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Physical Exam and Self-Reported Pain Outcomes from a Randomized Trial on Chronic Cervicogenic Headache

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Abstract

Objective—Objective clinical measures for use as surrogate markers of cervicogenic headache (CGH) pain have not been established. In this analysis, we investigate relationships between objective physical exam (PE) measures with self-reported CGH outcomes.

Methods—This is an exploratory analysis of data generated by attention control PE from an open-label randomized clinical trial. Forty of 80 subjects were randomized to 8 treatments (spinal manipulative therapy or light massage control) and 8 PE over 8 weeks. The remaining subjects received no PE. PE included motion palpation of the cervical and upper thoracic regions, active cervical range of motion (ROM) and associated pain, and algometric pain threshold evaluated over articular pillars. Self-reported outcomes included CGH and neck pain and disability, number of CGH headaches, and related disability days. Associations between PE and self-reported outcomes were evaluated using generalized linear models, adjusting for socio-demographic differences and study group.

Results—At baseline, number of CGH and disability days were strongly associated with cervical active ROM ($p < .001$ to $.037$). Neck pain and disability were strongly associated with ROM-elicited pain ($p < .001$ to $.035$) but not later in the study. After the final treatment, pain thresholds were strongly associated with week 12 neck pain and disability and CGH disability and disability days ($p = < .001$ to $.048$).

Conclusions—Cervical ROM was most associated with the baseline headache experience. However, 4 weeks after treatment, algometric pain thresholds were most associated. No one PE measure remained associated with the self-reported headache outcomes over time.

Keywords

Chiropractic; Headache Disorders; Cervicogenic Headache; Examination, Physical; Range of Motion, Articular

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INTRODUCTION

Globally, the estimate of those with an active headache disorder is 46% of the adult population.¹ According to a recent study, headache is the most common pain condition causing loss of productive time in the US workforce, with an average loss of 3.5 hours/week.²

Cervicogenic headache (CGH) is a type of headache causally associated with cervical myofascial tender spots or cervical spine dysfunction.³ The reported prevalence of CGH varies from 13.8% to 17.8% of the headache population in different epidemiological studies.⁴⁻⁶

Sufferers of headaches are frequent users of complementary and alternative medicine (CAM). 13% of those who reported headaches, in a survey published in 1998,⁷ visited a CAM practitioner for their condition within the last twelve months. CAM practitioner visitation, within the last twelve months, was 37.5% among those who reported neck problems.

Manual therapy of the spine for the treatment of cervicogenic headache is practiced by chiropractors, osteopaths, physical therapists, and naturopaths. Spinal manipulative therapy (SMT) is here defined as controlled directional, high-velocity, low-amplitude thrust.⁸ The primary objectives of SMT in the treatment of headache and neck pain is the alleviation of pain, muscle spasm, and functional impairment.⁸⁻¹⁰

The scientific evidence on SMT for the relief of chronic headache has been well discussed in systematic reviews of randomized trials.¹¹⁻¹⁸ These reviews have primarily evaluated patient self-reported outcomes, such as pain intensity, headache index, frequency, duration, and improvement. Physical and functional measures commonly used by treating physicians have not been as systematically included in clinical trials.

The research presented here uses data gathered during attention control visits to serve 2 goals: first, to find observed differences in physical exam outcomes between low dose groups; second to assess relationships between subjective patient-reported outcomes and objective physical exam measures. What can this tell us about CGH pathophysiology, or about potential outcomes for use by the practicing physician or in future clinical trials? Observed relationships and the potential utilization of physical exam procedures as objective surrogate markers of the patient's headache experience in clinical practice and clinical trials will be discussed.

METHODS

Design

This secondary analysis utilized data from an open-label prospective randomized controlled trial registered on ClinicalTrials.gov (NLM identifier NCT00246350). The trial is discussed in detail by Haas et al.¹⁹ The study made a preliminary evaluation of the relative efficacy of SMT for the treatment of CGH; it also looked at the effect of SMT dose. The study was conducted in the Portland, Oregon area between September 2004 and July 2007. A total of 40 out of 80 participants (n = 20 per group) were randomized to receive 8 treatments and 8 additional attention visits comprised of a physical exam. The participants had one treatment visit and one examination visit weekly for 8 weeks. The remaining 40 patients received 16 treatments and no attention physical exams after baseline and were thus excluded from this paper. The 40 patients receiving 8 treatments and 8 attention control visits were randomized

to 2 levels of care: SMT or a minimal light massage (LM) control to isolate the effect of SMT above the effect of touching the patient therapeutically.

Patients were randomized immediately preceding the first treatment using computer-generated, design adaptive allocation,²⁰⁻²² a minimization technique to balance potential confounders across groups. This included the following variables: age, gender, migraine, baseline CGH pain intensity index, baseline number of CGH, relative confidence in SMT and massage, and difference in expected optimal number of visits for treatment with SMT and LM. Hence, study group allocation was concealed from all study personnel prior to randomization.

Data for the objective measures were collected at baseline and weekly for 8 weeks; subjective measures were collected at baseline and at 4, 8, 12, and 24 weeks after the first treatment by phone interview and mailed questionnaire. Study guarantees of the participants' rights and safety were approved by Western States Chiropractic College Institutional Review Board (FWA 851) and data were secured in the College's Center for Outcomes Studies. All participants signed a consent form.

Participants

Volunteers were eligible if they had a history of at least 5 CGH per month for a minimum of three months, with CGH as defined by the International Headache Society (IHS) in 1998 (excluding the radiographic criterion)²³ and used in the trial by Nilsson et al.²⁴ The IHS criteria were: 1) pain localized in the neck and occipital region, may project to forehead, orbital region, temples, vertex, or ears; 2) pain precipitated or aggravated by particular neck movements or posture; and 3) either resistance/limitation of passive neck motion, palpatory changes in neck musculature or altered response to stretching/contraction, or abnormal neck muscle tenderness. The newer IHS criteria³ differ in that they include post hoc headache resolution unusable for study eligibility. To prevent a floor effect, participants were required to have a minimum score of 25 on the 100-point pain intensity scale described below.

A chiropractor/faculty member with 15 years experience screened potential participants for study eligibility through case history, standard orthopedic/neurological exam, heat sensitivity test, and 3-view cervical x-ray using the protocols of Vernon et al¹² and Souza²⁵ for CGH, and those of Gatterman and Panzer¹⁰ for the cervical region.

Potential participants were excluded if they were taking prophylactic prescription medication for the treatment of headache, or had manipulation/professional massage care for the neck or headache in the 3 months prior to baseline. Participants were ineligible for contraindications to spinal manipulation¹⁰ or complicating conditions that may be related to clinical outcomes: malignancy or history of active cancer in the last 5 years, spinal infection, vertebral tumors or fracture, cervical instability, blood dyscrasia, anti-coagulant therapy (warfarin/Coumadin or heparin), thrombophlebitis, long-term corticosteroid use, current use of prophylactic headache medication, severe head/neck trauma within the last 12 months, neck/intracranial surgery within the previous 5 years, radiating pain to the upper extremities or cervical disc condition, arthritis of the cervical spine, severe osteoporosis (suspected from x-ray), referred neck pain of organic origin, or pregnancy (x-ray prohibited).

Persons were also ineligible for other types of headache with etiologies that may confound the effects of manipulation on the cervicogenic component. These headache types³ include: cluster, metabolic/toxic, sinus, and HA associated with temporomandibular disease, tumors, and glaucoma.

Patients were permitted to have concomitant migraine and tension-type headaches because of apparent strong concomitance with CGH. Most respondents to ads for our feasibility study reported concomitant headache, usually migraine,²⁶ many CGH sufferers were shown to have migraine in a previous study,²⁷ and a common pathway had been proposed for the headache types.^{28, 29} In addition, these headache types had been shown to be responsive to SMT.¹⁵

Intervention

Four chiropractors with over 20 years of experience each served as the study therapists. Chiropractors provided all interaction with the participants during the 10-minute study visits. During each visit patients received either SMT, light massage, or an attention control physical exam.

The SMT visit consisted of high velocity, low amplitude spinal manipulation of the cervical and/or upper thoracic spine as described by Peterson and Bergmann.⁸ Modifications in manipulation recommended for older patients were permitted as required.^{30, 31} To relax the neck and upper back in preparation for spinal manipulation,³² the chiropractor administered a moist heat pack for five minutes and conducted a light massage for two minutes as in previous headache trials.^{33, 34}

The light massage visits consisted of five minutes of moist heat followed by five minutes of light massage - gentle effleurage (gliding) and gentle pétrissage (kneading) of the neck and shoulder muscles.^{8, 35}

The attention control visits began with an initial one to two minutes of a “sympathetic ear” in which the treating physician elicits information regarding recent headache history and related pain. This was followed by an 8 to 9-minute standardized manual examination described below.

Objective Measures

Physical examination included: motion and static palpation of the cervical and upper thoracic regions, inclinometric evaluation of active cervical range of motion and associated pain, and algometric pain threshold evaluated over articular pillars/transverse processes.⁸ Assessments of Endplay restriction and pain were conducted in a sitting position and recorded as a yes/no result at C₀₋₁ to C₂₋₃, C₃₋₄ to C₅₋₆, C₆₋₇ to C_{7-T1}, and T₁₋₂ to T₃₋₄. Compression and Distraction tests for midline neck pain were measured on a 0 to 10 scale, with 10 being worst imaginable. Cervical active range of motion was measured in all cardinal planes using a handheld inclinometer. Elicited pain on cervical active ROM was measured on a 0 to 10 scale, with 10 being the worst. Pain pressure threshold was measured using a pressure algometer, with the participant in a neutral position and recorded as initial pain perception. Cervical active ROM^{36, 37} and elicited pain,³⁸ endplay restriction,^{38, 39} pain pressure threshold,⁴⁰ compression,⁴¹ and distraction^{37, 41, 42} have been shown to have moderate to good inter-rater reliability and were chosen for their brevity, simplicity, and acceptability for the attention physical exam. It is important to note that the treating physician also performed the attention control physical exam and therefore was not blinded to treatment group after baseline.

Patient Self-Reported Subjective Outcome Measures—CGH pain intensity and disability, and neck pain intensity and disability, were collected every four weeks, in questionnaire form, using the Modified Von Korff Scales of Underwood et al.⁴³ This outcome was a Pain Scale and is the average of three 11-point numerical rating scales: CGH

pain today, worst CGH pain in last 4 weeks, and average CGH pain in the last 4 weeks. This question was repeated for neck pain.

The Disability Scale (secondary outcome) is the average of three 11-point scales evaluating interference with daily activities, social and recreational activities, and the ability to work outside or around the house. This question was repeated analogously for neck disability.

The 4 scales are scored from 0 to 100 with a lower score designated as more favorable. The scales have been shown to be reliable, valid, and responsive instruments for measuring pain and disability (including HA) and were chosen for their brevity, simplicity, acceptability to participants, and validity as a phone questionnaire.⁴³ Other subjective outcomes were the number of CGH and days with CGH-related functional disability in the last 4 weeks.⁴⁴ Study personnel who interacted with patients via the phone questionnaire or through entering study data were blinded to treatment group.

Baseline Variables

Baseline variables included measures of outcomes, socio-demographics, and co-morbidity. Participants were classified as having “other co-morbidity,” a predictor of pain outcomes,⁴⁵ ⁴⁶ if they checked any from the following list: arthritis, asthma or allergies, GI problems, gynecological problems, hypertension, or other chronic condition.

Statistical Analysis

A full intention-to-treat analysis was conducted with each participant included in the original allocation groups; missing data were imputed. The imputation was done as follows. If a missing datum was preceded and followed by present data, then the imputed value was the average between the two. If the missing datum was at the end of the present data, then the last present value was carried forward.

In this exploratory analysis, the comparisons of group means of continuous baseline variables were conducted using two-sample t-tests. Group differences in baseline categorical variables were compared using Fisher's Exact tests. Group differences in baseline count data were compared using a Poisson model. Text and table notation represents mean and standard deviation as (mean $\pm$ sd), 95% confidence interval as [lower, upper], and counts and percentages as n (%).

The comparisons of differences between treatment groups for physical exam outcomes were conducted using multiple linear, logistic, or Poisson regression models, as appropriate; adjusting for baseline value of the outcome and those patient characteristics which differed at baseline. Linear models were used for continuous data, logistic models for categorical data, and Poisson models for count data.

Associations between physical exam and self-reported outcomes were assessed using multiple linear and Poisson regression models across both groups combined. This approach allows for associations to be observed unconfounded by which treatment group they are in. Linear models were used to find associations between four of the continuous subjective outcomes and the physical exam data, after adjusting for covariates including the treatment group and those socio-demographic characteristics which differed. Poisson models were used, with similar caveats, to find associations between the two subjective outcomes that were counts (number CGH and disability days). We chose not to adjust for baseline outcome or physical exam measures in this analysis because we are particularly interested in the association of most recent physical exam outcomes to patient reported outcomes.

Specifically, associations between baseline physical exams and baseline subjective outcomes were assessed. Week 4 and 8 physical exams were paired with week 4 and 8 subjective self-reported questionnaire outcomes for assessment, respectively. Week 8 physical exams (most recent and final physical exam) were paired with outcomes at 12 and 24 weeks. Due to the exhaustive nature of the results of this statistical analysis, only the p-value related to the physical exam variable being appraised is reported in the results section, and then only if the p-value is $<.05$.

Statistical testing for all variables was set at a two-sided alpha of 0.05. Multiple-testing adjustments were not made because this was an exploratory analysis on tertiary data for hypothesis generation. All analysis was conducted with Stata 11.0 [StataCorp, College Station, TX].

RESULTS

The study flowchart is presented in Figure 1. Adherence to attendance of study visits was sufficient and uniform across groups.

Baseline

Table 1 shows the baseline participant characteristics for the two study groups in this analysis. Participants tended to be young (37 ± 11), white, non-Hispanic (75%) women (78%). The mean CGH pain intensity and functional disability were 54.0 and 48.3 respectively. The sample averaged approximately fifteen CGH per month. About 1/4 of subjects reported suffering from migraine, 1/2 had low back pain, and 2/3 identified another co-morbid condition.

Statistically significant differences were observed in race and smoking variables. There are 19 white non-Hispanic participants in the SMT group and 11 in the LM group. There are five smokers in the SMT group and none in the LM group. No other statistically significant differences between groups in baseline participant characteristics were observed.

Table 2 shows the baseline physical exam characteristics for the two study groups with tests of the between-group differences adjusted for race and smoking. On average, participants had cervical range of motion pain of 1.4 on a zero to ten scale, 20° (55° out of 75°) of restricted extension cervical range of motion, four endplay restrictions, mean pain pressure threshold of 3.2 kg across all cervical segments, a score from orthopedic tests for midline pain of 0.7 on a zero to ten scale, and an overall mean pain score of 1.1 across all ten-point-scale physical exam measures. Pain pressure threshold had statistically significant differences between group means for pain over the right C₇ and left C₂ pillars (joints), but Table 2 shows that these differences are no longer statistically significant after adjusting for smoking and race. Only three physical exam variables showed statistically significant differences between group means after adjusting for smoking and race. These included cervical active ROM on right rotation and C₆-C₇ left and right rotation endplay restrictions ($p=.043$, $.034$, and $.028$ respectively).

Final Outcomes

Differences in final subjective outcomes were reported by Haas et al.¹⁹ Final adjusted differences between SMT and LM group means in the once-a-week group, also analyzed in this paper, favored SMT: -5.2 [-17.5 , 7.1] for CGH pain, -3.2 [-15.7 , 9.4] for CGH disability, -1.3 [-5.2 , 2.6] for number CGH in past for weeks, -2.9 [-17.0 , 11.2] for neck pain, and -4.2 [-17.5 , 9.1] for neck disability.

Table 3 shows the final physical exam outcomes following the end of treatment at eight weeks with tests of the between-group differences adjusted for race, smoking, and baseline physical exam measure. On average, participants tended to have an overall score of 0.5 across all zero to ten point pain scale physical exam measures, 20° (55° out of 75°) of restricted extended cervical range of motion, three endplay restrictions, mean pain pressure threshold of 3.4 kg across all cervical segments, compression midline pain measuring 0.3 on a zero to ten pain scale, and no distraction midline pain. While group differences consistently favored SMT for cervical active ROM and elicited pain, pain pressure threshold, and compression tests for midline pain, most observed statistically significant differences in means disappeared after adjusting for smoking and race. Statistically significant differences were observed between adjusted treatment group means only for pain on right rotation and pain on cervical extension ($p=.023$ and $.035$). These adjusted group differences were moderate in magnitude: $-1.0 [-1.8, -.1]$ and $-1.0 [-1.9, -.1]$ respectively.

Associations

Table 4 shows the statistically significant associations of physical exam measures with the nearest measure, in time, of subject's subjective headache experience after adjusting for smoking, race, and study treatment group. Textures are shown when the association of a physical exam measure with a subjective outcome (reflective of CGH experience) was statistically significant ($p\text{-value} < .05$).

Inclinometric cervical active ROM—Cervical active ROM measured at baseline was associated with number of CGH and disability days in the past 4 weeks and remained so at 4 weeks and 8 weeks. This PE measure became less associated in weeks 12 and 24 when the time between subject questionnaires and physical exam is extended.

Elicited pain on cervical active ROM—Pain elicited by cervical ROM was associated with neck pain intensity and disability, CGH frequency, and disability days at baseline. Neck pain and disability were not measured at weeks 4 and 8 and were not significantly associated after baseline. Cervical ROM pain was associated with CGH frequency and disability days at four weeks, but that association faded over time. Only pain elicited by cervical flexion remained associated with number of disability days throughout the study.

Sitting endplay rotation restriction—Endplay restriction was associated with number of CGH and disability days in the past 4 weeks but this observed association did not remain strong after baseline.

Pain pressure threshold measured in kilograms—Pain pressure threshold measured at baseline was associated with number of CGH and disability days which disappeared until week 12. During treatment at week 4, headache pain was moderately associated with pain pressure threshold which also mostly disappeared until week 12. At week 12, pain pressure thresholds were highly associated with CGH pain and disability, neck pain and disability, and number of disability days. Thresholds remained moderately associated in week 24.

Orthopedic compression tests for midline pain—Orthopedic compression tests were moderately associated with subjective patient outcomes but no pattern was clear. Distraction test associations were limited by a floor effect; all participants scored zero on their right side at their four week exam and on both sides at their final physical exam.

DISCUSSION

We have noted that, at baseline, the study participants' subjective headache experience was most associated with physical exam measures of inclinometric cervical active ROM and elicited pain. However, this pattern shifted at week 12, four weeks after the final treatment. At week 12, the measure most associated with study participants' CGH subjective outcomes was the final exam pain pressure threshold.

Inclinometric cervical active ROM and elicited pain might be expected to be more associated with higher CGH and neck pain levels early on, due to potential associated splinting or muscle injury. This association did not appear in all participants since 11 out of 40 participants (~25%) reported no pain on cervical ROM at baseline. However, visual inspection of the raw data shows that those who had pain elicited by cervical active ROM also had worse subjective outcomes at baseline.

Later on, after the application of manual medicine, it is expected that the relationship of baseline inclinometric cervical active ROM and elicited pain with headache/neck pain would decrease. However, with the improvement of many study participants, zero pain reported on cervical ROM increased from 11 to 20 out of 40 participants (~50%) at their final physical exam; it is difficult to establish any type of linear relationship with this type of floor effect.

Differences observed between groups at low dose may be more pronounced at a higher dose as they were with the subjective outcomes. Inasmuch as these physical exam outcomes are associated with the subjective patient reported outcomes, we might see a stronger association between the two at a higher dose. Future studies that include cervical range of motion and associated pain as secondary outcomes, measured by a blinded study physician, will allow clinicians to assess these higher dose relationships.

The fact that pain pressure threshold over paraspinal tissues and joints is associated with headache/neck pain disability and frequency at 12 weeks, but not consistently throughout, is puzzling. This can be explained, in part, by the fact that the pain pressure threshold increases as the patient improves, thus avoiding the floor effect limitation that occurs in the other physical exam measures. Also, the development of a relationship at 12 weeks between pain pressure threshold and persistent headaches may have occurred because other musculoskeletal components potentially associated with the neck pain and headaches were not fully affected by thrust manipulation. Perhaps SMT improved joint mobility without fully ameliorating other soft tissue components of CGH such as paraspinal trigger points. Although we were underpowered to detect this type of result, both treatment groups experienced this change in association. Still, it is likely that those who continue to have a low pain pressure threshold tolerance are more likely to have persistent symptoms and thus be candidates for further manual care.

No one physical exam measure remained associated with the self-reported headache discomfort questions over time. This is likely due to patient improvement or a widespread floor effect. Thus, no single objective physical exam surrogate measure for CGH clinical research is suggested by this study as a useful longitudinal outcome.

A different analytical approach to the data would have been to do a prediction analysis of the data to assess if these baseline physical exam measures are predictive of treatment outcome, as has been done by Jull and Stanton⁴⁷ who found no consistent predictors of reduction in CGH. This will be our next analysis.

It is interesting to note that study subjects in both groups remained restricted on cervical extension after treatment (20°, or 55° out of 75°, restriction on average). Cleland et al⁴⁸

reported restricted cervical extension as predictive of success with SMT. Restricted cervical extension may be a part of the pathophysiology of the cervicogenic headache. In addition, perhaps decreased cervical range of motion on extension is indicative of a population who might suffer from chronic cervicogenic headaches and could be a future focus of treatment assessment.

Limitations

The treating physicians performed the attention control physical exam were not blinded to treatment arm after baseline. As a result, there might be significant bias in physician expectation of improvement based both on time in the study and upon treatment group assignment. However, the lack of differences between groups mitigates this concern to some degree.

With this sample size, 20 patients per treatment arm, there was minimal power to detect an association between physical exam and subjective outcome measures or the effect of treatment on the observed associations. The results obtained here need to be repeated by larger studies with blinded assessors, to further flush out the pathophysiology of cervicogenic headache.

There might be an observable relationship between patient-reported CGH measures and physical exam measures with a higher treatment frequency. It is possible that this potential relationship might be different between the SMT and light massage groups. We plan to look at this in future studies.

The physical exam measures, excluding pain pressure threshold and cervical extension, all had a floor effect. As study subjects improved, the values hovered closer and closer to zero (or normal) allowing for small amounts of variance. While the study design excluded subjects whose CGH pain scored lower than 25 to mitigate a floor effect, baseline physical exam pain scores still had a maximum average of 2.3 on a zero to ten pain scale. Even the cervical active ROM scores were within eight degrees of normal ROM, on average, at baseline. Surrogate measures are difficult to find under these constraints.

Subjects answered questions about their experience over the past four weeks after the fact introducing a potential recall bias. Optional headache diaries were provided but not collected throughout the study to prevent this risk of bias. We chose not to require this to decrease study patient burden thus relying on collecting the patient's subjective experience every four weeks throughout the study.

Generalizability beyond randomized clinical trial protocol is not clear. Subjects enrolled in the study went through a phone screen, two baseline exams, and had to meet study criteria before enrollment. Larger clinical trials on headache populations that gather longitudinal physical exam data will help to establish the generalizability of these results.

CONCLUSIONS

At 12 weeks, a lower pain pressure threshold was indicative of those that still had the most intense subjective experience with headache pain versus cervical active range of motion and pain with movement. This relationship is different from that at baseline, where the reverse was true. It is also important to note that cervical extension remained restricted throughout the study, indicating a possible direction for the study of pathophysiology behind cervicogenic headaches. While, this is useful information for the practicing clinician who may use these physical exam indicators to track patient progress, no consistent surrogate physical exam measure for the cervicogenic headache experience is indicated.

Yet, clinically important changes over time were observed in physical exam indicators for self-reported CGH pain and disability outcomes. This is an important step towards establishing objective measures of CGH pain and disability for clinical studies.

PRACTICAL APPLICATIONS

- Cervical ROM and ROM-elicited pain measures are predictive of subjective CGH experience at baseline
- Pain pressure threshold measures are predictive of subjective CGH experience after treatment
- Restriction of cervical active extension range of motion may be typical for this population and is a possible focus for treatment assessment
- Knowing which objective measures are indicative of CGH pain is important for clinical research as well as the practicing physician.

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Figure 1.

Patient Flow Diagram (SMT = spinal manipulative therapy; LM = light massage; Att = attention control visit).

Table 1**Baseline Participant Characteristics**

	SMT 8 visits* (n = 20)	LM 8 visits* (n = 20)	p-value
Socio-demographic information			
Age (years)	38 ± 10	37 ± 13	0.826 [‡]
Gender (female)	16 (80%)	15 (75%)	1.000 [§]
Race (white non-Hispanic)	19 (95%)	11 (55%)	0.008 [§]
Latino	1 (5%)	3 (15%)	0.605 [§]
Marital status (married)	10 (50%)	10 (50%)	1.000 [§]
Education (college degree)	8 (40%)	9 (45%)	1.000 [§]
Income (< \$24000/yr)	6 (30%)	9 (45%)	0.514 [§]
Study participation			
Compliance (> 2/3 visits attended)	16 (80%)	16 (80%)	1.000 [§]
Attendance (Average # Tx visits attended))	14 ± 5	14 ± 4	0.973 [‡]
Cervicogenic headaches			
Pain intensity [‡]	51.2 ± 17.7	56.8 ± 15.8	0.293 [‡]
Functional disability [‡]	47.3 ± 25.7	49.3 ± 21.6	0.791 [‡]
Number (last 4 wk)	14.8 ± 8.4	15.8 ± 8.7	0.442 ^{//}
Disability days (last 4 wk)	5.1 ± 4.0	5.2 ± 4.8	0.889 ^{//}
Neck			
Pain intensity [‡]	53.3 ± 19.2	60.5 ± 21.4	0.267 [§]
Functional disability [‡]	46.3 ± 21.7	48.5 ± 23.6	0.765 [§]
Health status			
Migraine sufferer (self report)	6 (30%)	5 (25%)	1.000 [§]
Smoker	5 (25%)	0 (0%)	0.047 [§]
Low back pain	10 (50%)	10 (50%)	1.000 [§]
Other co-morbidity present	15 (75%)	13 (65%)	0.731 [§]
Avg # of other co-morbidity present	1.2 ± 1.0	1.0 ± 1.0	0.527 [‡]

SMT – spinal manipulative therapy; LM – light massage.

* notation is (mean ± sd) or n (%) as appropriate.

[‡] 100-point visual analog scales with lower scores favorable.

[‡] Denotes comparison of means by two-sample t-test

[§] Denotes comparison of proportions using Fisher's exact test

^{//} Denotes group comparison using Poisson model

Table 2**Baseline Physical Exam Scores**

	SMT 8 visits[*] (n = 20)	LM 8 visits[*] (n = 20)	p-value[†]
Cervical Active ROM (Inclinometer)			
Right Rotation (Normal 80°- shoulder)	77 ± 11	72 ± 12	0.043 [§]
Left Rotation (Normal 80°)	80 ± 15	74 ± 15	0.071 [§]
Flexion (Normal 60°)	57 ± 9	57 ± 15	0.947 [§]
Extension (Normal 75°)	55 ± 13	55 ± 17	0.955 [§]
Right Lateral Bending (Normal 45°)	42 ± 9	43 ± 11	0.589 [§]
Left Lateral Bending (Normal 45°)	44 ± 12	41 ± 11	0.660 [§]
Cervical Active ROM (Pain: 0 – 10)			
Right Rotation [‡]	0.9 ± 1.7	1.8 ± 2.6	0.161 [§]
Left Rotation [‡]	0.8 ± 1.4	2.0 ± 2.6	0.300 [§]
Flexion [‡]	0.5 ± 1.1	1.2 ± 2.1	0.171 [§]
Extension [‡]	0.8 ± 1.4	1.6 ± 2.2	0.453 [§]
Right Lateral Bending [‡]	1.9 ± 2.4	2.3 ± 2.9	0.614 [§]
Left Lateral Bending [‡]	1.1 ± 2.3	2.2 ± 2.5	0.130 [§]
Sitting Rotation Endplay Restriction			
C ₀₋₁ to C ₂₋₃ Left	14 (70%)	13 (65%)	0.865 ^{//}
C ₀₋₁ to C ₂₋₃ Right	11 (55%)	15 (75%)	0.190 ^{//}
C ₃₋₄ to C ₅₋₆ Left	10 (50%)	12 (60%)	0.138 ^{//}
C ₃₋₄ to C ₅₋₆ Right	13 (65%)	10 (50%)	0.384 ^{//}
C ₆₋₇ to C _{7-T1} Left	2 (10%)	8 (40%)	0.034 ^{//}
C ₆₋₇ to C _{7-T1} Right	5 (25%)	8 (40%)	0.028 ^{//}
T ₁₋₂ to T ₃₋₄ Left	10 (50%)	10 (50%)	0.833 ^{//}
T ₁₋₂ to T ₃₋₄ Right	8 (40%)	12 (60%)	0.083 ^{//}
Pain Pressure Threshold (kg)			
C ₂ Right	3.9 ± 1.3	3.0 ± 1.5	0.116 [§]
C ₄₋₅ Right	3.5 ± 1.3	2.9 ± 1.3	0.227 [§]
C ₇ Right	4.7 ± 2.1	3.5 ± 1.9	0.124 [§]
C ₂ Left	3.7 ± 1.1	2.7 ± 0.9	0.037 [§]
C ₄₋₅ Left	3.7 ± 3.1	3.0 ± 1.1	0.161 [§]
C ₇ Left	4.6 ± 1.8	3.6 ± 1.6	0.303 [§]
Orthopedic Tests for midline pain (Pain: 0 – 10)			
Compression Left [‡]	0.6 ± 1.5	1.9 ± 2.5	0.152 [§]
Compression Right [‡]	0.5 ± 1.4	1.8 ± 2.5	0.093 [§]

	SMT 8 visits[*] (n = 20)	LM 8 visits[*] (n = 20)	p-value[†]
Distraction Left [‡]	0.1 ± 0.2	0.2 ± 0.7	0.848 [§]
Distraction Right [‡]	0.1 ± 0.3	0.3 ± 1.3	0.330 [§]

SMT – spinal manipulative therapy; LM – light massage; ROM – range of motion.

^{*} notation is (mean ± sd) or n (%) as appropriate.

[†] p-values are adjusted for smoking, and race

[‡] 10-point pain scale with 0 indicating no pain and 10 indicating highest pain conceivable.

[§] Denotes comparison of group means using linear regression

^{//} Denotes comparison of group odds using logistic regression

Table 3

Final Physical Exam Scores

	SMT 8 visits [*] (n = 20)	LM 8 visits [*] (n = 20)	p-value [†]
Cervical Active ROM (Inclinometer)			
Right Rotation (Normal 80°- shoulder)	79 ± 10	73 ± 12	0.518 [§]
Left Rotation (Normal 80°- shoulder)	79 ± 14	76 ± 12	0.223 [§]
Flexion (Normal 60°)	60 ± 8	60 ± 14	0.394 [§]
Extension (Normal 75°)	57 ± 13	54 ± 12	0.870 [§]
Right Lateral Bending (Normal 45°)	44 ± 7	43 ± 10	0.101 [§]
Left Lateral Bending (Normal 45°)	42 ± 9	41 ± 11	0.538 [§]
Cervical Active ROM (Pain: 0 – 10)			
Right Rotation [‡]	0.1 ± 0.2	0.7 ± 1.4	0.023 [§]
Left Rotation [‡]	0.4 ± 1.3	0.6 ± 1.1	0.416 [§]
Flexion [‡]	0.1 ± 0.2	1.0 ± 1.7	0.225 [§]
Extension [‡]	0.1 ± 0.2	0.8 ± 1.5	0.035 [§]
Right Lateral Bending [‡]	0.7 ± 1.5	1.1 ± 1.6	0.300 [§]
Left Lateral Bending [‡]	1.0 ± 1.6	1.3 ± 1.4	0.976 [§]
Sitting Rotation Endplay Restriction			
C ₀₋₁ to C ₂₋₃ Left	14(70%)	10(50%)	0.311 ^{//}
C ₀₋₁ to C ₂₋₃ Right	7 (35%)	14 (70%)	0.091 ^{//}
C ₃₋₄ to C ₅₋₆ Left	6 (30%)	9 (45%)	0.292 ^{//}
C ₃₋₄ to C ₅₋₆ Right	9 (45%)	8 (40%)	0.833 ^{//}
C ₆₋₇ to C _{7-T1} Left	5 (25%)	3 (15%)	0.503 ^{//}
C ₆₋₇ to C _{7-T1} Right	8 (40%)	6 (30%)	0.383 ^{//}
T ₁₋₂ to T ₃₋₄ Left	11 (55%)	6 (30%)	0.218 ^{//}
T ₁₋₂ to T ₃₋₄ Right	7 (35%)	8 (40%)	0.367 ^{//}
Pain Pressure Threshold (kg)			
C ₂ Right	3.5 ± 1.3	2.7 ± 1.5	0.420 [§]
C ₄₋₅ Right	3.8 ± 1.2	2.6 ± 1.8	0.202 [§]
C ₇ Right	4.2 ± 1.3	3.4 ± 1.8	0.451 [§]
C ₂ Left	3.8 ± 1.3	2.8 ± 1.5	0.492 [§]
C ₄₋₅ Left	4.1 ± 1.4	2.9 ± 1.9	0.228 [§]
C ₇ Left	4.4 ± 1.3	3.4 ± 1.7	0.373 [§]
Orthopedic Tests for midline pain (Pain: 0 – 10)			
Compression Left [‡]	0.4 ± 0.9	1.0 ± 1.6	0.690 [§]
Compression Right [‡]	0.1 ± 0.2	1.0 ± 1.7	0.060 [§]

	SMT 8 visits [*] (n = 20)	LM 8 visits [*] (n = 20)	p-value [†]
Distraction Left [‡]	0.0 ± 0.0	0.0 ± 0.0	1.000 [§]
Distraction Right [‡]	0.0 ± 0.0	0.0 ± 0.0	1.000 [§]

SMT – spinal manipulative therapy; LM – light massage; ROM – range of motion.

^{*} notation for unadjusted data is (mean ± sd) or n(%) as appropriate.

[†] p-values are adjusted for baseline PE, smoking, and race

[‡] 10-point pain scale with 0 indicating no pain and 10 indicating highest pain conceivable.

[§] Denotes comparison of group means using linear regression

^{//} Denotes comparison of group odds using logistic regression

Table 4
Statistically significant associations of subjective outcomes with physical examination adjusted for smoking, race, and treatment group
 (Table only shows textured p-values when the p-value from generalized linear model is <.05)

PE variables [†]	Patient-reported Subjective Outcomes											
	Baseline			wk 4			wk 8			wk 12		
	Headache Pain [‡] Headache Disability [‡]	Neck Pain [‡] Neck Disability [‡]	# HA \$ # days w/ HA \$	Headache Pain [‡] Headache Disability [‡]	# HA \$ # days w/ HA \$	Headache Pain [‡] Headache Disability [‡]	# HA \$ # days w/ HA \$	Headache Pain [‡] Headache Disability [‡]	# HA \$ # days w/ HA \$	Headache Pain [‡] Headache Disability [‡]	# HA \$ # days w/ HA \$	Headache Pain [‡] Headache Disability [‡]
Inclinometric Cervical Active ROM												
R. Rotation			0.001		<0.001				<0.001 0.001			
L. Rotation			0.011 0.005		<0.001				<0.001 0.001			
Flexion			0.037 0.010		0.001							
Extension			<0.001		0.044 0.001				0.020			0.021 0.001
R. Lat. B.			0.001 0.019						<0.001 0.001			0.042
L. Lat. B.				0.042	0.001				<0.001			
Elicited Pain (0-10) on Cervical Active ROM												
R. Rotation		0.035 0.014	<0.001 0.001	0.050	0.001 0.025							
L. Rotation		0.027	<0.001 0.001		<0.001	0.039						
Flexion		0.033	0.001		<0.001	0.027			<0.001		0.002	0.012
Extension			0.004						0.028			0.036
R. Lat. B.	0.018	0.006 0.011	<0.001 0.001		<0.001	0.011			<0.001		<0.001	<0.001
L. Lat. B.					<0.001	0.014			0.012 0.014			0.036
Sitting Rotation Endplay Restriction												
C ₀₋₁ to C ₂₋₃ L.			0.034		<0.001				0.036			<0.001
C ₀₋₁ to C ₂₋₃ R.	0.026		0.003		<0.001							0.046

	Patient-reported Subjective Outcomes									
	Baseline			wk 4		wk 8		wk 12		wk 24
PE variables [†]	Headache Pain [‡] Headache Disability [‡]	Neck Pain [‡] Neck Disability [‡]	# HA \$ # days w/ HA \$	Headache Pain [‡] Headache Disability [‡]	# HA \$ # days w/ HA \$	Headache Pain [‡] Headache Disability [‡]	# HA \$ # days w/ HA \$	Headache Pain [‡] Headache Disability [‡]	Neck Pain [‡] Neck Disability [‡]	# HA \$ # days w/ HA \$
C ₃₋₄ to C ₅₋₆ L.			0.023			0.049	0.003 <0.001			0.042
C ₃₋₄ to C ₅₋₆ R.										0.015
C ₆₋₇ to C _{7-T1} L.			0.036				0.045			<0.001
C ₆₋₇ to C _{7-T1} R.			0.004				0.005			
T ₁₋₂ to T ₃₋₄ L.					0.004 <0.001					
T ₁₋₂ to T ₃₋₄ R.			0.015 <0.001		0.018					
Pain Pressure Threshold (kg)										
C ₂ Right			<0.001 <0.001	0.036					0.006 0.006	0.025 0.005
C ₄₋₅ Right			0.026	0.015				0.020 0.036	0.013 0.006	0.030 0.001
C ₇ Right				0.036		0.029		0.035 0.028	0.034 0.005	0.002
C ₂ Left			0.008	0.022				0.046 0.034	0.001 0.001	<0.001
C ₄₋₅ Left			0.006 0.002					0.048	0.027 0.014	0.001
C ₇ Left			0.010	0.046		0.021		0.034	0.014 0.002	0.004
Orthopedic Tests for midline pain (0-10)										
Compression L.							<0.001			0.039
Compression R.	0.023 0.028									0.016
Distraction L.					<0.001	na na	na na	na na	na na	na na
Distraction R.				na na	na na	na na	na na	na na	na na	na na

* Neck pain and disability data were not gathered at weeks 4 and 8.

[†] Baseline compared to baseline, week 4 (w4) to w8, w8 PE (final) to w12 subjective outcomes, & w8 PE (final) to w24 subjective outcomes

[‡] Denotes prediction of subjective outcome by linear regression

[§] Denotes prediction of subjective outcome by Poisson regression.

Number of headaches and number of days with headache are over the past four weeks