

Spinal Manipulation in the Treatment of Episodic Tension-Type Headache

A Randomized Controlled Trial

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Context.—Episodic tension-type headache is common and is often treated using manual therapies. Few data exist for the efficacy of these interventions.

Objective.—To determine the effects of spinal manipulation therapy on adults with episodic tension-type headache.

Design.—Randomized controlled trial lasting 19 weeks.

Setting.—Outpatient facility of a National Health Service–funded chiropractic research institution in Denmark.

Participants.—Volunteer sample of 26 men and 49 women aged 20 to 59 years who met the diagnostic criteria for episodic tension-type headache as defined by the International Headache Society.

Intervention.—Participants were randomized into 2 groups, 1 receiving soft tissue therapy and spinal manipulation (the manipulation group), and the other receiving soft tissue therapy and a placebo laser treatment (the control group). All participants received 8 treatments over 4 weeks; all treatments were performed by the same chiropractor.

Main Outcome Measures.—Daily hours of headache, pain intensity per episode, and daily analgesic use, as recorded in diaries.

Results.—Based on intent-to-treat analysis, no significant differences between the manipulation and control groups were observed in any of the 3 outcome measures. However, by week 7, each group experienced significant reductions in mean daily headache hours (manipulation group, reduction from 2.8 to 1.5 hours; control group, reduction from 3.4 to 1.9 hours) and mean number of analgesics per day (manipulation group, reduction from 0.66 to 0.38; control group, reduction from 0.82 to 0.59). These changes were maintained through the observation period. Headache pain intensity was unchanged for the duration of the trial.

Conclusion.—As an isolated intervention, spinal manipulation does not seem to have a positive effect on episodic tension-type headache.

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nonpulsating quality, and symptoms characteristic of migraine (nausea, vomiting, photophobia, and phonophobia) are absent. The International Headache Society (IHS) classifies persons with 1 to 15 and 16 or more occurrences of TTH per month as having episodic TTH (ETTH) and chronic TTH, respectively.³ Episodic tension-type headache is by far the more common form, with a 1-year prevalence of more than 38%.¹ Because many sufferers report interference with their lifestyle, ETTH has a significant socioeconomic impact.¹

Although ETTH is typically medically treated with nonprescription analgesics, many people with ETTH seek hands-on therapy, delivered by various groups of practitioners. Several uncontrolled studies have suggested that a combination of physical treatment methods can lessen the symptoms of TTH,⁴⁻⁸ and the single randomized controlled study using IHS criteria suggested a positive treatment effect of a combination of therapies (including manipulation, heat, massage, and trigger-point therapy) for chronic TTH,⁹ compared with a hands-off pharmaceutical treatment protocol. In all these studies, however, it is unclear whether the effects were due to one, all, or a combination of the treatment elements. The common element in these studies was joint manipulation, recently demonstrated to be effective in the treatment of cervicogenic headache.¹⁰ The sole report using manipulation as an isolated treatment for TTH found a reduction in pain intensity immediately after the treatment, but the subjects were not further evaluated.¹¹

TENSION-TYPE headaches (TTHs) are extremely common, affecting more than one third of the population¹ and accounting for more than two thirds of all headache episodes.² The pain of TTHs is usually mild to moderate and typically bilateral. Symptoms are usually described as pressing or tightening with a

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The goal of this randomized controlled trial was to evaluate the long-term effect of joint manipulation as an isolated intervention for ETTH.

METHODS

Experimental Design

This was a randomized, controlled clinical trial with a blinded observer designed to evaluate the effect of spinal manipulative therapy in the treatment of ETTH. The trial was carried out in the outpatient facility of a National Health Service-funded independent chiropractic research institution (Nordisk Institut for Kiropraktik, Odense, Denmark). Data were interpreted by a blinded observer and analyzed at the Center for Biomechanics, Faculty of Health Science, Odense University, Odense, Denmark. All procedures were approved by the regional ethics committee (permit No. 97/12), and all subjects gave verbal and written informed consent prior to participation.

Participants

Participants were recruited from the general community by advertisements in the local newspapers. Initial eligibility screening was done over the telephone, followed by a personal interview and physical examination. Eligibility criteria for participation in this study were as follows: (1) fulfillment of IHS criteria for ETTH,³ with more than 5 but fewer than 15 headache episodes per month; (2) age 20 to 60 years; (3) score for typical headache intensity between 25 and 85 on a visual analog scale from 0 to 100; and (4) no relative or absolute contraindications to manipulation. The selection refinements of criteria 1 and 3 were designed to better allow the possibility of seeing a change by using more typical rather than very mild or severe cases. After acceptance, a participant could be excluded for any adverse reaction to treatment or any event triggering or potentially triggering a change in headache status (eg, vehicular crash with neck injury).

Participants were informed that the purpose of the trial was to compare the relative efficacy of 2 physical treatments commonly used for ETTH. Participants were instructed to continue their normal lifestyle during the trial, including their usual pattern of medication.

Interventions

After baseline data collection and randomization (see below), participants underwent 1 of 2 treatment protocols. All participants received 8 treatments over 4 weeks, all performed by one chiropractor (Birthe Hove Madsen, DC) and each

lasting approximately 15 minutes. The chiropractor routinely uses both treatment protocols in daily practice and was confident in performing both techniques. The manipulation group received joint manipulation of the cervical spine as determined by the chiropractor based on palpatory examinations and also deep friction massage (including trigger-point therapy, if indicated) of the trapezius and muscles deep to it. Specific manipulation maneuvers consisted of diversified and/or toggle-recoil techniques, depending on the level of the palpated segmental dysfunction.¹² These techniques use a high-velocity, low-amplitude thrust delivered in a specific line of drive at the palpated end point of the normal passive range of motion and are often accompanied by a clicking or cracking noise.

The control group also received deep friction massage. In addition, this group underwent the application of low-power laser light (Omega Biotherapy, London, England) to the upper cervical region. No effect, apart from placebo, can be expected from low-power laser therapy.¹³

The control group was designed to be an active control group for spinal manipulation, with the added goal of making the 2 groups more similar. A control group that receives no treatment is not ideal in procedures that use physical contact; in this study, every active intervention parameter was identical in the 2 groups except for the actual manipulation procedure. Our design allowed evaluation of the contribution of spinal manipulation, as it was the only difference between the 2 groups.

Measurements and Procedures

The trial lasted 19 weeks. In weeks 1 and 2, data were collected to determine a baseline for the outcome variables. Before starting week 3, participants were randomized to either the manipulation group or the control group by a blinded drawing of a ticket by a secretary. In weeks 3 through 6, subjects were treated 8 times, usually twice a week. Posttreatment data were collected from headache diaries completed during weeks 7, 11, 15, and 19.

All participants were required to fill out a headache diary¹⁴ for each of weeks 1, 2, 7, 11, 15, and 19. Recorded information included hours per day that headache was present, the intensity of the headache, and daily analgesic consumption. Additionally, to reveal any difference between the 2 physical treatment regimens in their ability to generate a placebo effect, participants scored their expected treatment outcome on a visual analog scale immediately before randomization and again immediately after

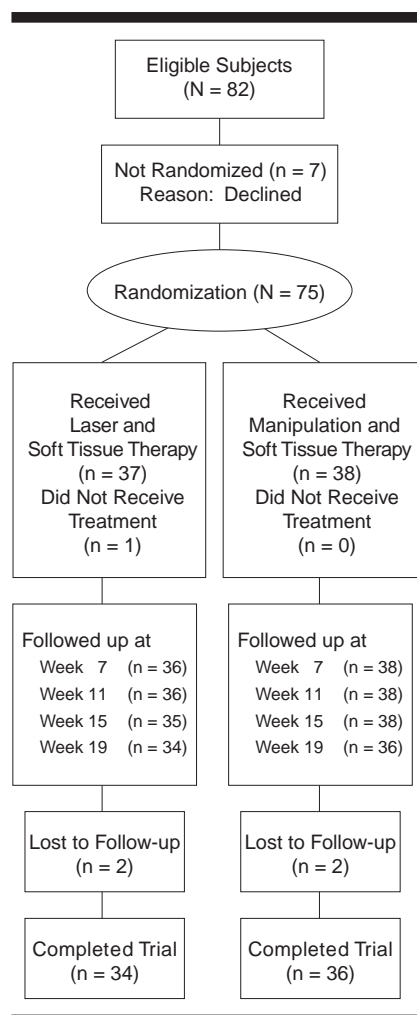


Figure 1.—Progression of subjects through the trial, including withdrawal and follow-up losses.

the first treatment session, before a new treatment effect could have been noted.¹⁵

Outcome Measures

The primary outcome measures were the number of headache hours per day, mean headache intensity per headache episode, and consumption of analgesics per day. From a previous study on a similar headache population,¹⁰ we expected most patients to stay with their preferred analgesic regimen throughout the trial period. In case of medication change, 500 mg of acetylsalicylic acid, 500 mg of paracetamol, and 200 mg of ibuprofen were regarded as equivalent doses. All data were retrieved from the diaries by assistants unaware of the treatment group assignment.

Statistical Analysis

The outcome measures were compared between pretreatment and each posttreatment period within and between the 2 treatment groups. A sample size of 84 was projected to provide a

power of 90% to detect a 1-hour difference between the 2 groups in mean number of daily headache hours and a difference in headache intensity of 13/100 per episode, as scored on the visual analog scale. All tests of hypotheses and reported *P* values are 2-tailed. Statistical analysis was conducted on an intention-to-treat basis, using StatView (Abacus Concepts, Berkeley, Calif).

RESULTS

Subjects

Participant flow and retention is summarized in Figure 1. Recruitment was conducted over a 9-month period from February through October 1997. Of the persons who responded to the advertisements and completed telephone and personal interviews, 82 fulfilled the inclu-

sion criteria; of these, 7 did not wish to take part in the study, leaving 75 participants to enter the trial. The characteristics of the randomized participants are shown in Table 1. There were no statistically significant differences between the 2 groups with respect to age, sex, mean headache hours per day, mean headache intensity per episode, or use of analgesics. No side effects were experienced by any participant in either group.

One participant was excluded in week 5 following a neck injury due to a car crash. One participant from the placebo group was lost to follow-up at week 15 and a further 3 (manipulation group, 2; control group, 1) were lost to follow-up in week 19.

Outcomes

There was no significant difference between the 2 groups for any outcome variable before or following treatment (Table 1 and Table 2, Figure 2). However, mean headache hours per day and analgesic use within both groups showed improvement from pretreatment to week 7. The mean headache hours per day was reduced by approximately 1.5 hours [by week 7 (95% confidence interval [CI], -2.4 to -0.6; Figure 2, B), and this change did not lessen significantly by the end of the trial. Headache intensity was unchanged for the duration of the trial (95% CI, -12 to 11; Figure 2, C). Analgesic consumption also lessened in both groups by week 7 (95% CI, -0.5 to -0.1; Figure 2, B). Of the 74 participants, 48 stayed with the same medication throughout the trial and 25 switched between 2 of the following: 500 mg of acetylsalicylic acid, 500 mg of paracetamol, or 200 mg of ibuprofen. One participant switched between acetylsalicylic acid and a morphine preparation; analgesic data for this person were not included in the results. Analysis of the 48

Table 1.—Pretreatment Characteristics of the Study Population*

| Variable | Whole Group | Control Group | Manipulation Group | <i>P</i> Value for Difference† |
|--|--------------------|--------------------|--------------------|--------------------------------|
| No. of subjects | 75 | 37 | 38 | ... |
| Sex | | | | |
| Male | 26 | 11 | 15 | .52 (Fisher exact) |
| Female | 49 | 26 | 23 | |
| Age, mean (range), y | 38 (20-59) | 38 (20-58) | 37 (22-59) | .86 |
| Mean headache hours per day (95% CI) | 3.1 (2.5-3.7) | 3.4 (2.4-4.4) | 2.8 (2.1-3.5) | .29 |
| Mean headache intensity, VAS, per episode (95% CI) | 38/100 (35-41/100) | 37/100 (33-41/100) | 37/100 (33-41/100) | .89 |
| Mean No. of analgesics per day (95% CI) | 0.74 (0.56-0.92) | 0.82 (0.50-1.14) | 0.66 (0.49-0.83) | .38 |

*CI indicates confidence interval; VAS, visual analog scale. Ellipses indicate data not applicable.
†Reported as *t* test, unless otherwise noted.

Table 2.—Results of Outcome Variables During the 13-Week Follow-up Period*

| Outcome Variable | Control Group | Manipulation Group | <i>P</i> Value for Difference (<i>t</i> Test) |
|--------------------------------------|------------------|--------------------|--|
| Mean analgesics per day (95% CI) | | | |
| Week 7 (n = 73) | 0.59 (0.00-1.49) | 0.38 (0.00-0.76) | .14 |
| Week 11 (n = 73) | 0.54 (0.30-0.78) | 0.41 (0.27-0.55) | .35 |
| Week 15 (n = 72) | 0.60 (0.26-0.94) | 0.48 (0.34-0.62) | .51 |
| Week 19 (n = 69) | 0.56 (0.22-0.90) | 0.48 (0.34-0.62) | .66 |
| Mean headache hours per day (95% CI) | | | |
| Week 7 (n = 74) | 1.9 (0.9-2.9) | 1.5 (1.1-1.9) | .33 |
| Week 11 (n = 74) | 1.7 (0.9-2.5) | 1.6 (1.2-2.0) | .77 |
| Week 15 (n = 73) | 2.1 (1.1-3.1) | 1.6 (1.2-2.0) | .30 |
| Week 19 (n = 70) | 2.2 (1.2-3.2) | 2.1 (1.3-2.9) | .87 |
| Mean headache intensity (95% CI) | | | |
| Week 7 (n = 74) | 34 (26-38)/100 | 38 (30-46)/100 | .43 |
| Week 11 (n = 74) | 30 (26-38)/100 | 36 (28-44)/100 | .28 |
| Week 15 (n = 73) | 33 (25-41)/100 | 29 (23-35)/100 | .41 |
| Week 19 (n = 70) | 26 (20-32)/100 | 35 (27-43)/100 | .13 |

*CI indicates confidence interval.

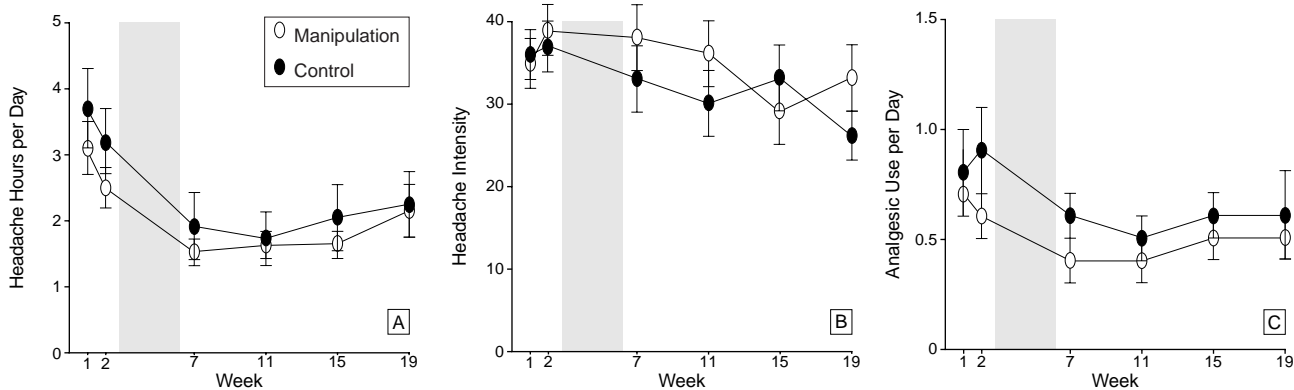


Figure 2.—Results of primary outcome measures. No difference was observed between groups for any measure. Intervention in weeks 3 to 6 indicated by shaded areas. Error bars equal 1 SE.

participants who continued their same medication yielded similar results (data not shown).

The expected treatment outcome was similar in both the manipulation group and the control group before (95% CI, 69-83/100 vs 68-80/100) and after (95% CI, 64-80/100 vs 69-81/100) the initial treatment. The treatment expectation did not change following the first treatment (95% CI, -2 to 10/100 vs -5 to 7/100), indicating that the 2 treatment methods had no major placebo differences.

COMMENT

This study showed that spinal manipulation did not significantly improve the outcome for ETTH. We point out that our study population was carefully selected based on accepted criteria for ETTH. In practice, ETTH and cervicogenic headache can be difficult to differentiate,¹⁶ and often occur together.¹⁷ Our conclusions are in stark contrast to those

of an earlier and very similar study of cervicogenic headache, in which the effect of spinal manipulation was quite dramatic.¹⁰ These data thus underline the importance of accurate diagnosis in the selection of headache patients for spinal manipulation.

The only other randomized controlled study including manipulation as a treatment for ETTH compared a hands-off pharmaceutical treatment (6 weeks of amitriptyline) with a chiropractic treatment that included personal contact, heat, massage, ergonomic advice, and spinal manipulation.⁹ There was a significant decrease in overall symptoms in the chiropractic treatment group, but this effect could have been due to the higher level of personal attention given to that treatment group. Our manipulation group was comparable to that chiropractic group, and we controlled for the treatment elements of personal attention and hands-on treatment.

As always, when a controlled clinical trial fails to demonstrate a treatment effect, the question of a possible type II error (ie, overlooking a real difference) is an issue. In this trial, the number of participants was relatively small, and it is possible that a larger trial might have identified an effect in 1 or more of the outcome variables. However, the data in Table 2 and Figure 2 suggest that any such effect, statistically significant or not, would be of little clinical significance.

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