

ORIGINAL ARTICLE

Effectiveness of suboccipital muscle inhibition combined with interferential current in patients with chronic tension-type headache: a randomised controlled clinical trial[☆]

R. Pérez-Llanes^a, J.D. Ruiz-Cárdenas^{b,*}, A.J. Meroño-Gallut^c,
M.I. Fernández-Calero^d, J. Ríos-Díaz^e

^a Physical Therapy Department, Faculty of Health Sciences, Catholic University of Murcia, Murcia, Spain

^b ECOFISTEM Research Group Physical Therapy Department, Faculty of Health Sciences, Catholic University of Murcia, Murcia, Spain

^c CEO Health Center Tú, Bienestar 360°, San Javier, Murcia, Spain

^d INGRIS Research Group, Physical Therapy Department, Faculty of Health Sciences, Catholic University of Murcia, Murcia, Spain

^e Physical Therapy Research Group (INFIS), Fundación San Juan de Dios, Centro de Ciencias de la Salud San Rafael, Universidad Antonio de Nebrija, Madrid, Spain

Received 26 June 2019; accepted 12 December 2019

Available online 25 September 2021

KEYWORDS

Physical therapy modalities;
Electrical stimulation therapy;
Neck pain;
Headache disorders;
Analgesia

Abstract

Introduction: Manual therapy has been shown to reduce self-reported symptoms in patients with chronic tension-type headache (CTTH). However, simultaneous application of suboccipital muscle inhibition and interferential current has not previously been investigated. This study evaluates the effectiveness of combined treatment with suboccipital muscle inhibition and interferential current compared to standard treatment for pain, disability, and headache impact in patients with CTTH.

Methods: Patients were randomly allocated to receive either standard treatment (n = 13) or the experimental treatment (n = 12), consisting of 20 minutes of suboccipital muscle inhibition plus interferential current twice weekly for 4 weeks. The primary outcome was improvement in pain, and secondary outcomes included improvement in headache-related disability and reduction in headache impact, which were assessed at baseline and at 4 weeks by a blinded rater.

Results: Statistical analysis showed improvements in the experimental treatment group at 4 weeks for headache-related disability (Neck Disability Index: Hedges' g = 1.01, P = .001; and Headache Disability Inventory: Hedges' g = 0.48, P = .022) and headache impact (6-item Headache Impact Test: Hedges' g = 0.15, P = .037) but not for self-reported pain (numerical rating scale: Hedges' g = 1.13, P = .18).

[☆] Please cite this article as: Pérez-Llanes R, Ruiz-Cárdenas JD, Meroño-Gallut AJ, Fernández-Calero MI, Ríos-Díaz J. Efectividad de la inhibición suboccipital combinada con corriente interferencial en pacientes con cefalea tensional crónica: un ensayo clínico controlado aleatorizado. *Neurología*. 2022;37:717–725.

* Corresponding author.

E-mail address: jdruiz@ucam.edu (J.D. Ruiz-Cárdenas).

Conclusions: Combined treatment with suboccipital muscle inhibition and interferential current in patients with CTTH did not significantly improve self-reported pain but did reduce disability and the impact of headache on daily life at 4 weeks. These improvements exceed the minimum clinically important difference, demonstrating the clinical relevance of our findings. © 2020 Sociedad Española de Neurología. Published by Elsevier España, S.L.U. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

PALABRAS CLAVE

Modalidades de fisioterapia;
Terapia por estimulación eléctrica;
Dolor de cuello;
Trastornos de cefalalgia;
Analgésia

Efectividad de la inhibición suboccipital combinada con corriente interferencial en pacientes con cefalea tensional crónica: un ensayo clínico controlado aleatorizado

Resumen

Introducción: Se ha demostrado que la terapia manual reduce los síntomas autoreportados en pacientes con cefalea tensional crónica (CTC). Sin embargo, la aplicación simultánea de la técnica de inhibición muscular suboccipital y corriente interferencial no se ha investigado previamente. Este estudio evalúa la efectividad de la inhibición muscular suboccipital y la corriente interferencial en comparación con los cuidados habituales sobre el dolor, la discapacidad y el impacto de la cefalea en pacientes con CTC.

Métodos: Los pacientes se asignaron al azar al grupo de cuidados habituales (n = 13) o experimental (n = 12) que consistió en 20 minutos de inhibición muscular suboccipital y corriente interferencial dos veces por semana durante cuatro semanas. El resultado primario fue el dolor, y los resultados secundarios incluyeron la discapacidad producida por el dolor de cabeza y el impacto del dolor de cabeza que se valoraron por un evaluador cegado al inicio y después de cuatro semanas.

Resultados: Los análisis mostraron diferencias entre los grupos a favor del grupo experimental a las cuatro semanas para la discapacidad producida por el dolor de cabeza (*Neck Disability Index*: g-Hedges = 1,01; p = 0,001; *Headache Disability Inventory*: g-Hedges = 0,48; p = 0,022) e impacto del dolor de cabeza (*HIT-6*: g-Hedges = 0,15; p = 0,037) pero no para el dolor autoreportado (*Numerical Rating Scale*: g-Hedges = 1,13; p = 0,18).

Conclusiones: La aplicación simultánea de inhibición muscular suboccipital y corriente interferencial en pacientes con CTC no reduce significativamente el dolor autoreportado a las cuatro semanas. Sin embargo, mejora la discapacidad y el impacto del dolor de cabeza en la vida diaria. Estas mejoras superaron el mínimo cambio clínicamente importante de las mediciones, destacando su relevancia clínica.

© 2020 Sociedad Española de Neurología. Publicado por Elsevier España, S.L.U. Este es un artículo Open Access bajo la licencia CC BY-NC-ND (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Introduction

Chronic tension-type headache (CTTH) is characterised by recurrent episodes of headache occurring on 15 or more days per month for at least 3 months (≥ 180 days per year). Pain is usually pressing or tightening (non-pulsating), bilaterally located, of mild to moderate intensity, and not aggravated by routine activity.¹

The pathogenesis of CTTH remains unclear. Some authors have suggested pathophysiological theories based on central or peripheral sensitisation.² Impairment of the musculoskeletal function of the head and neck has been observed, as well as forward head posture, impaired neck mobility, or activation of myofascial trigger points in the muscles of the suboccipital region.^{2–4} Although treatment strategies for CTTH are still non-specific,⁵ a recently published systematic review of 6 randomised controlled clinical trials has highlighted manual therapy interventions as an effective tool for managing CTTH, which are equally effective as prophylactic medication based on tricyclic antidepressants.⁶ However, the great variety of treatment options, together with the lack

of well-designed studies,^{6,7} makes it difficult to draw definitive conclusions.

Suboccipital muscle inhibition belongs to the group of manual therapy techniques aimed at myofascial areas compromised by restriction.⁸ The application of this technique as an isolated therapy has been found to improve pain in patients with CTTH.^{9,10} However, to our knowledge, the simultaneous application of suboccipital muscle inhibition and interferential current in patients with CTTH has not previously been analysed. As interferential currents have been shown to induce analgesia by reducing muscle electrical activity and muscular tension,¹¹ the simultaneous application of both techniques may lead to an improvement in these patients' self-reported symptoms.

The aim of this study is to analyse the effectiveness of simultaneous application of suboccipital muscle inhibition and interferential current in reducing pain, disability, and the impact of headache on the daily life of patients with CTTH. We proposed the hypothesis that simultaneous application of manual therapy and interferential current may be more effective than standard treatments in patients with CTTH.

Table 1 Inclusion and exclusion criteria.

<i>Inclusion criteria</i>
Recurrent episodes of headache on more than 15 days per month for at least 3 months (≥ 180 days per year)
Pain episodes lasting 30 minutes to 7 days
2 or more of the following characteristics:
Bilateral location of pain
Non-pulsating pain upon pressure
Mild to moderate pain
Headache not exacerbated by routine activity
Headache may be associated with pericranial pain sensitivity
Pharmacologically controlled
<i>Exclusion criteria</i>
Patients with other types of primary or secondary headache
Pain aggravated by head movement
Metabolic and musculoskeletal problems with symptoms similar to headache
History of trauma to the cervical spine
Vertigo, dizziness, uncompensated neck tension
Cardiac devices
Photophobia, phonophobia, nausea, or vomiting
Pregnancy

Material and methods

Participants

We conducted a single-blind randomised controlled clinical trial (prospectively registered on 21 July 2014 at www.clinicaltrials.gov, NCT02195648). All procedures complied with the Declaration of Helsinki and the study was approved by the ethics committee of Universidad Católica de Murcia (Spain). Secondary psychosocial endpoints (anxiety, depression, and healthcare-related quality of life) will be reported separately.

We selected patients by non-probability and convenience sampling. We recruited patients attended at a regional hospital (Hospital General Universitario Morales Meseguer, Murcia, Spain) and diagnosed with CTTH by a neurologist according to the International Headache Society (ICHD-third edition, beta version) criteria.¹² Table 1 shows the inclusion and exclusion criteria used.

Patients could withdraw from the study at any time, and could withdraw their consent without repercussion. The patients leaving the study did not undergo any additional follow-up and were not replaced; however, we used an intention-to-treat analysis. To determine the necessary sample size using ANOVA, we performed calculations based on previous studies^{9,10} in order to detect differences in treatment with an effect size of $f = 0.5$, an alpha level of 0.05, and a desired power (beta) of 80%, for a two-tailed test. The estimated sample size was 13 patients per group. However, we anticipated a drop-out rate of 10%, and therefore considered a total sample size of 29 subjects to be sufficient.

Interventions

Treatment was applied by a physiotherapist with more than 10 years' clinical experience. Patients were randomly assigned to the intervention or the control group (standard treatment) by a blinded researcher using a software tool. Both groups received pharmacological treatment prescribed by a neurologist. The intervention group attended a 20-minute session (5 minutes to receive the patient, 10 minutes of treatment, and 5 minutes for rest and

Table 2 Baseline sociodemographic variables.

Variables	Control group (n = 12)					Intervention group (n = 13)					P			
	Mean (SD)	Minimum	Q1	Median (IQR)	Q3	Maximum	Mean (SD)	Minimum	Q1	Median (IQR)		Q3	Maximum	Hedges' g (CL%)
Age (years)	46.2 (16.37)	28.7	34.3	41.4 (24.43)	58.8	82.4	43.3 (18.07)	19.2	27.0	43 (30.45)	57.4	73.8	0.16 (55%)	.679
Weight (kg)	68.9 (11.07)	50.0	62.8	67.5 (14.75)	77.5	89.0	67.5 (13.12)	48.0	58.0	64 (20.5)	78.5	90.0	0.11 (53%)	.777
Height (m)	1.63 (0.109)	1.45	1.54	1.63 (0.2)	1.74	1.80	1.65 (0.1)	1.52	1.55	1.68 (0.18)	1.73	1.81	0.19 (55%)	.54
BMI (kg/m ²)	26.3 (5.46)	19.1	22.7	25.9 (4.19)	26.9	40.5	24.7 (4.64)	18.4	21.1	24.8 (4.48)	25.6	36.3	0.31 (59%)	.44
Sex (women, %)	11 (92%)	—	—	—	—	—	10 (77%)	—	—	—	—	—	—	.65

BMI: body mass index; CL%: interpreted as the probability that a value sampled at random from the first population will be greater than a value sampled at random from the second; IQR: interquartile range; Q1: first quartile; Q3: third quartile; SD: standard deviation. Hedges' g with grouped standard deviation. P-value for one-way ANOVA and chi-square for the variable "sex."

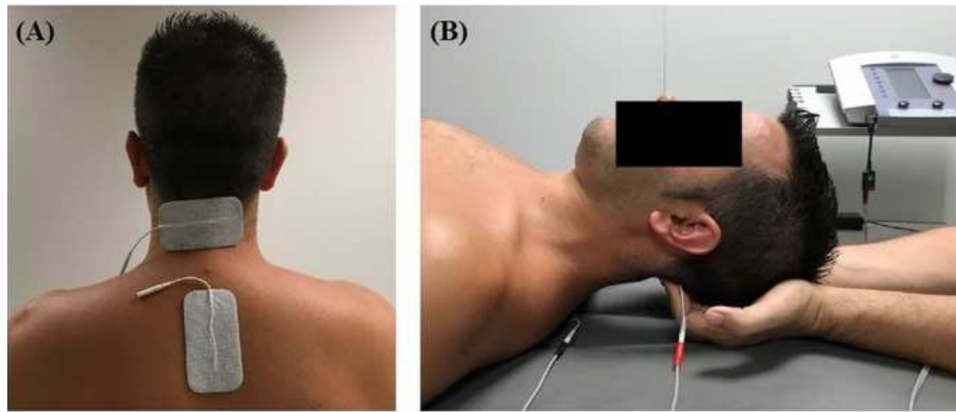


Figure 1 A) Adhesive electrodes applied over the suboccipital muscles. B) Simultaneous application of suboccipital muscle inhibition and interferential current.

haemodynamic stabilisation) twice a week for 4 weeks; during sessions, patients underwent muscle inhibition and interferential currents applied to the suboccipital muscles. Suboccipital muscle inhibition was applied with the patient in the supine position with the eyes closed and the physiotherapist's hands placed under the patient's head, in contact with the suboccipital muscles. The physiotherapist progressively increased the pressure exerted during the 10 minutes of treatment.^{9,10} Simultaneously, an interferential current was applied; the current was generated with a Sonopuls 492[®] device (Sonopuls 492 TM Enraf-Nonius, Rotterdam, the Netherlands) through one channel, with 2 adhesive electrodes applied over the suboccipital muscles (Fig. 1). The parameters selected were carrier frequency of 4000 Hz and amplitude modulated frequency of 100 Hz for a duration of 10 minutes. Current intensity was gradually increased during the first minute, until the physiotherapist noticed tension in the patient's muscles.

Results

We assessed the primary and secondary endpoints at baseline and at 4 weeks (end of intervention) using a paper form administered by a researcher blinded to treatment allocation.

The primary endpoint studied was the change in self-reported pain measured with a numerical pain rating scale (NPRS) scored from 0 to 10 points. Secondary endpoints were disability caused by headache and the impact of headache on daily life. The disability caused by headache was assessed with the Spanish-language version of the Headache Disability Inventory (HDI) and the Neck Disability Index (NDI), which have shown a high degree of consistency and reliability,^{13–15} as well as the Headache Impact Test–6 (HIT-6). The HDI includes 25 items that assess the emotional (13 items) and functional domains (12 items), with 4 possible answers on each item. The score ranges from 0 to 52 points for the emotional domain and from 0 to 48 points for the functional domain, with higher scores indicating greater disability. The NDI includes 10 questions that measure functional disability, with 6 possible answers for each item. The total NDI score ranges from 0 to 50, with scores from 0 to 4 indicating no disability, 5 to 14 mild disability, 15 to 25 moderate disability, 25 to 34 severe disability, and 35 to 50 complete disability. We used the HIT-6 to measure the impact of headache on daily life (Cronbach's alpha of 0.89; test-retest reliability of 0.78–0.90).¹⁶ The total HIT-6 score ranges from 36 to 78 points, with higher scores indicating greater impact.

Statistical analysis

Statistical analysis was performed with the IBM SPSS Statistics software, version 19.0 (IBM Corporation; Armonk, NY, USA). Data were

tested for normal distribution using the Shapiro-Wilks test and for homoscedasticity with the Levene test.

We used a one-way analysis of variance to compare clinical and sociodemographic variables. We calculated the effect size with the Hedges' *g*, which corrects bias of the Cohen's *d* for small samples,¹⁷ and also calculated the common language (CL) effect size statistic, which is interpreted as the probability that a value sampled at random from the first population will be greater than a value sampled at random from the second. Therefore, values close to 50% indicate similarity between groups and values close to 100% suggest significant differences between groups.¹⁸ Categorical variables were analysed with the chi-square test.

We used the repeated measures ANOVA to compare the effect of time (pre- and post-treatment) and the intergroup factor (control and intervention group) on scores in the NPRS, NDI, HDI, and HIT-6.

We performed univariate post hoc *t* tests for each dependent measurement with regard to baseline (intragroup comparisons) and to controls (intergroup comparisons). Significance was established at $P < .05$ (two-tailed tests) and corrected with the Duncan–Bonferroni method for multiple comparisons. The intention-to-treat analysis was performed using the last-observation-carried-forward method.

Results

Sample

A total of 29 patients with CTTH were assessed to participate in the study; 25 met all eligibility criteria and were randomly assigned to the intervention ($n = 13$) or control group ($n = 12$). After the randomisation process, no intergroup differences were observed in sociodemographic (Table 2) or clinical variables (Table 3) at baseline. No differences were observed between groups in prophylactic and symptomatic medication. Six patients in each group were taking antidepressants, whereas 2 patients in the control group were receiving antidepressants and anxiolytics vs 5 patients in the intervention group. Furthermore, 4 patients in the control group reported no pharmacological prescription, vs 2 in the intervention group. Regarding analgesic drugs, all patients were receiving paracetamol and non-steroidal anti-inflammatory drugs (NSAID).

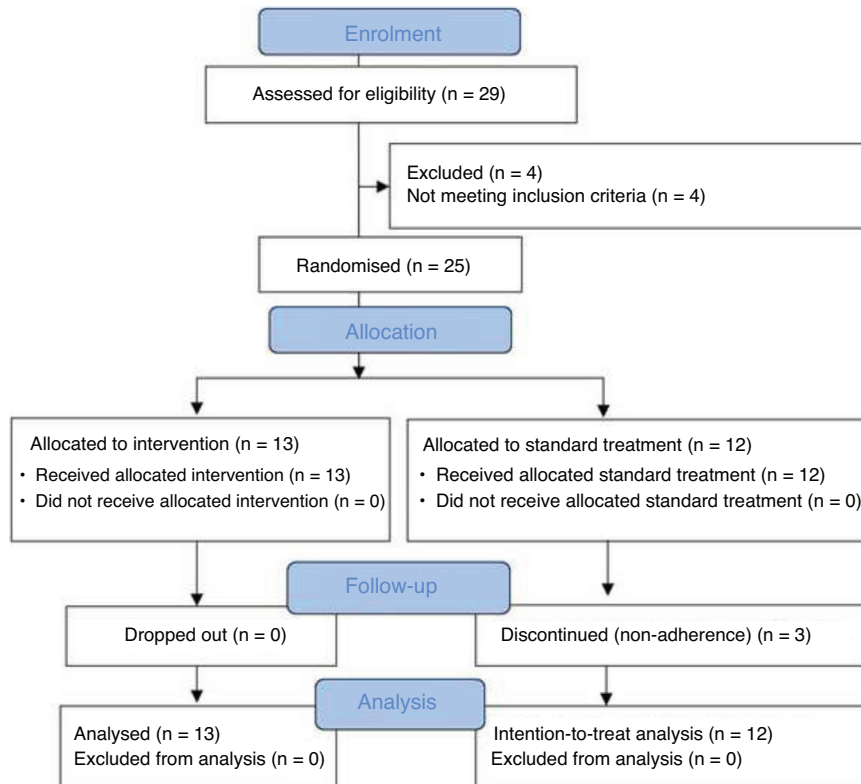
During follow-up, 3 patients from the control group dropped out of the study due to lack of adherence to the study protocol. We observed no adverse events during the study. Fig. 2 shows a flow diagram of the recruitment and follow-up processes.

Table 3 Baseline clinical variables.

Variable		Control group	Intervention group	Total	<i>P</i>
Sex	Women	11 (91.7%)	10 (76.9%)	21 (95.5%)	.65
	Men	1 (8.3%)	3 (23.1%)	4 (18.2%)	
Pericranial pain sensitivity	No	5 (41.7%)	9 (69.2%)	14 (63.6%)	.33
	Yes	7 (58.3%)	4 (30.8%)	11 (50%)	
Pain with activity	No	4 (33.3%)	6 (46.2%)	10 (45.5%)	.81
	Yes	8 (66.7%)	7 (53.8%)	15 (68.2%)	
Pain with neck movement	No	6 (50%)	9 (69.2%)	15 (68.2%)	.57
	Yes	6 (50%)	4 (30.8%)	10 (45.5%)	
Pain upon pressure	No	5 (41.7%)	7 (53.8%)	12 (54.5%)	.84
	Yes	7 (58.3%)	6 (46.2%)	13 (59.1%)	
Restricted neck mobility	No	4 (33.3%)	7 (53.8%)	11 (50%)	.53
	Yes	8 (66.7%)	6 (46.2%)	14 (63.6%)	
Pain in the last month (0-10)		Mean (SD)	Mean (SD)	Hedges' <i>g</i> (CL%)	<i>P</i>
		6.9 (1.33)	6.5 (1.33)	0.29 (58%)	.460

Data are reported in absolute values and relative frequencies; *P*-values are for the chi-square and for one-way ANOVA for the variable 'pain in the last month.'

BMI: body mass index; CL%: interpreted as the probability that a value sampled at random from the first population will be greater than a value sampled at random from the second; Hedges' *g*: effect size for the grouped standard deviation.

**Figure 2** CONSORT flow chart.

Primary endpoints

Self-reported pain decreased by 2.6 points ($P = .011$) in the intervention group, whereas the control group showed no changes at the end of the 4 weeks of intervention. However, in the intergroup comparison, we observed no significant differences at the end of the study but a large effect size (Hedges' $g = 1.13$) and a CL effect size of 79% (Table 4), which may suggest a significant real effect not detected due to the small size of the groups.

Secondary endpoints

The intervention group showed greater improvements than the control group in the disability caused by headache at the end of the 4 weeks of intervention. The results showed intergroup differences in mean scores of 24.2 points, 9.3 points, 10.7 points, and 19.8 points in NDI, HDI emotional domain, HDI functional domain, and total HDI scores, respectively ($P < .05$).

Table 4 Intragroup and intergroup effects for pain, disability, and headache impact.

Variables	Intervention group (n = 13)				Intragroup		Control (n = 12)				Intragroup		Intergroup	
	Mean (SD)	95% CI	Min	Max	Hedges' g (CL%)	P	Mean (SD)	95% CI	Min	Max	Hedges' g (CL%)	P	Hedges' g (CL%)	P
Pre-treat. pain (0-10)	4.6 (2.87)	6.4-2.9	0	9			4.7 (2.99)	6.3-2.6	0	8			0.03 (51%)	.96
Post-treat. pain (0-10)	2 (0.29)	3.7-2.8	0	8	1.23 (82%)	.011	3.5 (1.83)	5.3-2.7	0	10	0.47 (63%)	.27	1.13 (79%)	.18
Pre-treat. NDI (0-100)	26.9 (15.74)	38.1-18.5	6	68			38.8 (28.86)	48.8-15.7	22	78			0.50 (64%)	.097
Post-treat. NDI (0-100)	17 (6.99)	26.9-16.5	0	40	0.78 (72%)	.003	41.2 (32.63)	49.7-13.4	24	66	0.08	.46	1.01 (77%)	.001
Pre-treat. HDI emotional (0-52)	24.5 (17.39)	31.5-11.7	4	44			28.3 (19.58)	37.1-13.8	6	50			0.20 (56%)	.46
Post-treat. HDI emotional (0-52)	19 (13.4)	24.7-9.3	6	38	0.34 (60%)	.019	28.3 (20.91)	35.8-11.7	6	50	0.00 (50%)	.99	0.52 (65%)	.037
Pre-treat. HDI functional (0-48)	28.5 (21.95)	35.0-10.8	6	44			34.7 (28.29)	41.0-10.0	18	48			0.24 (57%)	.15
Post-treat. HDI functional (0-48)	22.6 (16.26)	28.9-10.4	8	36	0.29 (59%)	.005	33.3 (26.52)	40.2-10.7	14	48	0.05 (51%)	.51	0.48 (63%)	.018
Pre-treat. total HDI (0-100)	53.4 (39.31)	67.5-23.3	10	92			62.5 (48.95)	76.0-21.3	26	98			0.20 (56%)	.32
Post-treat. total HDI (0-100)	41.7 (29.83)	53.6-19.6	18	74	0.32 (59%)	.006	61.5 (48.34)	74.7-20.8	26	98	0.02 (51%)	.81	0.48 (64%)	.022
Pre-treat. HIT-6 (36-78)	62.5 (58.47)	66.5-6.6	43	67			64.3 (61.02)	67.5-5.1	54	70			0.029 (51%)	.46
Post-treat. HIT-6 (36-78)	53.4 (46.25)	60.5-11.8	36	78	0.167 (55%)	.001	61.7 (58.17%)	65.1-5.5	47	68	0.04 (51%)	.31	0.15 (54%)	.037

95% CI: 95% confidence interval; BMI: body mass index; CL%: interpreted as the probability that a value sampled at random from the first population will be greater than a value sampled at random from the second; HDI: Headache Disability Index; Hedges' g: effect size with grouped standard deviation; HIT-6: Headache Impact Test-6; NDI: Neck Disability Index; SD: standard deviation.

P-value with Duncan-Bonferroni correction.

Furthermore, we observed improvements (differences between mean scores of 8.3 points) in the intervention group on the impact of headache on daily life as measured with the HIT-6 questionnaire at the end of the 4 weeks of intervention ($P = .037$) (Table 4).

Discussion

Our single-blind randomised controlled clinical trial assessed the effectiveness of suboccipital muscle inhibition and interferential current in improving pain and disability in patients with CTTH. Our results indicate improvements in self-reported pain, headache-related disability, and headache impact in the intervention group, whereas no improvements were observed in the control group. These findings support our hypothesis as they suggest that the simultaneous application of suboccipital inhibition and interferential current may be more effective than standard treatment in improving pain and disability in patients with CTTH in the short term.

Similarly to our findings, Espí-López et al.¹⁰ found improvements in self-reported pain, headache impact, and disability after 4 weeks of treatment with suboccipital muscle inhibition combined with an osteopathic cervical manipulation technique. Furthermore, the group that received both treatments showed greater improvement than those receiving suboccipital muscle inhibition, cervical manipulation, or sham treatment only, suggesting that a combination of treatments is sometimes more effective than an isolated therapy; this approach bears more similarity to everyday physiotherapy practice. However, the results obtained in that study after 4 weeks of suboccipital muscle inhibition combined with osteopathic manipulation did not exceed the minimum clinically important change (the change in the score on an instrument that reflects modification in a person's health status over time) or the minimum detectable change (the minimum amount of change that is probably not explained by random variation in the measurement) in self-reported pain,¹⁹ headache impact as measured with the HIT-6,²⁰ or disability caused by headache as measured with the HDI questionnaire²¹ in patients with CTTH, raising questions about the effects of the treatment and the clinical relevance of these findings.

In our study, while we observed no intergroup differences in self-reported pain, the results showed improvements exceeding the minimum clinically important change for disability measured with the NDI (mean change > 3.5 points),²² headache impact measured with the HIT-6 (mean change > 8 points),²⁰ and disability caused by headache measured with the HDI (mean change > 16 points).²¹ These findings are very promising for the rehabilitation of these patients in daily practice. However, our study does not address long-term effects, so these findings must be interpreted with caution.

To our knowledge, few studies have analysed interventions with manual therapy and analgesic electrotherapy to treat CTTH symptoms.^{6,7} Jay et al.²³ reported improvements in headache frequency and intensity after the application of transcutaneous electrical nerve stimulation (TENS) in isolation or combined with manual therapy. Furthermore, although these improvements persisted in both groups after 6 months of follow-up, the group that received both treatments showed a faster response. These findings underscore the relevance of manual therapies combined with analgesic electrotherapy in the short- and medium-term symptomatic management of patients with CTTH. That study addressed the hypothesis that such improvements were the result of decreased muscle spasm and increased blood serotonin, beta-endorphin, ACTH, and GABA levels.²³

Suboccipital muscle inhibition and interferential current may induce analgesia and decrease tension in suboccipital muscles by reducing muscle activity,¹¹ thereby decreasing peripheral and central sensitisation. However, our study was not specifically designed to identify the underlying mechanism explaining these improvements. Future studies are needed to better understand the main

mechanisms responsible for the decrease in self-reported symptoms in patients with CTTH.

Several studies have been designed to compare different individual treatment approaches, for example, head-neck massage vs ultrasound therapy,²⁴ or myofascial trigger point management vs standard treatment.²⁵ However, in daily practice, most therapists apply more than one treatment during the rehabilitation of patients, and the effect of each individual treatment is therefore not easy to determine. Our study may shed light on the impact of combining the treatment approaches used in physiotherapy sessions on rehabilitation outcomes.

The methodological quality of the studies assessing manual therapy interventions for CTTH is frequently criticised.^{6,7} It is well known that blinding in physiotherapy studies presents particular difficulties compared to other fields of medicine, as the nature of physiotherapy interventions (such as manual therapy) makes blinding of therapists and patients difficult or even impossible²⁶; however, blinding raters is crucial in randomised clinical trials, especially when such subjective instruments as self-reports are used.²⁷ If this blinding is not applied, results on pain and disability may be overestimated by up to 25%.²⁷

Study limitations

Our study is a randomised controlled clinical trial with blinding of the rater and assessor to minimise the risk of bias. However, despite our strict approach towards study design, data collection, and synthesis, our study still presents some limitations. Firstly, although calculations to determine the sample size were based on data from previous studies,^{9,10} the sample size in both groups was small, which limited the statistical power of our analysis; furthermore, we observed no statically significant differences in the intergroup analysis of pain, despite the large effect size (Hedges' $g = 1.13$). Secondly, as previously mentioned, we only analysed the short-term effects of the intervention, and the medium- and long-term effects remain unknown. Furthermore, headache frequency, one of the primary endpoints proposed by the International Headache Society, was not recorded in our study. However, this variable is particularly useful for assessing the results of pharmacological treatments in large-scale trials and in the long term.²⁸ Finally, the introduction of a sham treatment group may have revealed some mechanisms underlying the improvements reported in the intervention group, considering that manual therapies may involve a significant placebo component; therefore, the improvements observed in this study may not be fully explained by the intervention applied.²⁹

Conclusion

The simultaneous application of suboccipital muscle inhibition and interferential current in patients with CTTH does not significantly reduce self-reported pain at 4 weeks. However, it reduces disability and the impact of headache on the daily lives of these patients. These improvements exceeded the minimum clinically important change for the scales applied, highlighting the clinical relevance of the study. Suboccipital muscle inhibition combined with interferential current may be more effective than standard treatment in improving symptoms in patients with CTTH. However, there is a need for future studies with larger sample sizes and sham treatment groups to determine the effects of this therapy.

Funding

This study received no funding of any kind.

Protocol approval

The study was approved by the ethics committee at Universidad Católica de Murcia (Spain). This study was designed according to the CONSORT regulations and prospectively recorded in the ClinicalTrials.gov database (NCT02195648).

Conflicts of interest

The authors have no conflicts of interest to declare.

Acknowledgements

The authors wish to thank all the individuals who participated in the study.

References

- Headache Classification Committee of the International Headache Society (IHS). The International classification of headache disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1–211, <http://dx.doi.org/10.1177/0333102417738202>.
- Yu S, Han X. Update of chronic tension-type headache. *Curr Pain Headache Rep*. 2015;19:469, <http://dx.doi.org/10.1007/s11916-014-0469-5>.
- Fernández-de-Las-Peñas C, Alonso-Blanco C, Cuadrado ML, Gerwin RD, Pareja JA. Myofascial trigger points and their relationship to headache clinical parameters in chronic tension-type headache. *Headache*. 2006;46:1264–72, <http://dx.doi.org/10.1111/j.1526-4610.2006.00440.x>.
- Fernández-de-las-Peñas C, Alonso-Blanco C, Cuadrado ML, Gerwin RD, Pareja JA. Trigger points in the suboccipital muscles and forward head posture in tension-type headache. *Headache*. 2006;46:454–60, <http://dx.doi.org/10.1111/j.1526-4610.2006.00288.x>.
- Jensen R. Diagnosis, epidemiology, and impact of tension-type headache. *Curr Pain Headache Rep*. 2003;7:455–9.
- Chaïbi A, Russell MB. Manual therapies for primary chronic headaches: a systematic review of randomized controlled trials. *J Headache Pain*. 2014;15:67, <http://dx.doi.org/10.1129-2377-15-67>.
- Luedtke K, Allers A, Schulte LH, May A. Efficacy of interventions used by physiotherapists for patients with headache and migraine-systematic review and meta-analysis. *Cephalalgia Int J Headache*. 2016;36:474–92, <http://dx.doi.org/10.1177/0333102415597889>.
- Fernández-de-las-Peñas C, Arendt-Nielsen L, Gerwin R. Tension-type and cervicogenic headache: pathophysiology, diagnosis, and management. Jones & Bartlett Learning; 2010.
- Espí-López G, Gómez-Conesa A. Efficacy of manual and manipulative therapy in the perception of pain and cervical motion in patients with tension-type headache: a randomized, controlled clinical trial. *J Chiropr Med*. 2014;13:4–13, <http://dx.doi.org/10.1016/j.jcm.2014.01.004>.
- Espí-López GV, Gómez-Conesa A, Gómez AA, Martínez JB, Pascual-Vaca AO, Blanco CR. Treatment of tension-type headache with articular and suboccipital soft tissue therapy: a double-blind, randomized, placebo-controlled clinical trial. *J Bodyw Mov Ther*. 2014;18:576–85, <http://dx.doi.org/10.1016/j.jbmt.2014.01.001>.
- Acedo AA, Luduvic Antunes AC, Barros dos Santos A, Barbosa de Oliveira C, Tavares dos Santos C, Colonezi GLT, et al. Upper trapezius relaxation induced by TENS and interferential current in computer users with chronic nonspecific neck discomfort: an electromyographic analysis. *J Back Musculoskelet Rehabil*. 2015;28:19–24, <http://dx.doi.org/10.3233/BMR-140482>.
- Headache Classification Committee of the International Headache Society (IHS). The International classification of headache disorders, 3rd edition (beta version). *Cephalalgia Int J Headache*. 2013;33:629–808, <http://dx.doi.org/10.1177/0333102413485658>.
- Andrade Ortega JA, Delgado Martínez AD, Almécija Ruiz R. Validation of the Spanish version of the neck disability index. *Spine*. 2010;35:E114–8, <http://dx.doi.org/10.1097/BRS.0b013e3181afea5d>.
- Jacobson GP, Ramadan NM, Aggarwal SK, Newman CW. The Henry Ford Hospital Headache Disability Inventory (HDI). *Neurology*. 1994;44:837–42.
- Rodríguez Franco L, García C, Javier F, Blanco Picabia I. Conductas de dolor y discapacidad en migrañas y cefaleas tensionales. Adaptación española del Pain Behavior Questionnaire (PBQ) y del Headache Disability Inventory (HDI). *Análisis Modif Conducta*. 2000;26:739–62.
- Kosinski M, Bayliss MS, Bjorner JB, Ware JE, Garber WH, Batenhorst A, et al. A six-item short-form survey for measuring headache impact: the HIT-6. *Qual Life Res Int J Qual Life Asp Treat Care Rehabil*. 2003;12:963–74.
- Lakens D. Calculating and reporting effect sizes to facilitate cumulative science: a practical primer for t-tests and ANOVAs. *Front Psychol*. 2013;4, <http://dx.doi.org/10.3389/fpsyg.2013.00863>.
- Vargha A, Delaney HD. A Critique and Improvement of the CL Common Language Effect Size Statistics of McGraw and Wong. *J Educ Behav Stat*; 2016, <http://dx.doi.org/10.3102/10769986025002101>.
- Lauche R, Langhorst J, Dobos GJ, Cramer H. Clinically meaningful differences in pain, disability and quality of life for chronic nonspecific neck pain – a reanalysis of 4 randomized controlled trials of cupping therapy. *Complement Ther Med*. 2013;21:342–7, <http://dx.doi.org/10.1016/j.ctim.2013.04.005>.
- Castien RF, Blankenstein AH, van der Windt DAWM, Dekker J. Minimal clinically important change on the Headache Impact Test-6 questionnaire in patients with chronic tension-type headache. *Cephalalgia Int J Headache*. 2012;32:710–4, <http://dx.doi.org/10.1177/0333102412449933>.
- Jacobson GP, Ramadan NM, Norris L, Newman CW. Headache disability inventory (HDI): short-term test-retest reliability and spouse perceptions. *Headache*. 1995;35(9):534–9.
- Pool JJM, Ostelo RWJG, Hoving JL, Bouter LM, de Vet HCW. Minimal clinically important change of the Neck Disability Index and the Numerical Rating Scale for patients with neck pain. *Spine*. 2007;32:3047–51, <http://dx.doi.org/10.1097/BRS.0b013e31815cf75b>.
- Jay GW, Brunson J, Branson SJ. The effectiveness of physical therapy in the treatment of chronic daily headaches. *Headache*. 1989;29:156–62.
- Toro-Velasco C, Arroyo-Morales M, Fernández-de-Las-Peñas C, Cleland JA, Barrero-Hernández FJ. Short-term effects of manual therapy on heart rate variability, mood state, and pressure pain sensitivity in patients with chronic tension-type headache: a pilot study. *J Manipulative Physiol Ther*. 2009;32:527–35, <http://dx.doi.org/10.1016/j.jmpt.2009.08.011>.
- Ghanbari A, Rahimjaberi A, Mohamadi M, Abbasi L, Sarvestani FK. The effect of trigger point management by positional release therapy on tension type headache. *NeuroRehabilitation*. 2012;30:333–9, <http://dx.doi.org/10.3233/NRE-2012-0764>.

26. Fregni F, Imamura M, Chien HF, Lew HL, Boggio P, Kaptchuk TJ, et al. Challenges and recommendations for placebo controls in randomized trials in physical and rehabilitation medicine: a report of the international placebo symposium working group. *Am J Phys Med Rehabil.* 2010;89:160–72, <http://dx.doi.org/10.1097/PHM.0b013e3181bc0bbd>.
27. Savović J, Jones HE, Altman DG, Harris RJ, Jüni P, Pildal J, et al. Influence of reported study design characteristics on intervention effect estimates from randomized, controlled trials. *Ann Intern Med.* 2012;157:429–38, <http://dx.doi.org/10.7326/0003-4819-157-6-201209180-00537>.
28. Bendtsen L, Bigal ME, Cerbo R, Diener HC, Holroyd K, Lampl C, et al. Guidelines for controlled trials of drugs in tension-type headache: second edition. *Cephalalgia Int J Headache.* 2010;30:1–16, <http://dx.doi.org/10.1111/j.1468-2982.2009.01948.x>.
29. Bialosky JE, Bishop MD, Penza CW. Placebo mechanisms of manual therapy: a sheep in wolf's clothing? *J Orthop Sports Phys Ther.* 2017;47:301–4, <http://dx.doi.org/10.2519/jospt.2017.0604>.