were noted. OAA manipulative treatment and combined therapy treatments proved to be more effective than suboccipital soft tissue inhibition for tension-type headache. The treatment with suboccipital soft tissue inhibition, despite producing less significant results, also has positive effects on different aspects of headache.

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## Introduction

Tension-type headache (TTH) is the most common type of primary headache and it represents 47% of headache disorders in adult population worldwide (Jensen and Stovner, 2008). TTH was included in the group of primary headaches by the International Headache Society (IHS, 2004). The cause of TTH has not been established, whereas secondary headaches have a known cause. Most of the patients suffering from TTH are women, with ages around 40 years-old, with a mild to moderate average headache pain intensity (Espí and Gómez, 2010a,b). TTH has an enormous socio-economic impact in terms of hospital costs, medication, consultations with specialists, and laboratory tests (Stovner et al., 2006), and it affects patients' emotional, social and working lives (Holroyd et al., 2000).

The connection between TTH and craniocervical musculoskeletal disorders has already been described, as well as a higher frequency and intensity of pressure pain in suboccipital muscles (Couppe et al., 2007; Fernández-de-Las-Peñas et al., 2008) and variations in head position and neck mobility (Fernández-de-las-Peñas et al., 2006a,b) in patients with TTH. Regarding headache becoming chronic, Buchgreitz et al. (2008) argue that central sensitization caused by prolonged nociceptive input may lead to chronic headache.

Manual treatment reduces headache frequency and intensity (Moraska and Chandler, 2008) and cervical spine manipulation has been shown to be effective in reducing frequency, duration and intensity of headaches in patients with TTH (Fernández-de-las-Peñas et al., 2006a,b). However, although TTH is generally characterized by interparietal and occipital location of pain, the effectiveness of suboccipital soft tissue inhibition (SI) and occiput-atlas-axis (OAA) articulatory manipulation in the treatment of TTH has not been investigated to date. The hypothesis of this study is that both SI and OAA can be effective on their own, but will be even more effective when combined. The objective of SI is to release tension in the suboccipital muscles, reducing the muscular tension that may contribute to the onset of headache and OAA articulatory manipulation is aimed at restoring the range of motion and reducing suboccipital muscle spasm which we expect will reduce pericranial pain and will improve different aspects of headache.

Therefore, the purpose of this study is to evaluate the effectiveness of the use of OAA articulatory and SI soft tissue techniques in the treatment of TTH, assessing the effectiveness of each intervention both separately and combined (SI + OAA), on different parameters, such as age, sex, frequency and intensity of headache, severity of pain and pericranial tenderness, disability and impact of headache, and ranges of motion of the craniocervical junction.

## Subjects and methods

### Patient population

All patients in this study have been diagnosed TTH, they were recruited between January 2010 and December 2011 and fulfil the criteria defined by the International Headache Society (IHS, 2004), subsequently revised (IHS, 2006). Inclusion and exclusion criteria are shown in Table 1.

Eighty-four patients diagnosed with episodic tension-type headache (ETTH) and chronic tension-type headache (CTTH) participated in this study. A non-probability and convenience sampling was performed. Sixty-eight of participants were women (81%). Mean age was 39.7 years (SD 11.4) within an age range of 18–65 years. All patients were invited to participate in the study when seeking treatment for headache pain on their own initiative: 51.2% came from

**Table 1** The study's inclusion and exclusion criteria.

| Inclusion criteria   | Exclusion criteria  |
|--|---|
| - Be between 18 and 65 years                                 | - Patients with infrequent ETTH, or with probable frequent and infrequent forms of TTH or other primary or secondary type of headache |
| - ETTH or CTTH diagnosed                                     | - Pain aggravated by movement of the head   |
| - Longer than three months of TTH                            | - Metabolic or musculoskeletal problems with similar headache symptoms  |
| - More than 1 headache day per month                         | - Previous trauma to the cervical spine   |
| - Episodes of pain from 30 min to 7 days                     | - Vertigo, dizziness, uncompensated tension   |
| - Fulfil 2 or more of the following characteristics:         | - Joint stiffness, atherosclerosis, or advanced osteoarthritis  |
| o Bilateral location of pain                                 | - Patients undergoing pharmacological adaptation  |
| o Non-pulsatile pain pressure                                | - Emotional stress  |
| o Pain mild to moderate                                      | - Patients with heart devices   |
| o The headache does not increase with physical activity      | - Suffer from photophobia, phonophobia, nausea, or vomiting   |
| - The headache may be associated with pericranial tenderness | - Joint instability   |
| - Controlled pharmacologically                               | - Neurological disorders  |
|  | - Laxity of cervical soft tissues   |
|  | - Radiographic abnormalities  |
|  | - Generalized hyperlaxity or hypermobility  |
|  | - Pregnancy   |

a clinic specializing in headache treatment (where the study was conducted), and 48.8% were referred by doctors of various private and public healthcare centres.

This study has been supervised by the second author's employer institution and approved by the local research committee. Prior to conducting the pre-test assessment, informed consent of all patients was obtained, and all procedures were conducted in compliance with the Declaration of Helsinki.

## Study design

The study was a 4x3 factorial, randomized, double-blind, placebo-controlled clinical trial. Allocation of patients to control and experimental groups was randomized using a computer generated random sequence, and was carried out by an assistant who was not informed about the treatments used and the objectives of the study, therefore was blinded to group assignment. Patients were aware of the purpose of the study, but did not know which group they belonged to.

The two physiotherapists provided the different treatments without knowing which group the patient formed part of. Since there were only four possible treatments they could infer the treatment group but this information was never provided to them by the researchers and neither were the parameters that were being measured, nor the objective of the study.

Patients were randomly divided into 4 groups (3 treatment groups and 1 control group): Group 1) SI treatment; Group 2) OAA manipulative treatment; Group 3) combination of SI + OAA; and Group 4) placebo control. The required number of subjects in each group was estimated with the nQuery Advisor program, also used in other physical therapy studies (Callaghan et al., 2001). According to the nQuery Advisor program, the required number for an ANOVA with one inter-subject factor, with 4 groups, assuming a 5% significance level for a large effect, and considering as the primary factor the frequency and intensity of pain, is 19 subjects in each group. This has been the minimum number of subjects per group in our study and therefore nQuery Advisor program criteria have been met.

All patients were assessed under the same conditions and over a period of three moments: before the treatment, after the treatment (at 4 weeks), and at follow-up (after 8 weeks).

## Manual therapy intervention

Four treatment sessions, with an interval of one session per week, which is the estimated time for all treatments to achieve a positive effect, were carried out by two physiotherapists with over 10 years experience in the treatment of headaches and a good knowledge of the techniques used. Moraska and Chandler (2008) and Toro-Velasco et al. (2009) performed a treatment based on manual therapy similar to our study, which also applied a session with one week interval. Prior to each treatment session, the physiotherapist performed the vertebral artery test bilaterally in all four groups of patients. Although there is some controversy regarding its effectiveness in ensuring the absence of vascular injury (Johnson et al., 2008; Thiel and Rix, 2005), we have seen fit to include it in the study. In addition, prior

to the study, patients with symptoms that could refer vertebral artery insufficiency were excluded. After receiving the treatment, the subjects in the experimental groups stayed for 5 min in the supine resting position, in neutral ranges of cervical flexion, extension, lateral flexion and rotation.

**SI intervention.** The SI treatment aims to release the suboccipital muscle spasm that determines the occiput-atlas-axis joint dysfunction. In order to apply this treatment, the patient was placed supine on the couch. The therapist's hands are placed under the patient's head making contact with the suboccipital muscles in the region of the posterior arch of the atlas, where pressure was progressively and deeply applied. This technique was administered for 10 min to produce an inhibitory effect (Toro-Velasco et al., 2009).

**OAA intervention.** The OAA manipulation was bilaterally administered attempting to restore the motion dysfunction of this complex. For this manipulative technique the patient starts in the same position as in the preceding treatment. It is performed on a vertical axis passing through the odontoid process of the axis; it involves very little lateroflexion, and no flexion or extension. It is applied in two stages: firstly, a slight cephalic decompression is performed, then small circumductions are performed prior to manipulation; the joint barrier is located through selective pressure and subsequently a rotation towards the side to be manipulated is performed with a cranial helical movement (Fryette, 1936).

**Combined treatment intervention.** The study aims to establish if the combination of both treatments (administered in the above described order: SI + OAA) is more effective than the application of each treatment separately.

**Placebo control intervention.** The control group received no treatment, although patients of this group attended the same sessions as the intervention groups. In the sessions the control group underwent the artery test and remained 10 min in a resting position, five more than groups with treatment. They also underwent the same evaluations as the experimental groups.

## Primary assessment

Primary assessment consisted on an individual structured clinical interview conducted to collect socio-demographic data and headache characteristics in a one-month base period (the previous 4 weeks) (Ajimsha, 2011). This interview gathers information related to age, sex, intensity and frequency of headache, severity of pain, qualities of pain, cranial location of pain, family history of headache, trigger factors, pain-aggravating and pain-relieving factors, as well as any previous physiotherapy treatment for headache relief. The physiotherapist who carried out this interview did not participate in the outcome assessment (pre-test, post-test and follow-up) or in the administration of treatments.

## Secondary assessment

Outcome assessment was carried out through a pre-test performed prior to the first treatment session, a post-test after the treatment period (after the fourth session) and finally a follow-up 8 weeks after the first session (4 weeks after finishing the treatment). All patients, both in the control and the experimental groups, were assessed under the same conditions in all phases of the trial and follow-up one month later; assessment included:

- Impact of headache on daily life, measured by the Headache Impact Test-6 (HIT-6) (Ware et al., 2000), which consists of 6 items each with 4 response options: never, 6 points; rarely, 8 points; sometimes, 10 points; very often, 11 points; always, 13 points, with a total score ranging from 36 to 78 points; Internal consistency (Cronbach alpha 0.89) and test–retest reliability (ICC ranging from 0.78 to 0.90) have been demonstrated to be good (Kosinski et al., 2003).
- Disability caused by headache, measured by the Spanish version of the Headache Disability Inventory (HDI), with 25 items assessing emotional and functional aspects with 4 possible response options, with an alpha reliability of 0.76–0.83 (Jacobson et al., 1994; Rodríguez et al., 2000). For thorough analysis, the present study examined the emotional and functional aspects separately.
- Headache pain intensity, rated daily by the patient on the 0–10 Visual Analogue Scale (VAS) from 0 to 10 along a line, wherein 0 is no pain at all and 10 the maximum possible pain. The result has been expressed in millimetres (mm), ranging from 0 to 100 mm. (0 = no pain, 10 = the most severe pain) (Mottola, 1993).
- Ranges of motion of the craniocervical junction, measured with the CROM-device. This instrument has demonstrated a good intra-tester reliability for cervical flexion, extension, lateral flexion and rotation movements (ICC > 0.80) (Tousignant et al., 2000; Hall and Robinson, 2004; Hall et al., 2008). However, not having found any previous studies about its reliability for the assessment of the range of motion of the craniocervical junction (upper cervical joint), before using this device in our study our two examiners conducted an inter-tester reliability analysis (10 patients were not participating in this study), which showed a Pearson's correlation of 0.98.
- Headache diary. Patients recorded on a daily basis the characteristics of headache with data regarding headache frequency, intensity and pericranial tenderness.

## Statistical analysis

Data were codified and analyzed using the statistical software SPSS for Windows (version 17.0). Descriptive analyses were carried out on the sample as a whole and on each group separately, with absolute and relative frequencies, mean scores, standard deviation and confidence interval. An ANOVA was performed on the pre-test scores to test the homogeneity of the groups before beginning the treatment, including calculation and interpretation of the partial eta-

squared effect size index. In ANOVA-type analyses, Levene's test was used to test the assumption of homogeneity of variance. In the cases where it was statistically significant, Welch and Brown-Forsythe F-tests were performed.

Likewise, *t*-test for dependent samples was performed to compare pre-test and post-test mean values, and pre-test and follow-up mean values (for each group separately), as well as calculation and interpretation of the standardized mean difference effect size index. In the *t*-tests, the Kolmogorov–Smirnov test was used separately for each group and for each outcome measurement, in order to test the normality assumption. When this assumption was violated, means were compared using the Wilcoxon test. In order to analyse between-group differences, the degree of variation for each variable (pre-test minus post-test 1-variable; post-test minus follow-up 2-variable) was determined and the Kuskal–Wallis test was applied. The significance level was established at 5% in all analyses. As for the effect size, it was rated as follows: small (0.2–0.5), medium (0.5–0.8) or large (>0.8).

## Results

### Sample characteristics

The sample was initially made up of 84 subjects, 80 of which completed the trial (8 weeks), as shown in flow chart of Fig. 1. Mean age was 39.7 years (SD 11.4). In the month prior to the study, average pain intensity, measured by a VAS, was rated at 6.49 (SD 1.69), and 56 patients (66.7%) suffered headaches of moderate intensity, 17 patients (20.2%) of severe intensity, and 11 patients (13.1%) of mild intensity. Other socio-demographic characteristics are shown in Table 2. In the ANOVA performed on the pretest scores the results showed there were no global differences between groups, so it was possible to compare the main parameters assessed between groups.

### Intra-group results at post-treatment and follow-up

Regarding the impact of headache measured by the HIT-6, the OAA group stands out since it reported statistically significant changes after the four-week treatment period ( $p = 0.001$ ). In the follow-up at 8 weeks, the three treatment groups (SI, OAA, and SI + OAA) showed statistically significant differences ( $p = 0.01$ ,  $p = 0.001$ ,  $p = 0.002$  respectively) (Table 3).

With regard to the disability caused by headache, measured by the HDI, several aspects were analysed:

Overall HDI results showed statistically significant differences in the OAA group ( $p = 0.001$ ) and the SI + OAA group ( $p = 0.001$ ). At follow-up all groups showed significant differences, including the control group. However, the effect size was greater in the OAA and OAA SI + groups. When HDI results were analysed separately, in the *functional subscale* of the HDI, the three treatment groups (SI, OAA and SI + OAA) showed statistically significant improvements, both after the treatment and at follow-up. In the *emotional subscale*, the groups with OAA and SI + OAA treatment, as well as the control group, reported significant improvements after the treatment. At 8 weeks, only

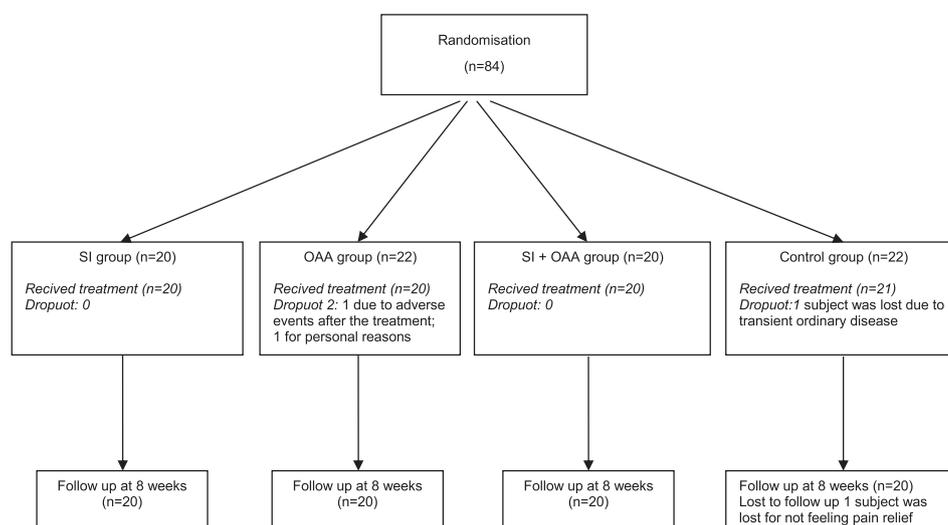


Figure 1 Flow chart, representing the design of the trial on Tension-Type Headache (TTH).

the OAA group maintained a statistically significant improvement (Table 3).

Regarding the ranges of motion, *craniocervical flexion* significantly improved statistically after the treatment period in all study groups. This improvement was only maintained at follow-up in the three treatment groups (SI, OAA and SI + OAA), and disappeared in the control group. *Craniocervical extension* improved significantly after the treatment in OAA, SI + OAA and control groups. This improvement was maintained at follow-up only in the treatment groups (Table 4).

Regarding the *frequency of headache*, the headache diary kept by patients in the OAA and SI + OAA groups showed statistically significant reductions after the treatment; at 8-week follow-up, only the SI + OAA group still showed statistically significant differences. As for the *weekly average of pain intensity*, the groups with OAA and SI + OAA treatment, as well as the control group, showed statistically significant improvements both at post-treatment and at follow-up. As for the weekly frequency of *pericranial tenderness*, the three treatment groups (SI, OAA and SI + OAA) showed significant reductions both after the treatment and at follow-up. The results with statistically significant differences and effect sizes are shown in Tables 3–5.

### Results at post-treatment between groups

For the new variables calculated, in the functional subscale of the 1-HDI the score difference between the treatment groups,  $\chi^2(3) = 18.741$ ,  $p = 0.000$  was statistically significant; and pairwise comparisons were performed using Dunn's (1964) procedure with a Bonferroni correction for multiple comparisons. For functional subscale of the 1-HDI, the score difference between the control group and OAA ( $p = 0.021$ ), control group and SI + OAA ( $p = 0.001$ ) and SI and SI + OAA ( $p = 0.015$ ) was statistically significant.

In the overall 1-HDI, the score difference between the treatment groups,  $\chi^2(3) = 12.132$ ,  $p = 0.007$  was statistically significant; and pairwise comparisons were performed

using the same procedure as for the preceding variable. Overall 1-HDI the score difference between the control group and SI + OAA ( $p = 0.028$ ) was statistically significant.

The score difference was not statistically significant between groups in the 1-HIT-6, 2-HIT-6, *emotional subscale* of the 1-HDI and 2, *functional subscale* of the 2-HDI, and Overall 2-HDI.

For the ranges of motion, the score difference in *craniocervical flexion* after the treatment period was statistically significant between the treatment groups,  $\chi^2(3) = 12.574$ ,  $p = 0.006$ ; and pairwise comparisons were performed using the same procedure as the preceding variable. The score difference in *craniocervical flexion* after the treatment period was statistically significant between the control group and OAA ( $p = 0.003$ ). The score difference for *craniocervical flexion* follow-up was not statistically significant between the treatment groups. The score difference in *craniocervical extension* after the treatment period was statistically significant between the treatment groups,  $\chi^2(3) = 10.337$ ,  $p = 0.016$ ; and pairwise comparisons were performed using the same procedure as the preceding variable. The score difference for *craniocervical extension* after the treatment period was statistically significant between the control group and OAA ( $p = 0.013$ ). The score difference for *craniocervical extension* follow-up was statistically significant between the treatment groups  $\chi^2(3) = 12.831$ ,  $p = 0.005$ ; and pairwise comparisons showed statistically significant differences between control group and SI ( $p = 0.037$ ), control group and SI + OAA ( $p = 0.017$ ), and between control group and OAA ( $p = 0.016$ ).

### Discussion

The results regarding the impact of headache, measured using the HIT-6, showed a mean score of 59.44 at baseline and 55.79 after the treatment. The OAA and SI + OAA groups proved to be the most effective ones, both of them showing significant differences ( $p \leq 0.05$ ) and a large effect size (1.21 y 0.93, respectively).

**Table 2** Clinical characteristics of the patients in the study.

| Characteristics                     | All patients n 84 | Treatment SI n 20 | Treatment OAA n 22 | Treatment SI + OAA n 20 | Control group n 22 |
|-------------------------------------|-------------------|-------------------|--------------------|-------------------------|--------------------|
| Mean age (range)                    | 39.76 (18–65)     | 42.75 (18–65)     | 34 (18–50)         | 40.70 (24–62)           | 41.95 (18–62)      |
| Gender (female)                     | 68 (81)           | 17 (85)           | 20 (90.9)          | 18 (90)                 | 13 (59.1)          |
| ETTH ( $\leq 15$ days/month)        | 48 (57.1)         | 9 (45)            | 15 (68.2)          | 11 (55)                 | 13 (59.1)          |
| CTTH ( $\geq 15$ days/month)        | 36 (42.9)         | 11 (55)           | 7 (31.8)           | 9 (45)                  | 9 (40.9)           |
| Pain Location                       |                   |                   |                    |                         |                    |
| Occipital                           | 31 (36.9)         | 7 (35)            | 6 (27.3)           | 8 (40)                  | 10 (45.5)          |
| Interparietal                       | 30 (35.7)         | 10 (50)           | 9 (40.9)           | 4 (20)                  | 7 (31.8)           |
| Frontalis-temporalis                | 23 (27.4)         | 3 (15)            | 7 (31.8)           | 8 (40)                  | 5 (22.7)           |
| Mild to moderate severity           | 78 (92.9)         | 19 (95)           | 20 (90.9)          | 19 (95)                 | 20 (90.9)          |
| Bilateral location of pain          | 82 (97.6)         | 20 (100)          | 21 (95.5)          | 19 (95)                 | 22 (100)           |
| Pulsating pressure                  | 16 (19)           | 5 (25)            | 4 (18.2)           | 2 (10)                  | 5 (22.7)           |
| Not aggravated by physical activity | 60 (71.4)         | 13 (65)           | 15 (68.2)          | 13 (65)                 | 19 (86.4)          |
| Pericranial tenderness              | 38 (45.2)         | 12 (60)           | 7 (31.8)           | 11 (55)                 | 7 (31.8)           |
| Family history of headache          | 49 (58)           | 18 (90)           | 14 (63.6)          | 11 (55)                 | 5 (22.7)           |

All results presented as absolute frequencies and relatives (%) unless indicated otherwise.

**Table 3** Results of Impact of headache (HIT-6) and Disability (HDI).

|                       | Treatment SI n 20       | Treatment OAA n 20      | Treatment SI + OAA n 20  | Control group n 20     |
|-----------------------|-------------------------|-------------------------|--------------------------|------------------------|
| <i>HIT-6</i>          |                         |                         |                          |                        |
| Pretreatment          | 59.20 (8.77)            | 60.23 (5.85)            | 60.75 (7.78)             | 57.68 (8.34)           |
| Posttreatment         | 57.30 (7.76)            | 53.50 (6.12)            | 56.70 (8.62)             | 55.67 (7.74)           |
| Follow-up             | 54.90 (7.25)            | 52.85 (6.27)            | 53.20 (7.17)             | 56.10 (7.22)           |
| Pre-Posttreatment     | $t = 1.06; p = 0.30$    | $t = 4.25; p = 0.001^*$ | $z = -1.75; p = 0.79$    | $z = -1.69; p = 0.09$  |
| Effect size           | 0.21                    | 1.10                    | 0.50                     | 0.23                   |
| Pre-Follow-up         | $t = 2.74; p = 0.01^*$  | $t = 5.83; p = 0.001^*$ | $z = -3.04; p = 0.002^*$ | $z = -0.97; p = 0.18$  |
| Effect size           | 0.47                    | 1.21                    | 0.93                     | 0.18                   |
| <i>HDI Global</i>     |                         |                         |                          |                        |
| Pretreatment          | 47.20 (23.10)           | 43.45 (21.67)           | 21.67 (24.16)            | 44.72 (26.29)          |
| Posttreatment         | 42.30 (22.75)           | 30.20 (20.95)           | 20.95 (26.61)            | 26.61 (24.74)          |
| Follow-up             | 35.30 (22.39)           | 25.60 (16.62)           | 16.62 (22.08)            | 22.08 (24.84)          |
| Pre-Posttreatment     | $t = 1.97; 0.06$        | $t = 4.86; 0.001^*$     | $z = -3.53; 0.001^*$     | $t = 1.56; p = 0.13$   |
| Effect size           | 0.20                    | 0.57                    | 0.56                     | 0.13                   |
| Pre-Follow-up         | $t = 3.05; p = 0.007^*$ | $t = 0.58; p = 0.001^*$ | $z = -3.81; p = 0.001^*$ | $t = 2.16; p = 0.05^*$ |
| Effect size           | 0.49                    | 0.79                    | 0.88                     | 0.35                   |
| <i>HDI Functional</i> |                         |                         |                          |                        |
| Pretreatment          | 26 (11.85)              | 21.82 (11.51)           | 28.70 (12.72)            | 23.27 (12.64)          |
| Posttreatment         | 23.10 (11.32)           | 14.80 (10.08)           | 19.30 (13.28)            | 22.57 (11.63)          |
| Follow-up             | 18.20 (11.22)           | 13.20 (8.32)            | 15.80 (11.70)            | 19.70 (12.55)          |
| Pre-Posttreatment     | $t = 2.36; p = 0.02^*$  | $t = 4.84; p = 0.001^*$ | $z = -3.77; p = 0.001^*$ | $t = 0.66; p = 0.51$   |
| Effect size           | 0.23                    | 0.59                    | 0.71                     | 0.05                   |
| Pre-Follow-up         | $t = 3.71; p = 0.001^*$ | $t = 5.36; p = 0.001^*$ | $z = -3.88; p = 0.001^*$ | $t = 1.50; p = 0.14$   |
| Effect size           | 0.63                    | 0.72                    | 0.97                     | 0.27                   |
| <i>HDI Emotional</i>  |                         |                         |                          |                        |
| Pretreatment          | 21.20 (12.40)           | 21.64 (11.47)           | 23.20 (12.09)            | 21.45 (14.75)          |
| Posttreatment         | 19.20 (12.06)           | 15.40 (11.29)           | 18.40 (14.07)            | 18.48 (13.62)          |
| Follow-up             | 17.10 (11.62)           | 12.40 (9.03)            | 13.90 (10.87)            | 15.50 (13.22)          |
| Pre-Posttreatment     | $t = 1.25; p = 0.22$    | $t = 3.79; p = 0.001^*$ | $t = 2.52; p = 0.02^*$   | $t = 2.10; p = 0.04^*$ |
| Effect size           | 0.15                    | 0.52                    | 0.38                     | 0.19                   |
| Pre-Follow-up         | $t = 1.88; p = 0.07$    | $t = 5.33; p = 0.001^*$ | $t = 5.22; p = 0.20$     | $t = 2.72; p = 0.39$   |
| Effect size           | 0.32                    | 0.77                    | 0.74                     | 0.39                   |

All results are presented as means (SD. standard deviation) unless indicated otherwise.

z Wilcoxon; t Student;  $*p \leq 0.05$ .

**Table 4** Results of craniocervical range of motion, in degrees.

|                                 | Treatment SI n 20       | Treatment OAA n 20       | Treatment SI + OAA n 20  | Control group n 20       |
|---------------------------------|-------------------------|--------------------------|--------------------------|--------------------------|
| <i>Craniocervical flexion</i>   |                         |                          |                          |                          |
| Pretreatment                    | 8.35 (5.05)             | 8.68 (3.44)              | 7.15 (3.37)              | 7.95 (4.56)              |
| Posttreatment                   | 12.55 (4.61)            | 15.10 (4.77)             | 11.90 (5.02)             | 9.24 (4.34)              |
| Follow-up                       | 12.10 (5.26)            | 12.00 (5.04)             | 11.05 (4.67)             | 9.10 (3.99)              |
| Pre-Posttreatment               | $z = -2.53; p = 0.01^*$ | $z = -3.73; p = 0.001^*$ | $z = -3.23; p = 0.001^*$ | $z = -1.38; p = 0.004^*$ |
| Effect size                     | 0.80                    | 1.51                     | 1.35                     | 0.27                     |
| Pre-Follow-up                   | $z = -2.09; p = 0.03^*$ | $z = -2.89; p = 0.004^*$ | $z = -2.64; p = 0.008^*$ | $z = -0.59; p = 0.55$    |
| Effect size                     | 0.71                    | 0.93                     | 1.11                     | 0.25                     |
| <i>Craniocervical extension</i> |                         |                          |                          |                          |
| Pretreatment                    | 17 (10.06)              | 16.32 (9.53)             | 14.55 (8.59)             | 11.91 (6.06)             |
| Posttreatment                   | 18.20 (8.27)            | 22.95 (9.76)             | 20.75 (10.82)            | 14.29 (6.19)             |
| Follow-up                       | 19.85 (12.44)           | 20.70 (10.31)            | 21.00 (12.54)            | 11.95 (5.26)             |
| Pre-Posttreatment               | $z = -0.98; p = 0.32$   | $z = -2.97; p = 0.003^*$ | $z = -3.79; p = 0.001^*$ | $z = -2.86; p = 0.004^*$ |
| Effect size                     | 0.11                    | 0.67                     | 0.69                     | 0.38                     |
| Pre-Follow-up                   | $z = -0.52; p = 0.50$   | $z = -2.09; p = 0.04^*$  | $z = -2.97; p = 0.003^*$ | $z = -0.35; p = 0.72$    |
| Effect size                     | 0.27                    | 0.44                     | 0.72                     | 0.01                     |

All results are presented as means (SD, standard deviation) unless indicated otherwise.  
z Wilcoxon; t Student; \* $p \leq 0.05$ .

The effects of treatment in the emotional aspect of disability caused by headache, measured using the HDI, showed statistically significant differences when comparing initial outcomes with post-treatment in groups OAA, SI + OAA and control-placebo. However, one month later,

only the OAA group still showed statistically significant results ( $p = 0.001$ ) with a large effect size (0.77).

In the functional scale of the HDI, both after the treatment and at follow-up, the three treatment groups showed significant differences, but not the control group. Effect

**Table 5** Results of weekly self-record of headache and associated symptoms.

|                               | Treatment SI n 20     | Treatment OAA n 20          | Treatment SI + OAA n 20      | Control group n 20     |
|-------------------------------|-----------------------|-----------------------------|------------------------------|------------------------|
| <i>Frequency of headache</i>  |                       |                             |                              |                        |
| Pretreatment                  | 3.25 (2.29)           | 2.90 (1.86)                 | 3.80 (1.79)                  | 3.24 (1.57)            |
| Posttreatment                 | 2.60 (2.13)           | 1.70 (2.00)                 | 1.55 (1.50)                  | 2.45 (1.50)            |
| Follow-up                     | 2.45 (2.08)           | 2.15 (2.25)                 | 1.65 (1.75)                  | 2.85 (1.92)            |
| Pre-Posttreatment             | $t = 1.68; p = 0.10$  | $z = -2.63; p = 0.008^{**}$ | $z = -3.64; p = 0.001^{***}$ | $t = 1.89; p = 0.07$   |
| Effect size                   | 0.27                  | 0.62                        | 1.21                         | 0.48                   |
| Pre-Follow-up                 | $t = 1.59; p = 0.12$  | $z = -1.49; p = 0.13$       | $z = -3.03; p = 0.002^{**}$  | $t = 0.55; p = 0.58$   |
| Effect size                   | 0.34                  | 0.39                        | 1.15                         | 0.24                   |
| <i>Intensity of pain</i>      |                       |                             |                              |                        |
| Pretreatment                  | 4.79 (2.26)           | 5.12 (1.95)                 | 4.80 (1.68)                  | 5.24 (1.80)            |
| Posttreatment                 | 3.77 (2.51)           | 3.03 (2.80)                 | 3.24 (2.72)                  | 3.95 (2.12)            |
| Follow-up                     | 2.82 (2.20)           | 3.28 (2.39)                 | 3.02 (2.60)                  | 3.86 (2.00)            |
| Pre-Posttreatment             | $t = 1.49; p = 0.15$  | $t = 2.69; p = 0.01^{**}$   | $z = -2.21; p = 0.02^*$      | $t = 2.34; p = 0.03^*$ |
| Effect size                   | 0.43                  | 1.03                        | 0.89                         | 0.69                   |
| Pre-Follow-up                 | $t = 1.30; p = 0.20$  | $t = 2.86; p = 0.01^{**}$   | $z = -2.42; p = 0.01^{**}$   | $t = 2.24; p = 0.03^*$ |
| Effect size                   | 0.54                  | 0.91                        | 1.01                         | 0.74                   |
| <i>Pericranial tenderness</i> |                       |                             |                              |                        |
| Pretreatment                  | 0.80 (1.39)           | 0.62 (1.71)                 | 1.20 (1.93)                  | 0.86 (1.59)            |
| Posttreatment                 | 0.35 (1.13)           | 0.80 (1.85)                 | 0.30 (0.65)                  | 0.70 (1.41)            |
| Follow-up                     | 0.70 (1.49)           | 0.35 (1.34)                 | 0.20 (0.52)                  | 0.85 (1.59)            |
| Pre-Posttreatment             | $z = -1.40; p = 0.15$ | $z = -0.41; p = 0.68$       | $z = -2.25; p = 0.02^*$      | $z = -0.10; p = 0.91$  |
| Effect size                   | 0.31                  | 0.10                        | 0.44                         | 0.09                   |
| Pre-Follow-up                 | $z = -0.15; p = 0.76$ | $z = -1.89; p = 0.06$       | $z = -2.44; p = 0.01^*$      | $z = -0.67; p = 0.49$  |
| Effect size                   | 0.07                  | 0.15                        | 0.50                         | 0.01                   |

All results are presented as mean (SD, standard deviation) unless indicated otherwise.  
z Wilcoxon; t Student; \* $p \leq 0.05$ .

†The standard error of the difference is 0.

sizes were medium-large and large for groups SI, OAA and SI + OAA (0.63, 0.72 and 0.97 respectively). Therefore, according to the results, the three treatments are effective in improving the functional aspects of disability, both immediately after the treatment and in the short term (one month later); OAA treatment shows greater improvements for the emotional aspect of disability, both after the treatment and at an 8-week follow-up.

Overall disability improved in those groups that included spinal manipulation. In fact, these groups obtained the largest effect size (high effect > 0.08) in most of the assessments.

Regarding the ranges of motion of the craniocervical junction, measured with the CROM-device, an inter-tester reliability test was performed, showing a Pearson's correlation of 0.98; this is because it is a situational test that may be subject to different interpretations by the examiner, before the development of the trial, notwithstanding the extensive experience (over 10 years) of both examiners participating in the study. Hall and Robinson (2004) had previously used the CROM-device showing high reliability, with 0.92 for flexion and 0.99 for extension, and a later study showed 0.93 for rotation (Hall et al., 2008). However, this study has not taken into account the assessment of proprioception, strength and endurance in the craniocervical region (Strimpakos, 2011).

Immediately after the treatment period, all four study groups showed statistically significant differences in craniocervical flexion, but one month later, only the three treatment groups maintained statistically significant improvements, with large effect sizes (0.71 in SI group; 0.93 in OAA group; and 1.11 in SI + OAA group). Regarding craniocervical extension, patients in both groups including OAA manipulation (administered on its own or after suboccipital inhibition, SI + OAA) showed statistically significant improvements both after the four-week treatment and at follow-up one month later. As for the effect sizes, these were medium and medium-large (0.44 in OAA group and 0.72 in SI + OAA group).

Our results show that the OAA treatment, administered both separately and in combination with suboccipital inhibition (SI + OAA), improves craniocervical flexion and extension, and these effects are maintained at 30 days after the treatment period. The greater effectiveness of treatments with articulatory manipulation on neck mobility may be due to the fact that the manipulative intervention with suboccipital bilateral rotation exerts an effect of relaxation in this anatomic region, and facilitates joint motion at this level. The SI treatment is effective in improving craniocervical flexion, and this may be explained by the fact that this technique induces relaxation of the suboccipital muscles that participate in the extension of the upper cervical vertebrae, and this effect may have helped to achieve greater flexion.

The records of headache frequency kept by patients during the trial period, when comparing outcomes at baseline, after the treatment and at follow-up, showed statistically significant differences in the SI + OAA group, with a large effect size (1.15). As for headache intensity records, a statistically significant reduction was obtained, both in post-test and at follow-up, in the groups OAA, SI + OAA and control-placebo, with large effect sizes for

treatment groups (0.91 and 1.01) and a medium-large effect size for the control group (0.74).

Therefore, the OAA and SI + OAA treatments have been shown more effective in reducing headache frequency and intensity in patients with tension-type headache. The SI + OAA treatment shows greater improvements, since both immediately after the treatment and one month later headache frequency and intensity report statistically significant reductions, with a large effect size in both aspects.

The patients in our study that received combined treatment (SI + OAA) showed improvement after the administration of treatment and at follow-up, with statistically significant reductions in pericranial tenderness showing small effect size (0.20).

The positive and statistically significant results ( $p < 0.05$ ) obtained in the control group in some outcome measures (Pre/Post-treatment HDI Emotional sub-scale and Pre/Post-treatment craniocervical flexion and extension) have presented small effect sizes in all cases and have vanished in the course of time, as at one-month follow-up, none of these results is still significant. The positive results found for the control group in some of the parameters may be due to the rigorous nature of this study with regard to the placebo used and the randomized allocation process. Besides, the patients in the control group, apart from being assessed under the same conditions as the other three groups, received the same number of sessions and with the same periodicity and duration as the rest. Moreover, these patients completed the weekly headache records, as did the groups with manual therapy treatment.

The effectiveness of OAA manipulation in the treatment of tension-type headache, both separately and in combination with SI, has been demonstrated in our study, reporting statistically significant results in most of the outcome assessments carried out, both after the four-week treatment and at follow-up after 8 weeks. Previous systematic reviews (Astin and Ernst, 2002; Lenssinck et al., 2004) have found spinal manipulation effective regarding some TTH parameters, but the results were not conclusive, probably due to a poor quality of the study design, as these studies failed to include a blind control group or had no control group at all. Other authors (Niere and Robinson, 1997; Moraska and Chandler, 2008) have reported the reduction in frequency, duration and intensity of headache after the treatment with cervical manipulation in other spinal segments.

For the time being, headache treatments that include joint and muscle or connective tissue mobilization have not been considered independently, but in combination with other techniques such as superficial heat or massage (Demirturk et al., 2002; Espí and Gómez, 2010a,b); with muscle relaxation, cranial osteopathy, and functional, muscle-energy and strain-counterstrain techniques (Anderson and Seniscal, 2006); and lately, combined with cervical mobilization, upper thoracic manipulation, muscle endurance exercises and posture correction (Castien et al., 2011).

On the other hand, our study has administered the SI technique, chosen with the purpose of reducing tension in suboccipital muscles, considering that headache is mainly aggravated by stress and work-related factors. Taking into account that relaxation is one of the most used treatments

in patients with TTH (Espí and Gómez, 2010a,b), we expected the SI treatment to be the most effective among the three studied, as it induces notable relaxation in patients treated. However, SI treatment, compared to OAA and SI + OAA, has reported statistically significant results in a lower number of variables, showing to be the least effective treatment. Nevertheless, the results of SI have been positive in headache impact, functional aspect of headache disability, and craniocervical flexion. The poorer results of SI compared to the other two treatments may be due to the fact that this technique is extremely gentle, and some patients may even have perceived it as a placebo. Other authors obtained good results by applying myofascial techniques to this region, but it involved a greater number of combined techniques (Ajimsha, 2011).

Therefore, the study hypothesis is evidenced based on the fact that the combined SI + OAA treatment proves to be more effective than SI and OAA separately. However, OAA treatment alone is more effective than SI treatment alone.

The short follow-up period, only one month after treatment, may be considered a limitation of this study. However, although a longer follow-up period would have been desirable, the outcome assessment performed at 8 weeks (four weeks after finishing the treatment) showed conclusive results regarding the maintenance of treatment effects, which were both statistically ( $p < 0.05$ ) and clinically significant (effect sizes 0.05 to  $<0.80$ ).

On the other hand, a strength of this study is the adherence to treatment in all study groups, including the control group. Gaul et al. (2011) point out that adherence to non-pharmacological treatment is associated with an improved outcome; compliance with treatment during our study was very high both in the groups with better outcomes (OAA and SI + OAA) and in the SI group -and even in the control group. Besides, adherence was very high in all study groups both during and after the treatment, regarding the daily recording of symptoms. Another noteworthy factor of this study is that manual therapy can be an alternative for treatments and therapies used for TTH which are not fully effective.

This study has shown that the SI + OAA treatment is slightly more effective than OAA, and since OAA treatment implies a shorter time of administration, it may be considered more suitable for TTH. Nevertheless, future studies will require a longer follow-up period in order to determine the duration of its therapeutic effect in the longer term.

## Conclusions

For TTH, the SI treatment is effective in reducing the impact of headache and the functional aspect of headache disability, and in increasing craniocervical flexion. OAA treatment is effective in reducing impact of headache, emotional and functional disability, frequency and intensity of headache, and in increasing craniocervical motion in flexion and extension. The combined SI + OAA treatment is effective in reducing impact of headache, functional disability, frequency and intensity of headache, pericranial tenderness, and in increasing craniocervical flexion and extension. Moreover, the combined SI + OAA treatment has

proved to be more effective than each treatment separately.

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No conflict.

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