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AMERICAN CONGRESS OF REHABILITATION MEDICINE

Archives of Physical Medicine and Rehabilitation

journal homepage: www.archives-pmr.org

Archives of Physical Medicine and Rehabilitation 2016;■:■■■-■■■

ORIGINAL RESEARCH

Additional Effects of a Physical Therapy Protocol on Headache Frequency, Pressure Pain Threshold, and Improvement Perception in Patients With Migraine and Associated Neck Pain: A Randomized Controlled Trial

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Abstract

Objective: To evaluate the additional effect provided by physical therapy in migraine treatment.

Design: Randomized controlled trial.

Setting: Tertiary university-based hospital.

Participants: Among the 300 patients approached, 50 women (age range, 18−55y) diagnosed with migraine were randomized into 2 groups: a control group (n=25) and a physiotherapy plus medication group (n=25) (N=50).

Interventions: Both groups received medication for migraine treatment. Additionally, physiotherapy plus medication patients received 8 sessions of physical therapy over 4 weeks, comprised mainly of manual therapy and stretching maneuvers lasting 50 minutes.

Main Outcome Measures: A blinded examiner assessed the clinical outcomes of headache frequency, intensity, and self-perception of global change and physical outcomes of pressure pain threshold and cervical range of motion. Data were recorded at baseline, posttreatment, and 1-month follow-up.

Results: Twenty-three patients experienced side effects from the medication. Both groups reported a significantly reduced frequency of headaches; however, no differences were observed between groups (physiotherapy plus medication patients showed an additional 18% improvement at posttreatment and 12% improvement at follow-up compared with control patients, $P>.05$). The reduction observed in the physiotherapy plus medication patients was clinically relevant at posttreatment, whereas clinical relevance for control patients was demonstrated only at follow-up. For pain intensity, physiotherapy plus medication patients showed statistical evidence and clinical relevance with reduction posttreatment ($P<.05$). In addition, they showed better self-perception of global change than control patients ($P<.05$). The cervical muscle pressure pain threshold increased significantly in the physiotherapy plus medication patients and decreased in the control patients, but statistical differences between groups were observed only in the temporal area ($P<.05$). No differences were observed between groups regarding cervical range of motion.

Conclusions: We cannot assume that physical therapy promotes additional improvement in migraine treatment; however, it can increase the cervical pressure pain threshold, anticipate clinically relevant changes, and enhance patient satisfaction.

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Migraine is a prevalent disease affecting approximately 12% of the world's adult population.[1] It is a burdensome disease that affects individuals, their families, and society.[2,3] As part of migraine pathophysiology, sensitization of certain neuronal groups in the

Supported by the São Paulo Research Foundation (process no. 2011/07952-1).
Brazilian Clinical Trials Registry No.: RBR-6kvx74.
Disclosures: none.

0003-9993/16/$36 - see front matter © 2016 by the American Congress of Rehabilitation Medicine
http://dx.doi.org/10.1016/j.apmr.2015.12.006

brainstem leads to allodynia and muscle sensitivity.[4] Furthermore, muscle dysfunctions, especially in the craniocervical area, may trigger migraine attacks and also increase their frequency.[5,6]

Compared with individuals without migraine, individuals with migraine are more likely to report cervical pain,[7,8] altered postural alignment,[9] reduced cervical mobility,[10] myofascial trigger points,[5,6,11] and increased muscle sensitivity.[12,13] Cervical pain contributes to disability in individuals with migraine[14] and may be a risk factor for migraine chronification.[15]

Accordingly, physical therapy addressing the craniocervical region may be beneficial for patients with migraine. Most recent reviews of manual therapy for migraine report that massage and combined modalities of physical therapy are as effective as pharmacologic treatment; however, recommendations for spinal manipulation remain controversial.[16-18] A common feature of these reviews is the lack of more robust evidence for recommending, or not recommending, some manual therapy modalities to treat migraine because of the poor methodologic quality of the available clinical trials. Most of these studies were not randomized or controlled, as recommended by the Consolidated Standards of Reporting Trials (CONSORT) statement,[19] and they did not follow the criteria of the International Headache Society.[20] The physiotherapy treatment chosen in this study was based on current literature[16-18] and on our clinical routine at the Temporomandibular Disorders and Headache Dysfunction Physiotherapy Clinic.

Pharmacologic treatment has been established as the criterion standard approach for patients with migraine. However, because a multidisciplinary approach is also recommended,[21] it is important to verify to what extent physiotherapy, as an additional protocol, can influence or enhance the effectiveness of prescribed medications to justify its inclusion in the management of migraine and optimize prognosis.

The aim of this study was to evaluate the effect of medication combined with a physical therapy protocol for migraine treatment using the International Headache Society recommendations[22] and the CONSORT recommendations.[19]

Methods

Design

The design was a randomized controlled trial.

Participants

This study was performed from January 2011 to March 2013 at a tertiary, university-based hospital in Ribeirão Preto City, Brazil. Volunteers were recruited by radio and television advertisements.

After agreeing to participate, volunteers came in for a prescreening visit. The study procedure and consent forms were approved by the Ethics Committee of the University of Sao Paulo (process no. 14027/2010). Migraine diagnosis, according to the International Headache Society classification criteria,[20] was assigned by a neurologist with 10 years of experience in headache diagnosis. Inclusion criteria were women between 18 and 55 years old who fulfilled the criteria for migraine with a headache frequency of at least 5 days per month and self-reported cervical pain for at least 3 months.

Exclusion criteria were concomitant headaches, including tension-type and cervicogenic headaches, previous facial and neck trauma, noncontrolled systemic diseases associated with the musculoskeletal system, physiotherapy treatment for craniocervical dysfunction in the previous year, and unwillingness to complete all of the stages of the study or to follow study procedures.

An examiner who was blinded to the nature of the study performed the sample characterization at baseline by administering the following questionnaires to evaluate comorbidities and related disabilities.

The first questionnaire was the Migraine Disability Assessment,[23] which is used to verify the severity of migraine-related disability. Classifications include no disability (0−5 points), mild (6−10 points), moderate (11−20 points), or overall illness severity (≥21 points). It is a reliable measurement with a Cronbach α of .83 and a Spearman correlation coefficient of .84.[24]

The second questionnaire was the Neck Disability Index,[25] which is used to verify disability caused by neck pain and classify it as mild (5−14 points), moderate (15−24 points), severe (25−34 points), or complete disability (≥35 points). This is the most recommended questionnaire to assess neck-related disability with a Cronbach α of .74 and moderate reliability (intraclass correlation coefficient = .50 or Spearman correlation = .92).[26,27]

The third questionnaire was the Allodynia Symptom Checklist/Brazil,[28] which is used to identify the presence and severity of cutaneous allodynia as a symptom associated with central sensitization. Presence of cutaneous allodynia during a migraine attack could be considered as mild (3−6 points), moderate (7−8 points), or severe (≥9 points). It is a reliable tool, with a Cronbach α of .76 and moderate reliability (weighted κ = .58).[28]

The fourth questionnaire was the 8-item Patient Health Questionnaire depression scale (PHQ-8)[29] to identify depressive symptoms. Classification of severity of depressive symptoms includes no significant depressive symptoms (0−4 points), mild (5−9 points), moderate (10−14 points), moderately severe (15−19 points), or severe (20−24 points). The reliability of the PHQ-8 can only be assumed to be satisfactory with regard to its internal consistency (Cronbach α = .82)[30] because test-retest reliability has not been published.

After the baseline assessment, volunteers were allocated to the control group (n = 25) or physiotherapy plus medication group (n = 25), according to the results of a simple 1:1 randomization sequence provided in sealed opaque envelopes. A researcher, who was not involved in the actual study assessment and intervention, was responsible for preparing the envelope, opening it in front of the patient, and scheduling the sessions.

This randomized controlled trial followed the checklist of the CONSORT statement.[19]

Outcome measures

Frequency of headaches was considered the primary outcome. Secondary outcomes were headache intensity, global change perception, pressure pain threshold, and cervical range of motion. Data were classified into clinical and physical outcomes; both were assessed by a blinded examiner at baseline and posttreatment, which was performed between 2 and 7 days after the last physiotherapy

List of abbreviations:

CI	**confidence interval**
CONSORT	**Consolidated Standards of Reporting Trials**
PHQ-8	**8-item Patient Health Questionnaire depression scale**

session. Only headache frequency and intensity were requested at follow-up by way of telephone calls by the same blinded evaluator. Each participant was enrolled for 3 months comprising the baseline, posttreatment, and follow-up.

All study participants completed a 30-day headache diary reporting pain frequency and intensity using a scale ranging from 1 to 3 (where 1 is mild pain, 2 is moderate pain, and 3 is severe pain).

Global change perception was assessed by the Patient Global Impression of Change Scale to quantify subjective perception of worsening or improvement, as suggested by the International Headache Society.[20,31]

Pressure pain threshold was measured by a digital manual dynamometer (DDK-10[a]). A 1-cm^2 rubber disk was adapted to the metal point of the device to avoid any damage. Pressure pain threshold values were recorded twice (kg/cm^2) in random order and bilaterally for the upper trapezius, sternocleidomastoid, suboccipital, temporal, frontal, and sternocleidomastoid muscles. This measure has excellent reliability in patients with migraine (intraclass correlation coefficient = .74–.98).[12]

Cervical flexion, extension, bilateral rotation, and lateral flexion ranges were measured twice by the cervical range of motion device,[b] in a random sequence of movements. Subjects were asked to sit comfortably on a chair with both feet on the ground; ankles, knees, and hips at 90°; with their back supported on the back of the chair; and arms resting on their thighs.[10] The cervical range of motion data have excellent reliability with intraclass correlation coefficients >0.8.[32]

The averages of both repetitions were used for pressure pain threshold and cervical range of motion analysis.

Intervention

Both groups received prescribed prophylactic drugs (eg, amitriptyline, topiramate) and rescue medications for migraine in similar daily doses, according to the judgment of a neurologist specializing in headaches. Patients were instructed to not take any additional medications during the study period.

Weekly telephone calls were made to control patients to encourage them to complete the headache diary, in order to enhance health care attention and control the placebo effect related to the weekly sessions in the physiotherapy plus medication group.

A senior physical therapist administered the treatment to physiotherapy plus medication patients, twice a week for 4 weeks, and each session lasted 50 minutes. Sessions were performed with the patients in supine position, and the protocol was the same for all patients, as subsequently described.

Fifteen minutes of diaphragm respiratory training

The relaxation period included smooth diaphragmatic breathing with gentle expirations while instructing the patients to pull down their superior ribs.

Five minutes of cervical mobilization and traction

The physical therapist performed a mobilization technique, with slow, progressive, and regular stretching of the soft tissue, with the hands overlapped and resting on the suboccipital region, followed by cervical spine traction,[33] while the patient continued diaphragmatic breathing.

Fifteen minutes of massotherapy and myofascial release

The physical therapist performed deep massage and myofascial release on the craniocervical muscles.

Six minutes of digital compression on muscle trigger points

When a trigger point was identified according to Simons and Travell,[34] digital compression was performed for 90 seconds. Eight trigger points on the craniocervical muscle were considered the limit for treatment in each session.

Passive stretching of neck muscles

Passive stretching was done 3 times for neck flexion and rotation associated with the ipsilateral flexion directions using moderate force within the limits of the patient's pain and maintained for 30 seconds.

Data analysis

According to a previous study,[35] the sample size calculation was made based on 2 primary outcomes, chosen at the development of the study design: frequency of pain (number of days in a month) and intensity of pain (0–3). Furthermore, it was feasible to establish the sample size on frequency of migraine attacks, based on a sample power calculation adopting a β of 80% and α of .05 to detect a difference of 1 day in the occurrence of headache per month from baseline to posttreatment and baseline to follow-up. This resulted in a sample size estimate of at least 17 participants in each group.

To compare the difference between groups at baseline, the Fisher exact test was performed for the variables of Migraine Disability Assessment and PHQ-8, whereas the nonparametric Wilcoxon rank-sum test was used for comparisons of the Allodynia Symptom Checklist/Brazil.

Data were analyzed by intention to treat, and a simple imputation of means was performed for missing data. Intragroup (pre- and posttreatment) and intergroup (comparing the improvement average between the groups) differences in clinical outcomes were analyzed by a linear regression model, with mixed effects for frequency, and by a paired t test for dependent samples for pain intensity. Global change perception at posttreatment was contrasted between groups using the nonparametric Wilcoxon rank-sum test.

Intragroup differences between baseline and posttreatment concerning pressure pain thresholds and cervical ranges of motion were analyzed by a linear regression model with mixed effects. Because a difference between groups in pressure pain thresholds was observed at baseline, to avoid the influence of this baseline difference on the treatment response results, a repeated measures analysis of variance corrected by multiplicity was performed to compare the magnitude of the changes observed in both groups. For all tests, SAS software version 9.2[c] was used, and a significance level of 5% was adopted.

To complement the main results of the aforementioned analysis, the effect size and minimal clinically important difference were calculated for headache diary variables.[36,37] These combined data provide an additional interpretation of the results by classifying the clinical relevance of the intragroup differences found.

Values for the minimal clinically important difference were calculated using mean $\pm$ SD of control patients at baseline and follow-up and the time interval considered for the greatest therapeutic effect of the medicine. As suggested by Armijo-Olivo et al,[36] the minimal clinically important difference used as reference was calculated considering an arbitrary effect size of 0.4 because it represents a moderate effect. The minimal clinically important difference reference was established for frequency of headaches (d) as equal to 4.3 and for headache intensity as equal to .12. To be considered as clinically relevant, the difference found

for the primary outcomes between assessments should be higher than the minimal clinically important difference and have an effect size $\geq$.40.[36]

Results

Among the 300 patients approached, 98 demonstrated an interest in participating. Of these, 48 were excluded because of the presence of other headache diagnoses, sex, age, unavailability, or refusal of medication. The remaining volunteers were randomized to the treatment groups in equal proportions: 25 subjects in the control group and 25 in the physiotherapy plus medication group. Four physiotherapy plus medication volunteers dropped out of the study because of lack of time and for personal reasons. Five control group volunteers also dropped out of the study, claiming side effects of the medications and lack of time for posttreatment evaluation (fig 1). Side effects reported were excessive sleepiness, dry mouth, and forgetfulness; however, no harm because of physical therapy intervention was reported.

Demographic and baseline clinical characteristics are described in table 1. There were no differences between groups at the baseline assessment with regard to headache frequency and intensity, presence of allodynia, symptoms of depression, migraine affect, or neck disability ($P>.05$).

Clinical outcomes

A significant intragroup improvement was seen in both groups for headache frequency at posttreatment (physiotherapy plus medication group: −4.49; 95% confidence interval [CI], −7.00 to −1.96; control group: −3.68; 95% CI, −6.20 to −1.15) and follow-up (physiotherapy plus medication group: −5.21; 95% CI, −7.92 to −2.81; control group: −4.60; 95% CI, −7.21 to −2.70) in relation to baseline ($P<.05$) (table 2). The mean frequency reduction in physiotherapy plus medication patients was 18% higher than that in control patients at posttreatment and 12% higher during the follow-up period, but this additional effect showed no statistical significance ($P>.05$). The 2 groups did not differ with regard to headache frequency in the posttreatment

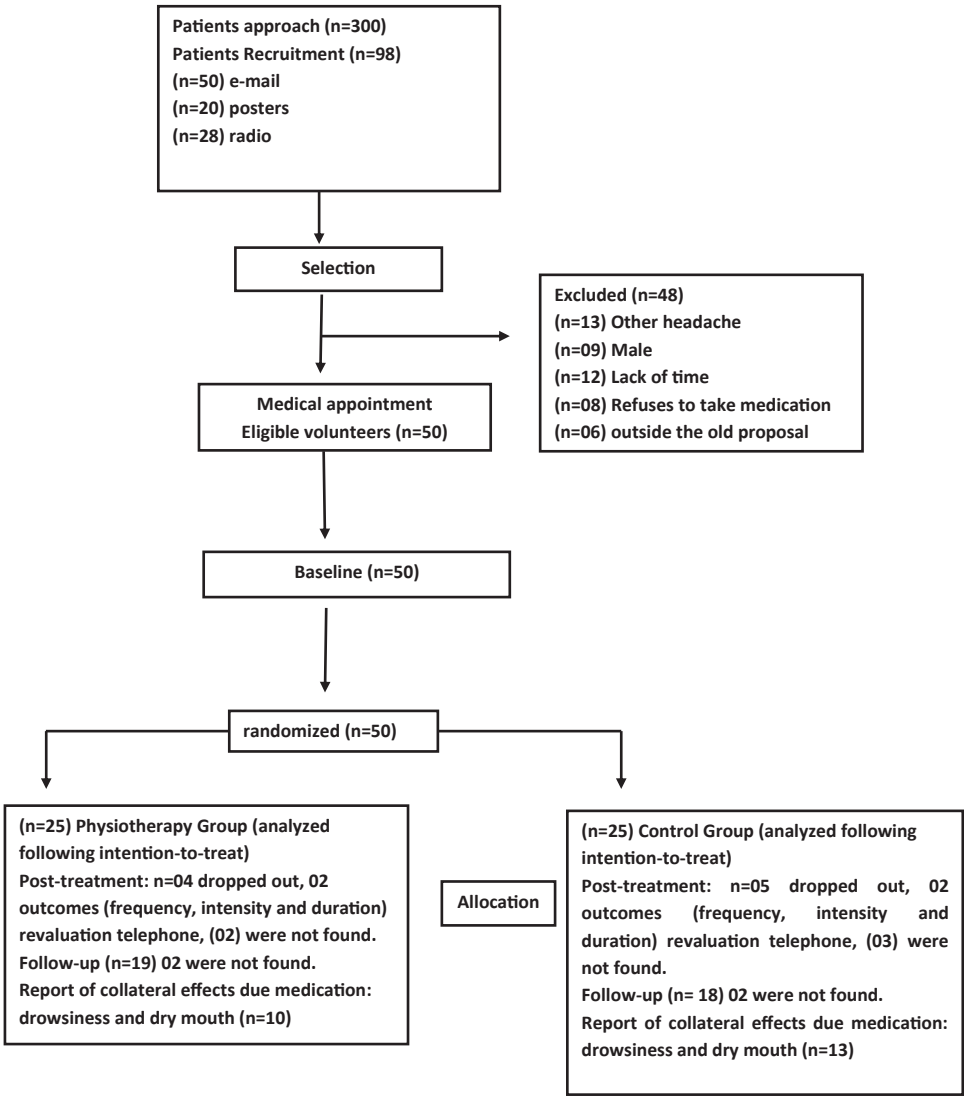

Fig 1 Flow diagram.

Table 1 Baseline demographic characteristics of the physiotherapy group (n=25) and control group (n=25)

Characteristic	Physiotherapy Group	Control Group	*P*
Age (y)	34 (20–54)	37 (20–54)	.41
Weight (kg)	69 (49–100)	68 (54–94)	.33
Years of disease	16 (2–40)	18 (6–30)	.90
Frequency (monthly)	16 (6–30)	18 (7–30)	.30
Duration (h)	15 (7–24)	17 (7–24)	.15
Headache intensity (periods)*			
Mild	14.7 (1–45)	16.9 (0–66)	.52
Moderate	10.4 (3–33)	14.6 (0–47)	.11
Severe	6.9 (2–22)	10.2 (0–34)	.12
MIDAS†			
No disability	4 (16)	2 (8)	.88
Mild disability	0 (0)	1 (4)	
Moderate disability	3 (12)	3 (12)	
Severe disability	18 (72)	19 (76)	
NDI‡			
No disability	3 (12)	2 (8)	.31
Mild disability	12 (48)	13 (52)	
Moderate disability	8 (32)	7 (28)	
Severe disability	2 (8)	3 (12)	
ASC-12/Brazil§			
Without allodynia	3 (12)	0 (0)	.15
Mild allodynia	4 (16)	4 (16)	
Moderate allodynia	9 (36)	9 (36)	
Severe allodynia	9 (36)	12 (48)	
PHQ-8†			
No disability	7 (14)	3 (6)	.14
Mild	6 (12)	6 (12)	
Moderate	8 (16)	12 (24)	
Moderate to severe	4 (8)	1 (2)	
Severe	0 (0)	3 (6)	

NOTE. Values are mean (range) or n (%).
Abbreviations: ASC-12/Brazil, Allodynia Symptom Checklist/Brazil; MIDAS, Migraine Disability Assessment; NDI, Neck Disability Index.
* A total of 90 periods were available to fulfill.
† Fisher exact test.
‡ Regression model with mixed effects.
§ Wilcoxon rank-sum test.

phase (−2.97; 95% CI, −1.55 to 7.08) or during the follow-up period (−2.77; 95% CI, −1.21 to 7.07; *P*>.05) (table 3).

Intragroup changes in pain intensity were observed only in the physiotherapy plus medication group, at the posttreatment assessment relative to baseline (−.17; 95% CI, −.04 to −.29; *P*<.05). No difference was observed between the groups for the other study periods (see table 2). There was no difference in pain intensity (*P*>.05) between groups (see table 3).

Clinical relevance can be attributed to the changes observed in headache frequency for the physiotherapy plus medication group (effect size=0.6, difference=−4.49d) but not for the control group (effect size=0.5, difference=−3.68d) at the posttreatment assessment. During the baseline to follow-up period, both groups showed clinically relevant changes (physiotherapy plus medication group: effect size=.77, difference=−5.21d; control group: effect size=.67, difference=−4.6d). For pain intensity, only physiotherapy plus medication patients showed clinical relevance during the baseline to posttreatment period (effect size=0.6, difference=−.17) (see table 2).

Satisfaction with treatment was higher in physiotherapy plus medication patients (mean, 7.32±1.31) than in control patients (mean, 6.16±1.18; *P*<.05) (fig 2A). In addition, the global perception of change was higher in the physiotherapy plus medication group than in the control group, with regard to small improvement (41% vs 18%, respectively) and great improvement (26% vs 12%, respectively; *P*<.05) (fig 2B).

Physical outcomes

Increases in pressure pain threshold were observed in the suboccipital (mean, .44±1.18) and trapezium muscles (mean, .46±1.25) of the physiotherapy plus medication group (*P*<.05). However, there was a decrease in pain threshold for the frontal and temporal muscle sites in control patients (*P*<.05) at the posttreatment assessment. Considering that physiotherapy plus medication patients had significantly lower pressure pain thresholds than control patients at baseline (*P*<.05), the comparison of changes in both groups revealed that the physiotherapy plus medication patients presented a greater increase in the pain threshold for the temporal muscle compared with the control patients (.76; 95% CI, −1.44 to −.09; *P*<.05) (table 4).

No statistically significant difference was observed for cervical range of motion changes between baseline and posttreatment in both groups (fig 3).

Table 2 Intragroup differences between the periods: baseline, posttreatment, and follow-up in clinical outcomes (change over time and 95% CI) in the physiotherapy group (n=25) and control group (n=25)

	Physiotherapy Group		Control Group	
Clinical Outcomes	Change Over Time (95% CI)	*P*	Change Over Time (95% CI)	*P*
Frequency (d/mo)*				
Baseline to posttreatment	−4.49 (−7.00 to −1.96)	.0006†	−3.68 (−6.20 to −1.15)	.004
Baseline to follow-up	−5.21 (−7.92 to −2.81)	<.0001†	−4.60 (−7.21 to −2.70)	.0005†
Posttreatment to follow-up	−0.72 (−3.44 to 1.67)	.49	−0.92 (−3.44 to −1.60)	.47
Headache intensity (1–3)*				
Baseline to posttreatment	−0.17 (−0.04 to −0.29)	.0099†	−0.04 (−0.18 to 0.09)	.52
Baseline to follow-up	−0.11 (−0.31 to 0.09)	.29	−0.06 (−0.19 to 0.06)	.34
Posttreatment to follow-up	0.06 (−0.12 to 0.24)	.50	0.01 (−0.14 to 0.11)	.81

* Reference of minimal difference to be relevant clinically for frequency of 4.3 and intensity of .12.
† Clinical relevant difference because the difference is >minimal clinically important difference and effect size >0.4.

Table 3 Intergroups differences at posttreatment and follow-up in clinical outcomes (mean and 95% CI) and differences between them (95% CI) in the physiotherapy group (n=25) and control group (n=25)

Clinical Outcomes	Physiotherapy Group	Control Group	Difference Between Groups	*P*
Frequency (d/mo)				
Posttreatment	11.63 (4–30)	14.60 (4–30)	−2.97 (−1.15 to 7.08)	.15
Follow-up	10.91 (2–30)	13.68 (3–30)	−2.77 (−1.21 to 7.07)	.16
Headache intensity (1–3)				
Posttreatment	1.74 (1.63–1.85)	1.79 (1.64–1.94)	−0.05 (−0.24 to 0.13)	.56
Follow-up	1.79 (1.62–1.98)	1.78 (1.68–1.88)	0.01 (−0.19 to 0.23)	.84

Discussion

Additional benefits of a physical therapy protocol, with regard to the frequency and intensity of migraine attacks, could not be confirmed. However, clinically relevant changes in headache frequency and intensity, associated with a better perception of change and patient satisfaction with the treatment, were observed in the physiotherapy plus medication group. Additionally, significant pressure pain threshold increments in the temporal muscle confirmed that the proposed therapy improved craniocervical sensitivity.

The objective of this study was to evaluate whether the combination of a physical therapy protocol with conventional treatment for migraine would confer any additional benefit over conventional treatment alone. Although significant reductions in headache frequency and intensity were observed, we were unable to confirm whether combined intervention has superior benefits over that provided with medication alone.

Among existing clinical trials, only Lemstra et al[21] considered the inclusion of subjects under conventional pharmacologic treatment alone as a control group. However, the intervention tested in the aforementioned study was 6 weeks of multidisciplinary intervention, not just physical therapy, and the patients in the intervention group demonstrated a superiority of 36% in frequency reduction, which is double of that found in the current study.

The physiotherapy protocol proposed in this study was demonstrated to be effective for reducing hypersensitivity of the trapezium and suboccipital muscles, considering the pressure pain threshold data. This finding is in support of the hypothesis that the protocol applied was able to reduce the amount of cervical nociceptive afferents that could contribute to central sensitization.

However, the pressure pain threshold improvement was not reflected in the headache frequency and intensity, suggesting that functional improvement precedes clinical improvement or that the duration of the intervention should be longer.

Moderate evidence has been contributed by existing studies with regard to the effects of massage, spinal manipulation, and multimodal disciplinary care in migraine treatment.[17] In addition, some interventions, including massage therapy, physiotherapy, relaxation, and chiropractic spinal manipulative therapy, might be as equally effective as propranolol and topiramate in migraine treatment.[16]

In this study, our results may be influenced by the weekly contact with the health care provider. It is possible that the weekly telephone calls made only to control group patients were not enough to minimize the discrepancy in health care attention provided during the physiotherapy sessions in the physiotherapy plus medication group. Nevertheless, because the magnitude of placebo-related hypoalgesia is dependent on the expectations of the individual, or on what individuals think will happen,[38] placebo effects were present in both groups because all patients started the pharmacologic treatment prescribed by the neurologist at their first appointment. In addition, the lack of significant differences between reductions in headache frequency and intensity reinforces the likelihood that a placebo effect caused by the physical therapy intervention was not sufficient to influence the results.

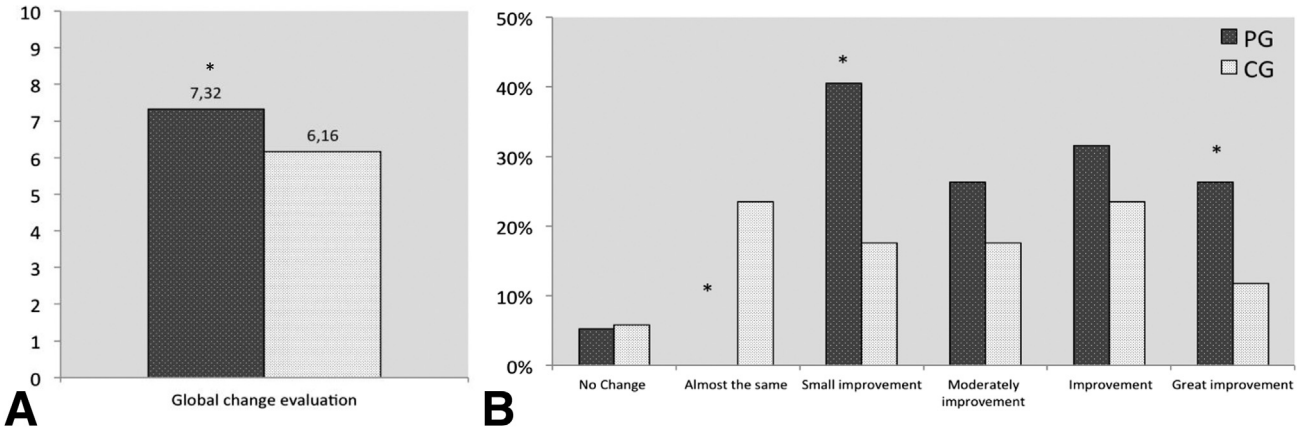

Fig 2 Perceived degree of change. (A) Total score on treatment satisfaction (0–10) between groups at posttreatment end point. (B) Self report of level of change after treatment. Abbreviations: CG, control group; PG, physiotherapy groups. *$P<.05$.

Table 4 Pressure pain threshold intragroup changes from baseline to posttreatment in the PG (n=25) and CG (n=25) and differences intergroup

Muscles	Intragroup Differences, Baseline to Posttreatment		Intergroup Differences, PG vs CG
	PG	CG	
Frontal	0.31±1.18	−0.38±1.31*	−0.66 (−1.11 to 0.25)
Trapezium	0.46±1.25*	−0.01±1.36	−0.44 (−1.12 to 0.23)
Suboccipital	0.44±1.18*	−0.16±1.34	−0.57 (−1.25 to 0.10)
Temporal	0.33±1.37	−0.46±1.83*	0.76† (−1.44 to −0.09)
SCM	0.25±0.82	−0.20±1.21	−0.43 (−1.11 to 0.25)

NOTE. Values are mean change ± SD or difference (95% CI).
Abbreviations: CG, control group; PG, physiotherapy group; SCM, sternocleidomastoid.
* Baseline versus posttreatment, $P<.05$.
† PG group versus CG, $P<.05$.

The physical therapy protocol proposed in this clinical trial mainly focused on the craniocervical muscles because muscle dysfunction has been demonstrated in migraine subjects,[5,6] and techniques applied are considered efficient.[17] Moreover, afferents of the structures treated converge to the trigeminocervical nucleus, and hypersensitivity of the craniocervical muscles confirms sensitization of these structures.[12,13] A reduction in this craniocervical hypersensitivity should reduce sensitization of the trigeminocervical nucleus and consequently reduce headache frequency.

This hypothesis of a reduction in sensitization is not attributed exclusively to craniocervical muscle treatment, considering that afferents of several other structures (eg, articular components of the temporomandibular joint or upper cervical spine) also converge to the trigeminocervical nucleus.

Because clinical relevance could be observed from the initiation of treatment with greater patient satisfaction, the addition of physical therapy for patients suffering from migraine may improve patient compliance and motivation. We speculate that the intervention period was not long enough to promote expressive changes, but our findings do provide preliminary support for further investigation with a more prolonged intervention.

Our study failed to demonstrate additional benefits of the physical therapy intervention directed at the craniocervical muscles. From a pragmatic point of view, we should be cautious in recommending the application of a 4-week protocol. From a theoretical point of view, however, there is evidence that physical therapy can be effective in reducing nociceptive afferents and enhancing patient satisfaction.

Study limitations

In considering the results of our study, some limitations remain to be addressed. As expected for all clinical trials, the generalizability of the results is limited to the same population and the same applied protocol. There is no evidence that the proposed 4-week protocol led to substantial additional reductions in headache frequency after 2 months in women with migraine, but it seems that clinical relevance was achieved first. We also cannot affirm that men would respond to the intervention in the same way as women because of differences in the perception of pain.[39] Also, different protocols or tailored interventions may have varied effects, and this remains to be tested.

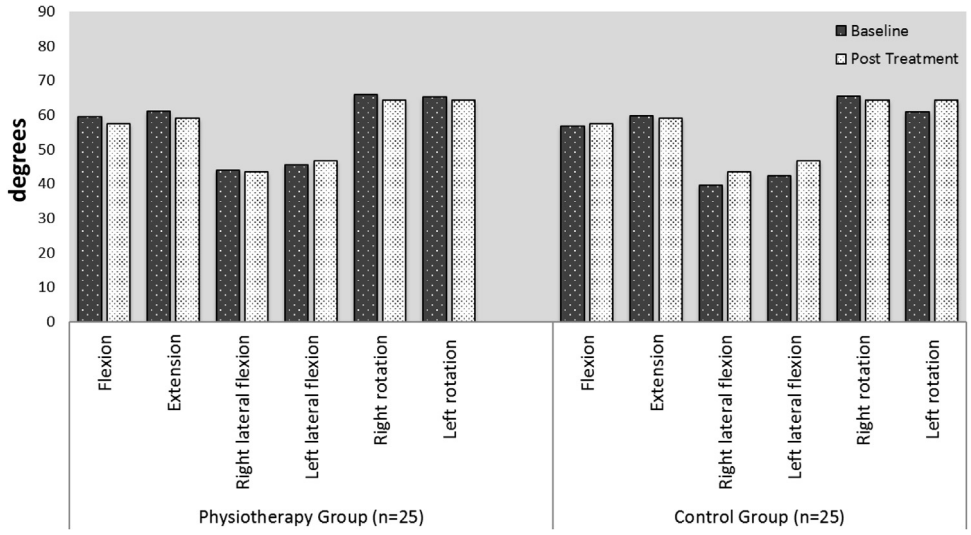

Fig 3 Physiotherapy group and control group cervical range of motion at baseline and posttreatment ($P>.05$).

We did not include a placebo treatment group, or a real control group, that did not undergo any intervention. In addition, the improvement difference established could have been overestimated, and the a priori sample power calculation might not have considered the expected differences between the groups and the high placebo effect of nonmedication therapies for patients. These questions should be addressed in clinical trials with larger sample populations. The Patient Global Impression of Change Scale was used to characterize the subjective significance of the physical changes because its use is recommended for clinical trials pertaining to the study of migraine[20]; however, no information regarding its reliability and responsiveness is available, and its interpretation is therefore limited.[40,41]

The follow-up period in this study may have been useful to observe how the outcomes changed after 1 month without physical therapy, but it is likely that this follow-up duration was not long enough to observe any long-term effects of the intervention. Finally, the natural course of the disease could have some influence on the generalizability of the results.

Conclusions

The physical therapy protocol proposed in this study did not enhance the effects of conventional treatment for migraine frequency and intensity. However, the clinically relevant changes in migraine frequency and intensity observed were associated with better perception of change and satisfaction with the treatment received. Furthermore, it was evidenced that physical therapy can be effective in reducing nociceptive afferents in the craniocervical region.

Suppliers

a. DDK-10; Kratos.
b. Cervical range of motion device; Performance Attainment Associates.
c. SAS software version 9.2; SAS Institute.

Keywords

Controlled clinical trial; Headache; Rehabilitation

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