The Impact of Acupuncture and Craniosacral Therapy Interventions on Clinical Outcomes in Adults With Asthma

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Objective: Synergy has been proposed between modalities operating at different levels of action. Acupuncture and craniosacral therapy are two very different modalities for which synergy has been proposed. This study sought to test for such synergy and to determine if complementary therapies would improve pulmonary function and quality of life for people suffering from asthma, as well as reducing anxiety, depression, and medication usage.

Design: Subjects were randomly assignment to one of five groups: acupuncture, craniosacral therapy, acupuncture and craniosacral, attention control, and waiting list control.

Methods: Subjects received 12 sessions of equal length with pretreatment and posttreatment assessment of pulmonary function, asthma quality of life, depression, and anxiety. Medication use was also assessed.

Results: Synergy was not demonstrated. When treatment was compared with the control group, statistically treatment was significantly better than the control group in improving asthma quality of life, whereas reducing medication use with pulmonary function test results remained the same. However, the combination of acupuncture and craniosacral treatment was not superior to each therapy alone. In fact, although all active patients received 12 treatment sessions, those who received all treatments from one practitioner had statistically significant reductions in anxiety when compared with those receiving the same number of treatments from multiple practitioners. No effects on depression were found.

Conclusions: Acupuncture and/or craniosacral therapy are potentially useful adjuncts to the conventional care of adults with asthma, but the combination of the two does not provide additional benefit over each therapy alone.

Key words: Acupuncture, asthma, complementary therapies

(Explore 2007; 3:28-36. © Elsevier Inc. 2007)

INTRODUCTION

Asthma is a serious chronic lung disease characterized by reversible airway obstruction and airway inflammation. According to the 2002 National Health Interview Survey, 30.8 million people in the United States have been diagnosed with asthma sometime during their lifetime.[1] This includes 21.9 million adults and 8.9 million children. Although the American Lung Association recently reported that asthma mortality rates and hospitalizations have declined over the past few years,[2] the burden from asthma has increased over the past two decades, and asthma continues to take a significant toll on daily activities and economic productivity for many patients. The National Health Interview Survey found that over the previous year, symptoms of asthma caused children aged 5 to 17 to miss 14.7 million school days due to asthma, and employed adults to miss 11.8 million workdays. The American Lung Association reported that asthma entails an annual economic cost to the United States of $16.1 billion, including $11.5 billion in direct healthcare costs and $4.6 billion in lost productivity.

Use of Complementary and Alternative Medicine for Asthma

Many asthma sufferers are attracted to complementary and alternative medicine. Blanc et al[3] found that 42% of the adults with allergies or asthma who were surveyed had tried some form of complementary and alternative medicine (CAM). Angsten[4] has proposed that asthma patients may be interested in CAM because of the chronic nature of their illness, the "perceived toxicities of therapies such as inhaled corticosteroids" and because they are attracted to the holistic approach of the treatments, which appreciates the psychological basis of disease. Davis et al[5] believe that the lack of success for conventional asthma therapy has resulted in the increasing number of patients seeking CAM approaches.

Acupuncture Studies to Date

Although numerous studies have been conducted to examine the effectiveness of acupuncture for adults with asthma, it is still difficult to draw definitive conclusions regarding its effectiveness. In one uncontrolled, clinical series of 25 steroid-dependent

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This study was supported by funds from the Spanier Foundation.

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ISSN 1550-8307/07/$32.00

doi:10.1016/j.explore.2006.10.003

asthma patients treated with acupuncture and Traditional Chinese Medicine, over 80% improved symptomatically and became less dependent on steroids.[6] In another uncontrolled clinical series of 80 patients treated with acupuncture and blood injections at the Back-Shu points, 39 patients were cured of their asthma (49%), 21 patients showed substantial improvement (26%), and 15 patients somewhat improved (19%), whereas only five patients (6%) showed no effect, the total effective rate being 94%.[7]

Systematic reviews of randomized controlled trials do not tend to support the use of acupuncture for asthma. A 1991 systematic review by Kleijnen et al[8] found 13 studies that sought to assess the efficacy of acupuncture in asthma therapy. These authors concluded that claims that acupuncture is effective are not based on the results of well-performed clinical trials. However, the requirement of double blinding, necessary to be deemed a high-quality study according to most review scoring systems, is extremely difficult to achieve in a practitioner-delivered intervention such as acupuncture. This issue often causes well-designed acupuncture studies to be rated as low-quality trials.

A Cochrane collaborative systematic review of acupuncture for chronic asthma in 2004 yielded similar results.[9] Their review of research of 11 studies with 324 participants found a lack of evidence that short-term acupuncture treatment has a significant effect on the course of asthma. However, they noted that it is questionable whether the acupuncture protocols used in the research were representative of acupuncture conducted in actual practice, considering that treatments were modified for the patient depending on the practitioners' assessments, and acupuncture often is one part of a package of care that includes diet and herbal medicines. The Cochrane reviewers commented that the underresearched aspect of treatment is the subjective element of this complex therapy. It is difficult to remove acupuncture treatment from its context, and this has not been addressed in existing research.

Martin et al[10] conducted a systematic review and meta-analysis of published data from 11 randomized controlled trials. The meta-analysis did not find evidence of an effect of acupuncture in reducing asthma. However, the meta-analysis "was limited by shortcomings of the individual trials, including small sample size, missing information, adjustment of baseline characteristics and a possible bias against acupuncture introduced by the use of placebo points that may not be completely inactive."[10]

Craniosacral Therapy

Osteopathic manipulation, including craniosacral therapy, is well established within the chiropractic and osteopathic community as a treatment for asthma.[11,12] A recent study by Guiney et al[13] demonstrated a statistically significant improvement of seven liters per minute to nine liters per minute for peak expiratory flow rates in pediatric asthma patients by using osteopathic manipulation.

One well-known variation of osteopathic manipulation that has grown in popularity in the past decade is craniosacral therapy. Craniosacral therapy (CST) is a gentle, noninvasive type of hands-on body treatment in which the therapist monitors the patient's craniosacral rhythm (subtle pulsations of the craniosacral fluid) by placing her or his hands at specific locations in the cervical and sacral regions. According to CST theory, disturbances in this rhythm can be corrected using gentle manipulative techniques, often leading to reduced pain and improved function. Many medical conditions in addition to pain are traced by CST practitioners, at least in part, to problems and misalignments of the craniospinal system. The body can often self-correct from restrictions and blockages of the skull, spine, and pelvis; however, left untreated, these restrictions can take more time and effort to correct. The result can be increased pain and organ dysfunction, and worsening of a condition such as asthma.[14] No research has been conducted to date supporting CST for asthma treatment.

Combining Therapies

In clinical practice, multiple CAM approaches are often combined in the treatment of a patient with asthma. However, to date no substantial evidence exists that supports the hypothesis that combining CAM therapies for asthma management is effective. When psychotherapy is combined with conventional medical treatment, synergistic improvement has been reported. Godding et al[15] studied 41 high-risk asthmatic children from 39 families. The subjects had a documented history of moderate-to-severe asthma for at least two years. During that two-year period, psychotherapy was added to conventional medical treatment. The number of hospital admissions and days spent in the hospital decreased significantly. The number of days in the hospital also fell, from 17 ± 20 in the two years prior to the onset of treatment to 2 ± 8 in the two years after the start of treatment ($P < .001$). The cost of care was subsequently cut by two thirds, despite the added cost of psychiatric care. The study found no significant correlation between the improvement of the symptom score or the therapeutic score. However, a significant correlation was found between improvement of the symptom score and that of the compliance score ($r = 0.499$; $P < .001$), suggesting that the improvement in the patient's symptoms after two years of treatment was related to improvement in compliance with treatment. What is not tested, however, is whether the improvement is due simply to adding more treatments, even though of a different type, or is due to a synergistic effect between the two, in which the result is greater than would be expected in a simple additive model.0

This study aimed to test the possibility of synergy between two very different complementary modalities–acupuncture and craniosacral therapy. In consultation with all the practitioners in our facility, these two modalities were chosen as being the most likely to demonstrate synergy among those for which our practitioners had strong clinical training and expertise. We also wanted to examine if the addition of complementary therapies to standard medical management would improve clinical outcomes in adults with asthma, and whether or not mixing two modalities would be more helpful over a fixed length of time than using one modality for that entire time. This was a pilot study aimed to explore how likely these concepts would be expected to demonstrate efficacy in a large-scale clinical trial.

METHODS

Subjects

The Institutional Review Board of Beth Israel Medical Center gave approval prior to beginning the study. From May 2001 to November 2003, 89 chronic adult asthma sufferers from the greater New York City area were enrolled into the study by using advertisements in local newspapers, internal publications, and flyers distributed in local university health centers and health food stores. Physicians in the pulmonary, family practice, and integrative medicine service practices of Beth Israel also made referrals when appropriate. Potential subjects were screened over the phone by using a standardized screening tool. They were accepted for pulmonary evaluation if they met criteria for the diagnosis of asthma as defined by the National Heart, Lung, and Blood Institute National Asthma Education and Prevention Program. Class II through IV asthma sufferers were included (mild persistent, moderate persistent, and severe persistent). Subjects were excluded if they were under age 18, had received acupuncture or craniosacral therapy treatments over the past six months, were involved in any other research study, were pregnant, or taking steroids unrelated to asthma. Mild intermittent diagnoses were excluded since symptoms may not have been severe enough to observe changes in a pilot study of this type. Subjects with life-threatening conditions or serious psychiatric conditions that would interfere with their ability to participate in the study and follow-up period were excluded. Patients who passed the phone-screening interview were sent to the Pulmonary Function Laboratories of Beth Israel for pulmonary testing to observe their sensitivities to bronchodilation and to assess their degree of respiratory compromise from their asthma.

Demographics

The median age of subjects was 37 years, with no statistically significant differences in age between groups. The 25th percentile was aged 30 years and the 75th percentile was aged 48 years. The subject ages ranged from 20 years to 80 years of age. The population was comprised of 26.5% men, with the remaining 73.5% being women. No significant variation in these proportions was found across groups. The preponderance of our sample was Caucasian (80.9%), followed by African American (16.2%), with 1.5% Hispanics, and 1.5% Asians. Race was not statistically significant across the different groups. Race, gender, and age were not statistically associated with outcome differences in this study, suggesting a balanced assignment to treatment and/or control groups, because these factors are known to effect asthma severity in epidemiological studies. The histogram of age followed a precise normal distribution except that it was truncated at age 20 (our youngest subject). The oldest subject was aged 80 years.

Study Protocol

Enrolled subjects were randomly assigned to one of the following five conditions: (1) acupuncture, (2) craniosacral therapy, (3) combination of craniosacral therapy with acupuncture, (4) attention control, and (5) standard of care control (waiting list). Subjects in the first three groups were to receive 12 sessions of their assigned modality over a period of six weeks, although scheduling constraints sometimes extended the treatment period beyond six weeks. One difference between the three treatment conditions, which emerged as important in the analysis, was that conditions one and two both involved 12 sessions with a single provider—either acupuncture or craniosacral therapy—whereas condition three involved six sessions with each of two different practitioners. Thus, the first two conditions involved longer, more intensive contact with a single therapist, whereas the third condition involved shorter contact with two therapists. The attention control condition consisted of six weekly sessions with an actor who had been trained by Ken Fry, RPT, with suggestions from John Upledger, DO, in how to pretend to do craniosacral therapy without actually doing it. This was followed by a class on holistic approaches to managing asthma, which also lasted for six sessions. Subjects were asked at the end of all sessions if they thought they had received placebo treatment.

Randomization was done by means of a random number–generating program. Preprinted numbers were placed in envelopes by a staff member unrelated to the study. A research assistant opened the next sequential envelope at the moment that a subject qualified for enrollment. Blinding was possible for craniosacral therapy, as none of the subjects in the attention-control condition thought they had received placebo treatment and more than 75% of participants wanted to continue their sessions with the actor after the treatment period had ended. Subjects receiving acupuncture knew that they were receiving acupuncture. Subjects who were in the waiting list group knew the group to which they had been assigned. Outcome questionnaires were completed at the office of the practitioner where treatment occurred and were presented and returned in envelopes marked only by subject number. They were returned sealed to our offices, where data entry occurred by a staff member who was unacquainted with the subjects or their assignments. The respiratory therapist performing pulmonary function testing was blind to the assignments of the subjects. Assessments after treatment concluded were conducted by research assistants who did not know subject assignment, though subjects could have informed them of their condition. An equal number of people wished to continue after the 12 sessions in each group, lending credence to the idea that our attention control seemed like authentic therapy. Although we did control for time and attention, we did not control for belief in acupuncture efficacy and what affect that might have had on the results.

Sample Size

Power size was calculated for $\beta = .80$, assuming a two-group comparison model across four points in time. Results indicated a minimum n of 26 per cell. A power analysis using five levels in the main effect across four repeated points in time was calculated for $\beta = .80$, using the means and standard deviations derived from previous pilot studies. Results indicated that there needed to be a minimum of 20 subjects per cell. A second estimate of power, using standard moderate effect size parameters, was also calculated. Results indicated the need for 20 subjects per cell. Total sample size desired was 100; enrollment challenges forced us to end recruitment at an N of 89. Because of recruitment and retention issues, the number of patients completing the trial was 68, resulting in cell sizes ranging from 10 to 16.

Table 1. Acupuncture Points for Asthma

Body points: required (bilateral except CV and GV points)
GV 14
Diang Chuan
Bl 13
Bl 43
GB 21
CV 22
CV 17
Flexible distal points (bilateral)
PC 6
Sp 4
Li 3
Lu 5 (Matsumoto)
Lu 7
St 40
St 36

Acupuncture Protocol (Group 1)
Subjects in the acupuncture group received 12 treatments of acupuncture. Acupuncturists at the Center for Health and Healing and in private practice in the local community provided the subjects' treatments. All acupuncture sessions followed a protocol that included a fixed core of seven body points that were always needled, and a set of up to seven bilateral distal points that were chosen by the practitioner, based on the needs of the patient as determined in an individualized diagnosis by the acupuncturist. This procedure allowed for a moderately standardized approach while still allowing the acupuncture to be administered the way it typically would be in a clinical setting, where the points are selected based on the diagnosis of the practitioners. Sessions lasted for approximately 45 minutes. Needles were inserted and manually stimulated. Patients then rested quietly in a darkened room for 20 minutes, at which time the needles were removed. No additional stimulation was administered. A summary of the acupuncture protocol is presented in Table 1.

Craniosacral Therapy Protocol (Group 2)
Subjects received 12 standard craniosacral therapy treatments in accordance with the protocol taught at the Upledger Institute in Michigan, the premier training site for practitioners of this discipline. Trained therapists in the local community provided the treatments. Subjects rested fully clothed on a massage table. The therapist monitored the craniosacral rhythm with his or her hands. She or he conducted other gentle assessments and corrected the sources of pain and dysfunction by using gentle manipulative techniques. In craniosacral therapy, seldom does the pressure exceed five grams (the weight of a nickel). The work is gentle and does not hurt. The practitioner treated skull, spine, and sacrum. Sessions lasted approximately 45 minutes.

Acupuncture Plus Craniosacral Therapy (Group 3)
Subjects in this group received six treatments of acupuncture and six treatments of craniosacral therapy. They were instructed to schedule one of each treatment per week, alternating between the two.

Attention Control Group (Group 4)
Subjects in this group received six sessions of sham craniosacral therapy and six one-on-one educational classes with an asthma educator covering the current state of knowledge about the causes of and possible treatments for asthma. During the sham sessions, subjects lay supine for 45 minutes while a trained actor, posing as a practitioner, simply placed their hands lightly on various nonsexual parts of the fully clothed body and held them in each position for two minutes, following techniques found in therapeutic touch and related studies. John Upledger, DO, and Ken Frey, RPT (an Upledger-trained craniosacral practitioner in New York City) were consulted regarding the sham procedure and assisted in its design so that it would be valid.

Standard of Care and Waiting List Control Condition (Group 5)
Subjects assigned to this condition were instructed to maintain their normal asthma care regimens for the duration of the study (12 weeks active study period plus six months follow-up). During the active study period, they monitored their symptoms, as did the subjects in the other four groups. For motivational and ethical reasons, all subjects randomized to the standard of care control condition were offered 12 treatments of acupuncture or craniosacral therapy, or a combination of the two, when they had completed the study.

Additional control groups were considered, including sham acupuncture, though there is controversy regarding this method, since sham points are not associated with the sensation of *da chi* felt at the site of actual acupoints which is expected by those familiar with acupuncture. Although a sham acupuncture control group would have been useful, five groups were as many as could be handled statistically. Since CST has been less studied than acupuncture, it seemed reasonable to control for CST and attention, given that not every control group could be used.

Primary Outcome Measures
All outcome measures were obtained on four occasions: (1) pretreatment: within two weeks before treatments began, (2) posttreatment: within two weeks after treatments were completed, (3) at three-month follow-up: three months after treatments were completed, and (4) at six-month follow-up: six months after treatments were completed.

Pulmonary function testing was performed on these four occasions at the Beth Israel Pulmonary Function Laboratory by using Sensor Medics Pulmonary Function equipment (Sensor Medics, Fullerton, CA). Additionally, subjects completed the following self-report measures at each of the four times: Asthma Quality of Life Questionnaire, Short Form 36; Profile of Mood States; Beck Depression Inventory; Beck Anxiety Inventory; and a medication form in which they reported the name, dose, and frequency of use of any asthma medications they used over the past year. This medication form was used to assess changes in medication that might occur during the course of the study. Shortly after beginning the study, we learned that several sub-

jects wished to continue treatments beyond the study treatment period at their own expense. Since we could not ethically prohibit this, we created a document, the follow-up treatment log, on which subjects could report which treatments (acupuncture, craniosacral therapy, or other treatments) they obtained after their study-authorized treatment ended.

Daily and Weekly Symptom Monitoring

Subjects were also asked to complete a daily diary form on which they recorded their peak flow measures, three times per day, and their respiratory symptoms (sleep disturbance, chest tightness on awakening, daytime wheezing and breathlessness, and coughing). Subjects were given peak flow meters when they began the study. Before each treatment (or two times per week if in the control condition), subjects completed the Profile of Mood States. Subjects in the first four conditions completed one additional form, a treatment session note, prior to each treatment. They reported medical problems since their last visit, changes in symptoms, and any problems or symptoms related to treatment.

Upon enrollment, subjects signed a medical records release form and provided names of their physicians so that medical records about their asthma care could be requested. Subjects were offered a modest stipend as an incentive to complete the follow-up evaluations. They received $25 for the 3-month follow-up and $50 for the 6-month follow-up.

A modified intent-to-treat analysis strategy was utilized, in that any subject who completed one treatment and then dropped out was invited to have the posttreatment assessment. If they agreed, their data was included. If they declined follow-up assessment, they were dropped from the study, because at least two data points were required for statistical analysis.

Statistical Methods

For assessing change in asthma quality of life, difference scores were used for each of the four data points. We assessed differences from the pretreatment baseline to posttreatment (end of intervention or control group), pretreatment baseline to 3-month follow-up, and pretreatment baseline to six-month follow-up. We also calculated the difference from posttreatment to three-month follow-up, posttreatment to six-month follow-up, and from 3-month follow-up to six-month follow-up. Assumptions of normality for the difference scores for all these variables were confirmed with histograms. Levene's test for equality of variances confirmed equal variances, so all statistical tests were performed on that basis. Exploratory data analysis was pursued with graphical techniques, which showed that the most robust change in compromised quality of life was from pretreatment baseline to posttreatment assessment–the duration of treatment.

No differences in baseline pretreatment values were found among the groups. Due to the relatively small number of cases in each group, we collapsed the groups into "treatment" and "control" and performed independent samples *t* test on the difference scores from baseline to the end of the intervention or the control. To look for differences between groups, one-way analysis of variance was performed with post hoc tests with *P* values adjusted by the Schade correction for multiple comparisons. To justify this collapse, we found no differences whatsoever between the two control groups. Additionally, differences among the three treatment groups were insignificant, with only acupuncture approaching statistical significance compared with the other two treatment groups.

Each subject had only one practitioner for each modality. There were two practitioners of CST involved in the study, and three practitioners of acupuncture. Two different individuals provided education and only one individual provided sham CST. No statistically significant differences were found for specific practitioners.

RESULTS

Of the 89 subjects enrolled in the trial, 68 completed at least two assessments and were included in the final analysis. This represented a 76.4% completion rate. There were 11 subjects in the active treatment groups, and 11 in the combined waiting list/control group who did not complete the protocol. Typically, subjects who withdrew could not be enticed to complete a posttreatment follow-up. No subject withdrew due to adverse effects of treatment. In fact, no adverse events or side effects of treatment were reported by any subject. Schedule conflicts were the most frequently reported reason for dropout and did not vary in frequency between treatment and control groups.

The cost per completed subject was $3800, which may reflect in part the high cost of healthcare in New York City. No subjects were referred by our medical or psychological colleagues, and less than one fifth of enrolled patients were referred by alternative medicine practitioners. Approximately two fifths of our subjects came from public lectures given in the community about alternative therapies for asthma and roughly the same number from newspaper advertisements. The remainder came from posters placed in colleges, laundromats, and other facilities.

Our primary proposed outcome variable was pulmonary function testing, followed by asthma quality of life, medication use, depression, and anxiety. The data was analyzed in that order.

Pulmonary Function Testing

Pulmonary function measures did not change. Our review of medication records and our discussions with patients showed that patients spontaneously reduced their medications or asked their doctor to reduce their medication when they were doing better. Given the expense and complex logistics of this outcome measure, we would consider omitting it from future trials. Data analysis of thrice-daily peak flows is currently underway to determine its utility as an outcome measure.

Although pulmonary function test outcomes did not change, other outcome measures which did show change included the asthma quality of life scale, part 1 (part 2 was not helpful) and medication changes. No changes were found in the Beck Depression Scale, though we would keep it for future studies as a potential confounder or interaction variable for multivariate analysis, given its place in the literature for affecting asthma.

Asthma Quality of Life

We first compared the means for absolute asthma quality of life scores (Table 2). As expected, difference scores performed best, since they reduce within-subjects variance. When we compared

Table 2. Comparisons of Means Between Asthma Quality of Life (Part 1) Scores and Difference Scores From Baseline Across Assessment Periods

Group		AQOL, Baseline	AQOL, Posttreatment	AQOL, 3 Mo Posttreatment	AQOL, 6 Mo Posttreatment
Control group	Mean	4.77	5.64	4.41	3.91
	SD	±3.91	+4.70	+4.35	+4.52
Active treatment	Mean	6.46	3.71	3.63	3.61
	SD	4.57	3.52	3.88	4.20
	T	1.49	−1.89	−0.74	−0.27
	P value	0.142	0.063	0.459	0.789
	Mean difference	1.68	−1.93	−0.78	−0.30
	95% CI	−.58 to 3.95	−3.96 to 0.11	−2.87 to 1.31	−2.53 to 1.93
			Difference Score Pretreatment and Posttreatment	Difference Score Pretreatment to 3 Mo Posttreatment	Difference Score Pretreatment to 6 Mo Posttreatment
Control group	Mean		0.86	−0.36	−0.86
	SD		±4.95	+3.44	+3.54
Treatment group			−2.75±4.52	−2.83±4.94	−2.85±4.91
	Mean difference		−3.61	−2.46	−1.98
	95% CI		−6.02 to −1.20	−4.80 to −0.12	−4.32 to 0.35
	t test		−2.99	−2.83	−2.85
	P value		*P* = .004	*P* = .039	*P* = .095
Single practitioner	Mean		−3.13	−3.17	−3.37
	SD		3.90	4.46	4.40
Multiple practitioners			−0.35	−1.13	−1.29
			5.35	4.63	4.57
	Mean difference		2.78	2.04	2.08
	95% CI		0.54 to 5.02	−0.18 to 4.25	−.106 to 4.26
	t test		2.48	1.84	1.90
	P value		*P* = .016	*P* = .071	*P* = .062

AQOL, Asthma Quality of Life score; CI, confidence interval.

the change in asthma quality of life scores from baseline to posttreatment, statistically significant differences were found between treatment and control groups. The disparity in the difference scores for the assessment immediately posttreatment was 3.61, which was significant at $P = .004$, favoring treatment over control. This gives us an estimate of effect size for 12 sessions of complementary therapy (acupuncture, CST, or both) of about 18%. The range of the total asthma quality of life score is from 0 to 20. A gradual erosion of the differences between groups occurred with statistically significant differences still present three months after treatment and present at borderline levels six months after the conclusion of treatment.

The means between attention control and waiting list control were virtually the same (no statistically significant differences were found), suggesting that combining the two control conditions was reasonable and that future studies did not need a waiting list control to assess the contribution of mere attention. The waiting list control group also had the least subject satisfaction, since people objected to being assessed and having no treatment, even though they were receiving nominal payment.

Tests comparing the differences from pretreatment to posttreatment for each treatment condition (12 acupuncture sessions, 12 CST sessions, or six acupuncture and six CST sessions) versus the attention control showed that only acupuncture achieved statistical significance ($P = .45$ for acupuncture; $P = .60$ for craniosacral therapy; and $P = .71$ for combination).

A significant ($P = .016$) difference in change scores from pretreatment to posttreatment was also seen when we compared treatment with a single practitioner (longer treatment: 12 sessions, same person providing treatment, as in acupuncture alone and CST alone) to treatments with multiple practitioners (shorter treatment: 12 sessions total, but with each provider giving only six sessions, as in the acupuncture plus CST condition). The mean difference in change scores was 2.78, with standard error of 1.12, for an effect size of 13.9%.

Repeated measures analysis of variance (SPSS [SPSS Inc., Chicago, IL], general linear models) was applied using Total Asthma Quality of Life (part 1) difference scores for each of the assessment periods. For active treatment versus control, the F ratio was 6.67 with significance of $P = .012$. The square of the estimated effect size was 0.092. Observed power was 72.1%. For longer versus shorter treatment, the F ratio was 6.21, with a significance of $P = .014$. The observed power was 69.7%.

Part 2 of the asthma quality of life scale showed no statistically significant differences.

Table 3. Comparisons of Means Between Level of Medication Use From Baseline Across Assessment Periods, Differentiated by Treatment Groups

Group		Medication Use Score, Baseline	Medication Change From Baseline to Posttreatment	Medication Change From Baseline to 3 Mo Posttreatment	Medication Change From Baseline to 6 Mo Posttreatment
Control group	Mean	0.74	0.19	0.01	0.06
	SD	±0.75	+0.71	+0.81	+0.66
Active treatment	Mean	1.17	−0.31	−0.29	−0.30
	SD	±1.06	0.33	0.62	0.67
	T	1.71	3.95	1.71	2.06
	P value	0.091	< 0.001	0.092	0.043
	Mean difference	−0.430	0.499	0.306	0.355
	95% CI	−.0.931 to 0.771	0.247 to 0.751	−0.051 to 0.663	0.012. to 0.697

CI, confidence interval.

Medication Use

Given our small sample size, we chose to look at total medication use rather than a change in the use of any one specific medication. Our patients were using inhaled beta-agonists, inhaled steroids, and leukotriene inhibitors in sufficient amounts to warrant analysis. Oral steroid use was so minimal as to be not worth analyzing, as was the case for other drugs (ipratropium, cromolyn, and others). We constructed a standardized scale of dosage so that the highest dose encountered in the study was scored as a "1" and all other doses were rendered proportionate to that dose. Then the three most commonly encountered drugs were added on that standardized scale for dosage (this prevented any one drug from being weighted more heavily that any other drug). Changes in drug use could range from 0 to 3. The mean difference in medication use between control and active treatment groups was 0.499, which was significant at $P < .001$, representing an effect size of 16.6% of maximum (see Table 3 for details). Reductions in medication use persisted six months after the conclusion of the treatment (mean difference of 0.355, significant at $P = .043$). The lack of change in pulmonary function across this time period suggested that medication reduction was not done to please investigators or because participants were willing to tolerate being more symptomatic, but probably because they did not need as much medication to maintain the same comfort level. Medication change was our most robust variable.

Repeated measures analysis of variance (through general linear models of SPSS) was used for comparison with comparisons of means. Repeated measures would be expected to yield lower estimates of association, since the effects of treatment were expected to gradually wear off, representing a nonlinear effect. The resulting F ratio for between-subjects effects for active treatment versus control was 4.74, with significance of $P = .033$. Observed power was 57.4%. Repeated measures analysis of variance for longer treatment versus shorter treatment for medication resulted in an F ratio of 5.69, with a significance of $P = 0.02$. Observed power was 65.1%.

Anxiety

The data from the Beck Anxiety Inventory (BAI), showed no difference for treatment versus controls. However, when we compared the longer treatment protocol to the shorter treatments and to the controls, a statistically significant reduction on the BAI was found. Having a longer, more intensive treatment protocol with a single practitioner was associated with better reductions of anxiety on the BAI (Table 4). The reduction in BAI persisted at the six-month follow-up. Repeated measures analysis of variance was used for comparison purposes with this same

Table 4. Comparisons of Means Between Levels of Anxiety From Baseline Across Assessment Periods, Differentiated by Longer or Shorter Treatment From One Individual

Group (Length of Treatment by One Individual)		BAI Score, Baseline	Medication Change From Baseline to Posttreatment	Medication Change From Baseline to 3 Mo Posttreatment	Medication Change From Baseline to 6 Mo Posttreatment
Shorter treatment	Mean	9.23	1.00	0.01	0.06
	SD	±7.56	+5.19	+0.81	+0.66
Longer treatment	Mean	9.50	−1.44	1.32	1.83
	SD	±5.75	5.74	−2.33	−1.86
	T	0.170	1.852	2.20	1.86
	P value	00.865	0.068	0.031	0.068
	Mean difference	−0.284	2.44	3.56	3.69
	95% CI	−.3.61 to 3.04	−0.190 to 5.06	0.230 to 6.89	−0.171 to 7.56

BAI, Beck Anxiety Inventory; CI, confidence interval.

data and resulted in a significant difference between subjects effect (for shorter vs longer duration) with an F ratio of 4.90, significant at $P = .030$.

DISCUSSION

Our study showed that the two complementary therapies studied—craniosacral therapy and acupuncture—could be expected to reduce medication use and improve asthma-related quality of life in adults with asthma. Depression was not affected, but anxiety was reduced by longer treatment exposure to the same practitioner. To our surprise, pulmonary function remained constant, suggesting that patients are optimizing medications to achieve their desired maximal benefit. Improved quality of life in the face of reduced medication usage and no change in pulmonary function suggests that the two complementary therapies added something to medication management despite the lack of measurable change in pulmonary function testing. The effect of our two complementary therapies in improving quality of life and reducing medication usage persisted over the six months following the conclusion of treatment.

In our review of the literature, we found no studies to date demonstrating improvement in quality of life in people with asthma by using complementary therapies. Likewise no studies were found that examined the effects on anxiety in asthma patients comparing treatment with a single complementary practitioner versus the same number of sessions with two separate practitioners. Both of these findings are potentially important in understanding how to apply CAM approaches to patients with asthma. The interventions had no impact upon depression as measured by the Beck Depression Inventory. Likewise, this has not been previously studied.

The initial hypothesis of synergy between craniosacral therapy and acupuncture was not demonstrated. In fact, treatment with a single modality and a single therapist, continued over a longer period of time, appeared to be more effective than treatment with two theoretically synergistic modalities over the same number of sessions. Thus, the common notion in the clinical practice of integrative medicine that applying multiple CAM therapies is an effective strategy for asthma is not supported by our findings. Of course, it is possible that a different combination of CAM approaches would have demonstrated synergy, although this particular combination did not.

The consistent superiority of one individual practitioner for 12 sessions—for both acupuncture and craniosacral approaches—over two individuals each for six sessions even with two different treatments, suggested that relationship plays a role in facilitating treatment effectiveness. It is possible that the healing properties of this relationship are more critical to improved patient well-being than the specific techniques or properties of a given CAM therapy.

Regarding the impact of CAM treatment in this study on anxiety, it is important to note that we do not know if the treatment directly reduced anxiety or if the improvement in asthma led to reduction in anxiety. This reduction did, however, persist for six months after the conclusion of treatment.

This study had a number of limitations. The effect sizes were smaller than we expected (range of 18%). Because of this, the study was underpowered (generally we were at about 70% power to detect an effect at the 0.05 level of significance). The presence of significant results, even with underpowering, suggests that these results are robust and demonstrable again. Costs of recruitment were higher than expected, partially due to the lack of referrals from colleagues. This also contributed to underpowering due to the difficulties in recruiting a sufficient number of subjects. The most cost-effective recruitment procedure was public lectures. Emphasis on this area of recruitment could reduce costs per subject for future studies.

Pulmonary function testing was our most expensive outcome measure, and the one which in future studies might be most readily eliminated as unhelpful. What was expected to be captured with PFTs was captured instead by medication changes. Patients and doctors appeared to optimize their lung function through increasing or decreasing medications. PFTs might be more useful in a population with less well-controlled asthma (new onset, newly diagnosed, and poor medical care). Eliminating pulmonary function testing would greatly reduce the cost per subject for future research. Since the biggest problem in getting follow-up data was scheduling the pulmonary function test, eliminating this measure would likely also improve the completion rate. These factors should be considered when planning future trials.

The relatively high dropout rate is a source of potential bias. Given that the same number of subjects dropped out of active and control groups, and that the reasons for dropout were relatively even in distribution across groups, it is unlikely that this introduced significant bias. A second potential source of bias is that patients volunteering for a study such as this might be predisposed to favor a CAM approach and thus might already be actively resisting some of the medication interventions that typical asthma patients might agree to. This could skew the data collected on change in medication use during the study period. A final problem is that the 9/11 attacks occurred in the middle of the intervention period for most of our subjects. This event had tremendous impact on overall anxiety levels for all of New York, as well as an impact on many patients with chronic respiratory conditions. Although one imagines that the effects of 9/11 would have been evenly distributed across treatment and control groups, it is obviously impossible to know for certain if this was the case or if the data was affected in some way by these events. Increased levels of dust and smoke could also have worsened asthma symptoms.

In conclusion, the data would appear to support the addition of complementary therapies (acupuncture or craniosacral therapy) to optimal medical management for the treatment of asthma and would warrant a larger-scale clinical trial. For future research, it would appear that the waiting list control can be eliminated. The attention control was much more enthusiastically accepted and did not provide a statistically significant benefit over the waiting list control. Since PFTs did not change and added significant expense to the study, future trials might omit this as an outcome variable, decreasing the cost per subject and thus potentially increasing the number of subjects who can be enrolled.

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