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## A COMPARISON OF ACTIVE AND SIMULATED CHIROPRACTIC MANIPULATION AS ADJUNCTIVE TREATMENT FOR CHILDHOOD ASTHMA

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### ABSTRACT

**Background** Chiropractic spinal manipulation has been reported to be of benefit in nonmusculoskeletal conditions, including asthma.

**Methods** We conducted a randomized, controlled trial of chiropractic spinal manipulation for children with mild or moderate asthma. After a three-week base-line evaluation period, 91 children who had continuing symptoms of asthma despite usual medical therapy were randomly assigned to receive either active or simulated chiropractic manipulation for four months. None had previously received chiropractic care. Each subject was treated by 1 of 11 participating chiropractors, selected by the family according to location. The primary outcome measure was the change from base line in the peak expiratory flow, measured in the morning, before the use of a bronchodilator, at two and four months. Except for the treating chiropractor and one investigator (who was not involved in assessing outcomes), all participants remained fully blinded to treatment assignment throughout the study.

**Results** Eighty children (38 in the active-treatment group and 42 in the simulated-treatment group) had outcome data that could be evaluated. There were small increases (7 to 12 liters per minute) in peak expiratory flow in the morning and the evening in both treatment groups, with no significant differences between the groups in the degree of change from base line (morning peak expiratory flow,  $P=0.49$  at two months and  $P=0.82$  at four months). Symptoms of asthma and use of  $\beta$ -agonists decreased and the quality of life increased in both groups, with no significant differences between the groups. There were no significant changes in spirometric measurements or airway responsiveness.

**Conclusions** In children with mild or moderate asthma, the addition of chiropractic spinal manipulation to usual medical care provided no benefit. (N Engl J Med 1998;339:1013-20.)

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THE use of alternative or complementary approaches to health care is increasing.<sup>1-3</sup> In 1993, 48 percent of Australians over the age of 15 used non-medically prescribed alternative treatments, and 20 percent visited a practitioner of alternative medicine.<sup>1</sup> In 1990, 34 percent of U.S. adults had used an unconventional treatment method in the previous year; one third of these had visited a provider of unconventional therapy.<sup>2</sup> Canadian physicians increasingly refer patients to practitioners of alternative medicine yet criticize the lack of evidence supporting the efficacy of such treatment.<sup>3</sup>

In Brisbane, Australia, 45 percent of families with a family member with asthma had consulted a practitioner of alternative medicine, most often a chiropractor, for management of the disease.<sup>4</sup> Most of these people were equally satisfied with orthodox medicine and alternative care, contradicting the suggestion that users of alternative therapy are dissatisfied with orthodox medicine.

Reviews of alternative approaches to the management of asthma have called for controlled studies to determine whether acupuncture, homeopathy, yoga, hypnosis, chiropractic treatment, and herbal medicine have efficacy.<sup>5-7</sup> Given the controversies regarding the adverse effects of long-term use of  $\beta$ -agonists<sup>8-10</sup> and inhaled corticosteroids,<sup>11-14</sup> an alternative approach that reduces the need for medication would be valuable. However, if alternative treatments are ineffective,

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the decline in pulmonary function associated with suboptimal treatment<sup>15-20</sup> would mandate firm cautions against such therapies.

Spinal manipulation has been shown in randomized, controlled trials to relieve back pain and other musculoskeletal conditions,<sup>21,22</sup> but many chiropractors and osteopaths report benefit in patients with nonmusculoskeletal conditions, including asthma.<sup>23-26</sup> The theoretical basis for expecting benefit from chiropractic manipulation in persons with asthma rests on two assumptions. First, reflex irritation of somatic and autonomic nerves at the spinal and nerve-root levels is caused by vertebral subluxation, defined as a palpable restriction of a spinal joint as evidenced by the loss of joint play with surrounding muscle tightness, pain, and tenderness.<sup>27</sup> Second, this mechanical and neurologic disturbance affects chest-wall function or alters airway tone or responsiveness directly or by means of neurogenic inflammation,<sup>28</sup> resulting in a predisposition to or inducement of asthma.<sup>29</sup> Chiropractic theory states that the correction of subluxation by manipulation, with restoration of normal mechanical and nerve function, should improve airway function and aid in the resolution of asthma.<sup>29,30</sup>

We assessed objective and subjective outcomes in children with asthma who were treated with active or simulated chiropractic manipulation in a randomized, controlled trial.

## METHODS

### Subjects

Children 7 to 16 years of age who had had asthma (diagnosed by a physician) for more than one year and who had symptoms requiring the use of a bronchodilator at least three times weekly were recruited through advertising. Responsiveness to bronchodilators (defined as a rise in the forced expiratory volume in one second [FEV<sub>1</sub>] of at least 15 percent after the use of an inhaled bronchodilator) or airway hyperresponsiveness to methacholine (defined as a decrease of 20 percent in FEV<sub>1</sub> in response to a methacholine concentration of no more than 8 mg per milliliter [PC<sub>20</sub> for FEV<sub>1</sub>, ≤8 mg per milliliter]) was required to confirm the presence of asthma.<sup>31</sup> The subject had to have been taking the same medication for at least six weeks. There had to be evidence of vertebral subluxation on palpation,<sup>27</sup> as determined by a single chiropractor on screening. Subjects were excluded if they had other lung diseases, had contraindications to spinal manipulation, had previously received chiropractic care, or had unstable asthma (as evidenced by hospital admission or the use of oral corticosteroids within one month before the beginning of the study) or if they were noncompliant with their prescribed medical regimen. For those with recent respiratory tract infections, enrollment was delayed until one month after recovery.

The study was approved by the research committee of St. Joseph's Hospital in Hamilton, Ontario, and by the ethics review board of the Canadian Memorial Chiropractic College. The parents or guardians of the children provided written informed consent.

### Base-Line Assessments

Questionnaires covering respiratory and musculoskeletal history were completed by the child and his or her parent or guardian. Spirometry was performed according to the standards of the American Thoracic Society with use of a Koko Trek computer-

ized spirometer (Pulmonary Data Service Instruments, Louisville, Ky.) before and after the inhalation of 200 μg of salbutamol through a valved holding chamber (Aerochamber, Trudell Medical, London, Ont.). The subjects were instructed in the use of a Personal Best peak expiratory flowmeter (Assess, Health Scan Products, Cedar Grove, N.J.), and the completion of a study-specific symptom diary, in which they were to record episodes of nocturnal wheezing and cough, daytime wheezing, cough, chest tightness or breathlessness, production of sputum, and episodes of limitation of activity. Each symptom was recorded on a 4-point scale (0 to 3) as being absent, slight, moderate, or severe. One week later, the subjects' compliance with recording diary entries and measuring peak expiratory flow (using the best of three attempts) twice daily was assessed, a methacholine challenge was performed (provided that the base-line FEV<sub>1</sub> exceeded 70 percent of vital capacity [VC]), and the Pediatric Asthma Quality of Life Questionnaire was administered by the research staff. This questionnaire is a validated three-domain asthma-specific instrument including 23 items (10 pertaining to symptoms, 5 to activities, and 8 to emotions).<sup>32</sup> Three of the items pertaining to activity are individualized, so that the questionnaire asks about activities the subject identifies as important and does frequently but which cannot be performed fully because of the subject's asthma. Responses could range from 1 (maximal impairment) to 7 (no impairment), with each item weighted equally. The scores for each item were averaged within each domain. A score that increased from base line represented an improved quality of life. "Moderate" and "large" changes in the overall quality of life are represented by changes of at least 1.03 and 1.98, respectively.<sup>32</sup> Minimally important differences within domains are represented by changes of at least 0.54 for items pertaining to symptoms, 0.70 for those pertaining to activity, and 0.28 for those pertaining to emotions. Minimally important differences in the overall quality of life are represented by a change of at least 0.42.

After a further two-week period of evaluation, eligibility was confirmed by a pulmonologist, and the subjects were randomly assigned to active or simulated treatment. Randomization was carried out in blocks of four within strata for age (approximating prepubertal and postpubertal status: 7 through 12 years and 13 through 16 years), sex, and severity of asthma (moderate asthma was defined as requiring the use of ≥200 μg of inhaled corticosteroid per day or as airflow obstruction at rest [ratio of FEV<sub>1</sub> to VC, <70 percent]; mild asthma was defined as that which was less than moderate in severity). A sealed numerical randomization code prepared by a research secretary was given to the treating chiropractor by the subject once the chiropractor had been selected by the subject's family.

Except for the treating chiropractor and one investigator, all the participants remained fully blinded to treatment assignment throughout the study. This investigator undertook a site visit at short notice to every chiropractor at least once to review charts, verify that treatments were active or simulated as stipulated by the randomization code, and verify that the treatments followed the protocol. He was not involved in the assessment of outcomes. Adults accompanying their children were not permitted to observe treatments. The success of the blinding of the subjects was assessed at the end of the study by asking each child to guess his or her own treatment assignment.

### Interventions

Each subject and his or her family selected 1 of 11 participating chiropractors, according to location. All the chiropractors had at least five years of clinical experience, ran successful private practices, and had had apparent success, on the basis of anecdotal evidence, in treating patients with pediatric asthma. The subjects visited the selected chiropractor three times weekly for four weeks, twice weekly for four weeks, then weekly for eight weeks. Some latitude in the scheduling of visits was allowed for vacations or illness, but each subject was required to receive between 20 and 36 treatments during the four-month study regardless of treatment

assignment. The treating chiropractor reviewed the subject's history, examined the subject, described his or her chiropractic findings, and obtained informed consent for treatment before opening the randomization code.

Active chiropractic treatment consisted of manipulation (adjustments) with the subject prone, lying on one side, and supine, in conjunction with the administration of gentle soft-tissue therapy to the overlying tissues. The specifics of treatment for each subject (vertebral segments treated, direction and type of manipulation, and use of soft-tissue therapy) were determined by the treating chiropractor. All the chiropractors used the diversified technique in common use in Canada and the United States, which involves manual contact with spinal or pelvic joints followed by a low-amplitude, high-velocity directional push often associated with joint opening, creating a cavitation, or "pop."<sup>33</sup>

For simulated treatment, the subject lay prone while soft-tissue massage and gentle palpation were applied to the spine, paraspinal muscles, and shoulders. A distraction maneuver was performed by turning the subject's head from one side to the other while alternately palpating the ankles and feet. The subject was positioned on one side, a nondirectional push, or impulse, was applied to the gluteal region, and the procedure was repeated with the subject positioned on the other side; then the subject was placed in the prone position, and a similar impulse was applied bilaterally to the scapulae. The subject was then placed supine, with the head rotated slightly to each side, and an impulse applied to the external occipital protuberance. Low-amplitude, low-velocity impulses were applied in all these nontherapeutic contacts, with adequate joint slack so that no joint opening or cavitation occurred. Hence, the comparison of treatments was between active spinal manipulation as routinely performed by chiropractors and hands-on procedures without adjustments or manipulation.

No additional therapeutic interventions were permitted in either group. Training sessions for chiropractors were held before and during the study to ensure compliance with the protocol. Satisfaction with treatment was determined by responses to 12 questions asked at the end of the study, including questions related to the attention the subjects received from the chiropractor, the explanations of procedures, communication, feeling at ease, the skill and ability of the chiropractor, and overall quality of care. The responses were scored on a scale of 1 to 7 (with 1 denoting "very poor" and 7 "the best").<sup>34</sup>

### Medical Assessments

All medical treatment the subjects were receiving before the study was maintained during the study, including the use of inhaled corticosteroids or cromolyn, at the dose used before randomization. Inhaled  $\beta$ -agonists were used only as needed for relief of symptoms. No additional medication was permitted except courses of oral corticosteroids for serious exacerbations of asthma, as determined by a pulmonologist who was unaware of the treatment assignments.

Diary records were forwarded from the chiropractor's office to the research center in sealed envelopes every two weeks. At two months, spirometric measurements were repeated, diaries were reviewed, and the quality-of-life questionnaire was readministered. Techniques for determining peak expiratory flow were checked, and compliance was encouraged. At four months, spirometry was repeated, followed by a methacholine challenge (provided the FEV<sub>1</sub>:VC was  $\geq 70$  percent). Diaries and medications were reviewed, the quality-of-life questionnaire was administered for a third time, and medical and chiropractic reassessments were performed.

### Outcomes

The primary outcome was the change from base line in the morning peak expiratory flow measured before the use of a bronchodilator at two and four months. In addition, the frequencies with which the morning peak expiratory flow fell below 85 percent of the base-line value were compared between the groups. Second-

ary outcomes were the changes in airway responsiveness, FEV<sub>1</sub>, symptoms of asthma, the need for inhaled  $\beta$ -agonists, the use of oral corticosteroids, quality of life, and overall satisfaction with treatment.

### Sample Size

On the basis of estimates of variability in peak expiratory flow (within-group SD, 15 percent), the enrollment of 72 subjects (36 in each group) was required to provide the study with 80 percent power to detect an increase from base line of at least 10 percent in morning peak expiratory flow, at a significance level of 0.05. To allow for a 25 percent attrition rate during the study, we planned to enroll 100 subjects.

### Statistical Analysis

Changes in morning peak expiratory flow for each subject were expressed as the percent change from the mean of the measurements taken 14 days before randomization to the means of those taken 14 days preceding the 2-month and 4-month assessments. Group mean data were adjusted for base-line differences between the groups by analysis of covariance.<sup>35,36</sup> Interactions among peak expiratory flow, sex, age, severity of asthma, and treatment group were examined. Airway responsiveness, measured as PC<sub>20</sub> for FEV<sub>1</sub>, was analyzed after the logarithmic transformation of values for PC<sub>20</sub>, and the change from base line to the end of the study was expressed in doubling-dose shifts.<sup>37</sup> If inhalation of saline alone induced more than a 20 percent decrease in FEV<sub>1</sub>, the lowest methacholine concentration (0.03 mg per milliliter) was considered to be the PC<sub>20</sub> value. If methacholine was not given because of base-line airflow obstruction (FEV<sub>1</sub>:VC, <70 percent), a PC<sub>20</sub> of 0.5 mg per milliliter was attributed.

Symptom scores (the mean daily score for five symptoms; range, 0 to 3) were averaged over the same 14-day period as the peak expiratory flow, as was  $\beta$ -agonist use (measured as the number of puffs per day). Changes in symptom scores and  $\beta$ -agonist use were compared by analysis of covariance, including differences from base line. Changes in quality-of-life scores were compared within domains and across all domains,<sup>32</sup> with adjustment for base-line differences by analysis of covariance. Satisfaction scores were computed as the group means of the individual average responses to the 12 questions.<sup>34</sup> All analyses were performed with SPSS for Windows (version 6.1.3, SPSS, Chicago). All P values are two-tailed.

## RESULTS

During an 18-month recruitment period (from October 1994 to April 1996), 199 subjects were assessed, 91 of whom were eligible. Of those who were ineligible, 49 had no current symptoms, 4 did not use enough  $\beta$ -agonist to meet the entry criterion, 17 had a PC<sub>20</sub> for FEV<sub>1</sub> of greater than 8 mg per milliliter, 3 had severe unstable asthma, 3 used medication erratically, 3 were smokers, 2 could not participate in the spirometric measurements, 10 could not meet the time requirements, 1 had previously received chiropractic care, and 16 were noncompliant with keeping symptom diaries during the base-line evaluation period. Eligible subjects were randomly assigned to active treatment (45 subjects) or simulated treatment (46 subjects). Because of difficulties in recruiting sufficient eligible subjects in the second year of the study, the numbers within each of the strata for sex, severity of asthma, and age were not uniform. Ten subjects dropped out (four in the simulated-treatment group and six in the active-treatment group) because of scheduling problems (two subjects), non-

compliance (seven), and a change of residence (one). No outcome data are available for these subjects. Data on another subject (in the active-treatment group) were excluded because in retrospect he did not meet the entry criteria, since he did not need to use a  $\beta$ -agonist three times per week. Base-line characteristics of the 80 subjects with data that could be evaluated are shown in Table 1. Adjustments have been made in all analyses for differences between groups resulting from differences in age and in severity of asthma.

Each of 11 chiropractors treated between 1 and 16 subjects (median, 4 in the active-treatment group and 4 in the simulated-treatment group). Selection of a chiropractor was based on location, and randomization was not stratified according to chiropractor. The numbers of treated subjects in the active-treatment and simulated-treatment groups differed by more than one for 4 of the 11 chiropractors (six vs. one, five vs. three, one vs. five, and three vs. seven).

TABLE 1. BASE-LINE CHARACTERISTICS OF THE SUBJECTS.\*

CHARACTERISTIC†	ACTIVE TREATMENT (N=38)	SIMULATED TREATMENT (N=42)
Male sex — no. (%)	20 (53)	23 (55)
Age — yr	11.4±2.5	12.1±2.7
<13 yr — no. (%)	25 (66)	22 (52)
Mild asthma — no. (%)	17 (45)	19 (45)
Symptom score‡		
During day	0.63±0.44	0.43±0.30
During night	0.51±0.50	0.31±0.33
$\beta$ -agonist use — no. of puffs		
During day	2.04±1.76	2.27±1.88
During night	0.43±0.68	0.51±0.83
Inhaled-corticosteroid use — no. (%)	19 (50)	21 (50)
Corticosteroid dose — $\mu$ g		
Median	400	500
Mean	633	560
Cromolyn use — no.	1	4
Morning peak expiratory flow — liters/min		
All	272.4±88.5	296.7±90.4
Boys	256.3±74.2	314.7±99.8
Girls	290.3±101.2	274.9±74.4
FEV <sub>1</sub> — % of predicted value		
All	98.4±15.5	95.8±21.7
Boys	92.5±11.8	90.4±19.6
Girls	104.9±16.8	102.5±22.8
Results of methacholine challenge — no.		
Obstructed, given $\beta$ -agonist	1	6
$\geq$ 20% fall in response to saline	2	1
PC <sub>20</sub> for FEV <sub>1</sub> — no.		
<0.25 mg/ml	8	5
0.25 to <2.0 mg/ml	13	22
2.0 to <8.0 mg/ml	14	8

\*Characteristics are shown for the 80 subjects for whom data could be evaluated. Plus-minus values are means  $\pm$ SD.

†FEV<sub>1</sub> denotes the forced expiratory volume in one second, and PC<sub>20</sub> for FEV<sub>1</sub> the concentration of methacholine that provoked a 20 percent fall in FEV<sub>1</sub>.

‡Symptoms were graded on a scale of 0 (absent) to 3 (severe).

Outcomes at Two and Four Months

There were small increases (7 to 12 liters per minute) in morning and evening peak expiratory flow in both treatment groups, with no significant differences in the change from base-line values between the groups (Fig. 1). Similar results were obtained after adjustment for the participating chiropractor. The frequency with which the morning peak expiratory flow fell below 85 percent of the base-line value during the treatment period did not differ significantly between groups. Spirometric changes were neither statistically significant nor clinically important. There was no change in PC<sub>20</sub> for FEV<sub>1</sub> as a measure of airway responsiveness to methacholine in either treatment group over the four-month study (mean shifts in log<sub>2</sub> PC<sub>20</sub>, +0.02 and +0.03) (Table 2).

Symptoms and use of  $\beta$ -agonists declined in both groups, with no significant difference between the groups either before or after adjustment for baseline differences (Fig. 2) (symptoms, P=0.59 and P=0.84 at two months and four months, respectively;  $\beta$ -agonist use, P=0.55 and P=0.35). Oral corticosteroids were needed by six subjects in the active-treatment group (six courses over a period of 52 days) and by four subjects in the simulated-treatment group (six courses over a period of 30 days). The increases in the quality of life were greater than the minimally important differences in both groups at two months and four months, but there were no significant differences between the groups overall or in any domain when adjustments were made for base-line differences (Table 3).

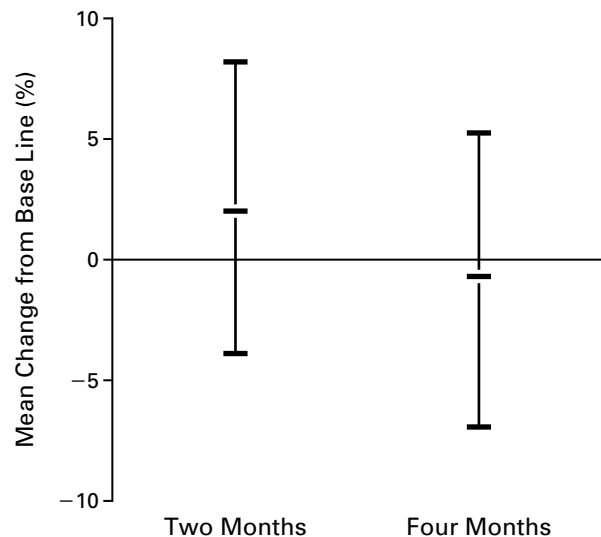


Figure 1. Differences in Percent Change in the Mean Morning Peak Expiratory Flow from Base Line to Two Months and Four Months.

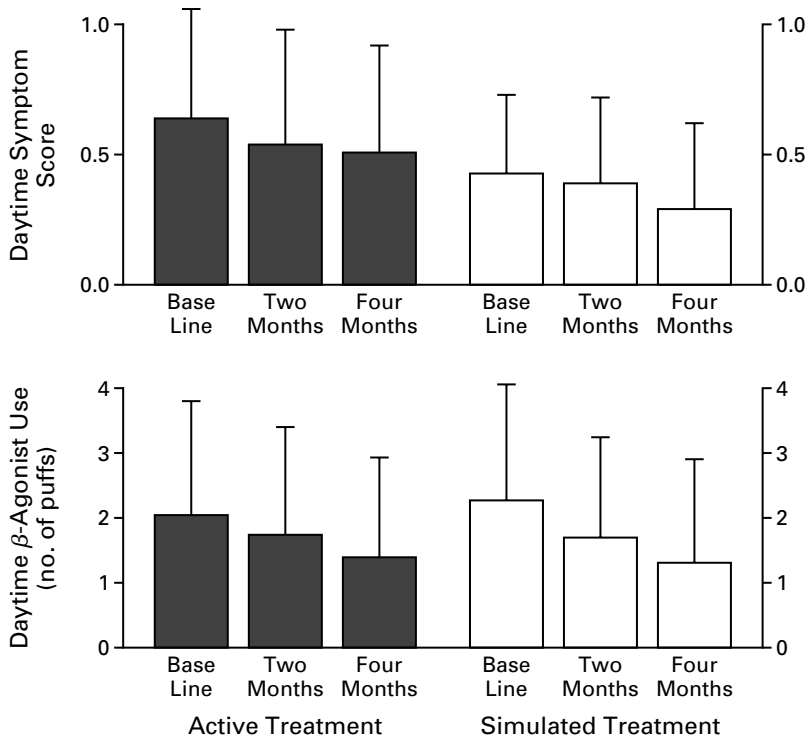
Values shown are the changes in the active-treatment group minus those in the simulated-treatment group. The I bars indicate means and 95 percent confidence intervals.

**TABLE 2.** CHANGES IN SPIROMETRIC OUTCOMES AND AIRWAY RESPONSIVENESS FROM BASE LINE TO TWO AND FOUR MONTHS.\*

VARIABLE	ACTIVE TREATMENT		SIMULATED TREATMENT		DIFFERENCE ±SE†	95% CI	P VALUE
	VALUE	NO. OF SUBJECTS	VALUE	NO. OF SUBJECTS			
Morning PEF (% of base line)							
Base line	—	38	—	42	—	—	—
2 Mo	103.4±12.7	35	101.3±13.1	40	+2.1±3.0	-3.9 to +8.0	0.49
4 Mo	103.6±13.7	38	104.3±13.3	42	-0.7±3.0	-6.7 to +5.3	0.82
Evening PEF (% of base line)							
Base line	—	38	—	42	—	—	—
2 Mo	101.7±11.7	35	102.0±10.7	40	-0.3±2.6	-5.5 to +4.8	0.90
4 Mo	104.0±13.7	38	104.5±10.2	42	-0.5±2.7	-5.8 to +4.9	0.87
Days with morning PEF <85% (no.)	11.8±12.3	38	14.7±23.3	42	-2.9±4.1	-11.1 to +5.3	0.48
FEV <sub>1</sub> (liters)							
Base line	2.20±0.77	38	2.40±0.86	42	-0.20±0.18	-0.57 to +0.16	0.27
2 Mo	2.23±0.69	37	2.52±0.77	42	-0.28±0.17	-0.61 to +0.05	0.09
4 Mo	2.21±0.69	38	2.49±0.75	42	-0.28±0.16	-0.61 to +0.04	0.16
Log <sub>2</sub> PC <sub>20</sub>							
Base line	-0.38±2.21	38	-0.60±1.77	42	+0.23±0.45	-0.66 to +1.11	0.62
4 Mo	-0.36±2.11	38	-0.57±2.12	42	+0.21±0.47	-0.74 to +1.15	0.66
Change	+0.02±1.52	38	+0.03±1.76	42	-0.02±0.37	-0.75 to +0.72	0.96

\*CI denotes confidence interval, PEF peak expiratory flow, FEV<sub>1</sub> forced expiratory volume in one second, and Log<sub>2</sub> PC<sub>20</sub> the logarithm of the concentration of methacholine. Except where otherwise specified, plus-minus values are means ±SD.

†Differences are the values in the active-treatment group minus those in the simulated-treatment group.



**Figure 2.** Mean (±SD) Daytime Symptom Scores and β-Agonist Use at Base Line, Two Months, and Four Months.

The possible range of symptom scores was 0 (absent) to 3 (severe). A decrease in the symptom score or in β-agonist use represents improvement.

TABLE 3. CHANGES IN QUALITY OF LIFE.\*

DOMAIN	ACTIVE TREATMENT		SIMULATED TREATMENT		DIFFERENCE $\pm$ SE†	95% CI	P VALUE
	CHANGE IN SCORE	NO. OF SUBJECTS	CHANGE IN SCORE	NO. OF SUBJECTS			
Activity							
Base line to 2 mo	0.92 $\pm$ 1.11	36	0.58 $\pm$ 0.96	40	0.34 $\pm$ 0.24	-0.13 to +0.81	0.15
Base line to 4 mo	1.22 $\pm$ 1.12	38	0.81 $\pm$ 1.14	40	0.42 $\pm$ 0.26	-0.10 to +0.93	0.11
Adjusted P value							0.24‡
Symptoms							
Base line to 2 mo	0.46 $\pm$ 1.16	36	0.18 $\pm$ 1.01	40	0.29 $\pm$ 0.25	-0.21 to +0.78	0.25
Base line to 4 mo	0.64 $\pm$ 1.34	38	0.49 $\pm$ 1.04	40	0.15 $\pm$ 0.59	-0.39 to +0.69	0.59
Adjusted P value							0.24‡
Emotions							
Base line to 2 mo	0.50 $\pm$ 0.78	36	0.24 $\pm$ 0.96	40	0.26 $\pm$ 0.20	-0.14 to +0.66	0.20
Base line to 4 mo	0.73 $\pm$ 0.91	38	0.44 $\pm$ 1.02	40	0.29 $\pm$ 0.22	-0.15 to +0.73	0.19
Adjusted P value							0.51‡
Overall quality of life							
Base line to 2 mo	0.63 $\pm$ 0.86	36	0.33 $\pm$ 0.86	40	0.29 $\pm$ 0.20	-0.10 to +0.69	0.14
Base line to 4 mo	0.89 $\pm$ 0.98	38	0.58 $\pm$ 0.95	40	0.32 $\pm$ 0.22	-0.12 to +0.75	0.15
Adjusted P value							0.17‡

\*Changes in overall quality-of-life scores and scores for activity, symptoms, and emotional domains were measured by the Pediatric Asthma Quality of Life Questionnaire. All changes are positive, representing improvement. Minimally important differences in the scores of each of the domains are as follows: activity, 0.70; symptoms, 0.54; emotions, 0.28; and overall quality of life, 0.42. CI denotes confidence interval. Except where otherwise indicated, plus-minus values for changes from base line are means  $\pm$ SD.

†Differences are the values in the active-treatment group minus those in the simulated-treatment group.

‡The P value was calculated by analysis of covariance after adjustment for base-line differences and for treatment group, age group, severity of asthma, and sex.

Mean satisfaction scores were similar — 6.22 for the active-treatment group and 6.46 for the simulated-treatment group (maximal score, 7.0). The majority of the subjects (63 percent) were uncertain whether they had received active or simulated treatment. The accuracy of guesses did not differ between the groups. No adverse events (apart from exacerbations of asthma) occurred during the study.

## DISCUSSION

Among the 80 subjects enrolled in this study of the efficacy of chiropractic manipulation as adjunct treatment for childhood asthma, there was a substantial improvement in symptoms and quality of life and a reduction in  $\beta$ -agonist use. However, these changes did not differ significantly between the active-treatment and simulated-treatment groups. There were no significant changes in objective measurements of airway function. Hence, the addition of chiropractic spinal manipulation to usual medical care for four months had no effect on the control of childhood asthma.

Previous trials in which there had been evidence of benefit of chiropractic treatment of asthma were inadequately controlled. In one study, among 19 subjects 2 to 70 years of age, mean peak expiratory flow at base line and after two, three, five, and eight treatments was 346, 329, 350, 354, and 397 liters per minute, respectively, whereas 11 control subjects not matched for age or respiratory status had no change.<sup>24</sup> In an uncontrolled study of 15 subjects 8 to

45 years old, the mean ( $\pm$ SD) FEV<sub>1</sub>:FVC ratio after three, five, and seven treatments was 74.3 $\pm$ 10.6 percent, 73.6 $\pm$ 10.9 percent, and 74.6 $\pm$ 13.1 percent, respectively, indicating no change despite subjective improvement.<sup>25</sup> Nevertheless, textbooks and articles relate specific spinal-segment abnormalities to pulmonary diseases and advocate spinal manipulation in the management of asthma.<sup>30,38-40</sup>

Recently, a randomized, controlled four-week crossover trial of chiropractic care was conducted among 31 adults 18 to 44 years of age with chronic asthma requiring bronchodilators or inhaled corticosteroids, in which the effects of twice-weekly active and simulated treatments were compared.<sup>41</sup> There were no clinically important or statistically significant differences in subjective or objective outcomes between the groups. The ratings of symptom severity (on a visual-analogue scale) decreased by 34 percent for all the subjects, but there was no improvement in lung function.

Other alternative treatments, including hypnosis, acupuncture, and yoga, have been reported to be effective in the treatment of asthma. In a single-blind study, subjects with a high susceptibility to hypnosis who were hypnotized had a 50 percent reduction in airway responsiveness, a 41 percent reduction in symptoms, a 5 percent increase in peak expiratory flow, and a 26 percent reduction in  $\beta$ -agonist use as compared with base-line values, whereas control subjects and hypnotized subjects with a low susceptibility to hypnosis had no significant improvements.<sup>42</sup> Subjects

receiving active acupuncture over a period of two months had increased morning and evening peak-expiratory-flow values at two weeks but were not significantly different from the placebo group thereafter.<sup>43</sup> In an unblinded, randomized, controlled study of 53 subjects who practiced yoga, as compared with age-matched subjects who continued their usual medications, asthma attacks decreased and peak expiratory flow increased significantly in the yoga group as compared with the control group.<sup>44</sup>

The possibility of spontaneous or placebo-driven improvement in chronic illness dictates that studies of the efficacy of treatment regimens be adequately controlled, randomized, and blinded. In our study, we controlled for the effects of positioning, palpation, soft-tissue therapies, and attention given to the subjects by using these techniques equally in both treatment groups. Although it was impossible for the treating chiropractors and the investigator undertaking treatment checks to remain unaware of the treatment assignments, the other investigators remained blinded. The inability of the subjects to guess their treatment-group assignments and the high levels of satisfaction with care regardless of treatment assignment provide evidence that the blinding was successful. It is unlikely that the simulated treatment had benefit other than nonspecific effects, which were found in both groups. We are unaware of published evidence that suggests that positioning, palpation, gentle soft-tissue therapy, or impulses to the musculature adjacent to the spine influence the course of asthma.

The improvements in symptom scores and quality-of-life scores and the reduced requirement for inhaled  $\beta$ -agonists for relief of symptoms irrespective of treatment group were consistent with anecdotal observations and uncontrolled studies of alternative approaches to the management of asthma. Improvement might have resulted from frequent professional attention (visits to a chiropractor three times weekly provide more contact with a care giver than the usual procedures for the management of asthma), increased compliance with medications under trial conditions, and the subjects' "growing out of" childhood asthma.<sup>45</sup> However, airway responsiveness did not change, suggesting that the last two possibilities are unlikely and that the effect is more likely to have been a placebo effect or study (Hawthorne) effect.

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