

Effectiveness of Osteopathy in the Cranial Field and Myofascial Release Versus Acupuncture as Complementary Treatment for Children With Spastic Cerebral Palsy: A Pilot Study

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Context: Case reports and clinical trials have indicated that osteopathic manipulative treatment (OMT) may improve motor function and quality of life for children with cerebral palsy.

Objective: To assess the effectiveness of osteopathy in the cranial field, myofascial release, or both versus acupuncture in children with moderate to severe spastic cerebral palsy, as measured by several outcomes instruments in a randomized controlled trial.

Methods: Children between the ages of 20 months and 12 years with moderate to severe spastic cerebral palsy were enrolled in a single-blind, randomized wait-list control pilot study. There were three arms in the study: OMT (ie, osteopathy in the cranial field, myofascial release, or both, using direct or indirect methods), acupuncture, and control (ie, nontherapeutic attention). Children who were initially randomly assigned to the control arm were subsequently randomly reassigned to the intervention arms, increasing the sample size. Outcome measures included standard instruments used in the evaluation of children with cerebral palsy. Less traditional measures were also used, including serial evaluations by an independent blind osteopathic physician and visual analog scale assessments by an independent osteopathic physician and the parents or guardians. A total of 11 outcome variables were analyzed.

Results: Fifty-five patients were included in the study. Individual analyses of the 11 outcome variables revealed statistically significant improvement in two mobility measures for

patients who received OMT—the total score of Gross Motor Function Measurement and the mobility domain of Functional Independence Measure for Children ($P < .05$). No statistically significant improvements were seen among patients in the acupuncture treatment arm.

Conclusions: A series of treatments using osteopathy in the cranial field, myofascial release, or both improved motor function in children with moderate to severe spastic cerebral palsy. These results can be used to guide future research into the effectiveness of OMT or acupuncture in treating children with spastic cerebral palsy.

J Am Osteopath Assoc. 2008;108:559-570

More than 2 of every 1000 children aged 3 to 10 years in the United States are affected by cerebral palsy,¹ with an estimated 764,000 US children and adults manifesting one or more symptoms of this neurologic condition.² Cerebral palsy is caused by an injury to the central nervous system (CNS) before or shortly after birth, when the brain is in its most rapid stage of development. This injury can result in various types of motor dysfunctions, depending on the part of the brain affected. Although motor impairments in some individuals may be mild, the impairments typically impede ambulation and controlled movements.

The CNS insult in cerebral palsy is static—that is, cerebral palsy is a nonprogressive condition. However, the peripheral manifestations of this condition often progress as the individual grows and matures. Complications include speech impairment, swallowing difficulties, inability to control elimination of urine and feces (often with constipation), seizure disorders, and worsening flexion contractures of muscles in the extremities (with extension of posterior neck and back muscles markedly affecting ambulation).^{1,2} These medical problems often lead to severe emotional trauma for children with cerebral palsy and strained relationships and financial hardships for families of affected children.²

Standard therapy for children with cerebral palsy includes pharmaceutical management (eg, muscle relaxants); physical, speech, and occupational therapies; use of orthotic devices; and such invasive orthopedic procedures as dorsal rhizotomy.² Unfortunately, these therapies serve as only temporizing solutions to the functional difficulties faced by children

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Funding of this project was provided by the National Institutes of Health (Grant No. P50 AT00008).

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Submitted February 14, 2007; revision received October 23, 2007; accepted October 29, 2007.

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with cerebral palsy. A multitude of alternate interventions have been suggested to ameliorate, modify, or prevent the medical and associated problems that characterize cerebral palsy.

Osteopathic manipulative treatment (OMT) has previously been reported to improve motor function and quality of life in children with cerebral palsy.³⁻⁵ In fact, the first treatment center for patients with cerebral palsy in the United States, the Cerebral Palsy Institute, was opened in the 1940s by an osteopathic physician, Beryl E. Arbuckle, DO, in Broomall, Pa.⁴ Children enrolled at this center received intensive OMT, and much was learned about the association of OMT with functionality and clinical improvement of patients.

Acupuncture is commonly used as complementary treatment for patients with cerebral palsy in many countries in East Asia—though this therapy remains unfamiliar to most clinicians in the Western medical world. Although evidence-based, controlled studies substantiating claims of acupuncture's efficacy in cerebral palsy are lacking, a plethora of case reports and large clinical trials—mostly in the Chinese literature—offer some evidence in this regard.⁶⁻¹² These case studies and trials vary greatly in methodology and lack the scientific rigor of well-designed, randomized controlled trials. Nevertheless, such positive reports seem to merit further investigation.

The overall objective of the present study was to evaluate the effectiveness of—and patient compliance with—two medical modalities complementary to standard therapy for children with spastic cerebral palsy: OMT (limited to the techniques of osteopathy in the cranial field and myofascial release) and acupuncture. We sought to determine if either or both of these medical modalities could decelerate complications of the muscle problems resulting from the original neurologic insult in children. Specifically, the study was designed to answer the following five questions:

- Is the complementary use of OMT more effective than the use of standard therapy alone for reducing muscle spasticity in children with cerebral palsy?
- Is the complementary use of acupuncture more effective than the use of standard therapy alone for reducing muscle spasticity in children with cerebral palsy?
- Is OMT or acupuncture more effective in reducing spasticity in children with cerebral palsy?
- Is there a difference in patient compliance or tolerance between intervention and control arms in the study?
- Of multiple outcome variables evaluated in the study, which are the most appropriate for measuring change in children with cerebral palsy?

Methods

Participants

The present study was conducted at the Children's Clinic for Rehabilitative Services in Tucson, Ariz, which belongs to the

Children's Rehabilitative Services program of the Arizona Department of Health Services. This program is a state- and federally-funded effort to provide healthcare services for children with special needs, including developmental disabilities and other diseases requiring specialized care.¹³ More than 500 children with cerebral palsy are enrolled at the Children's Clinic for Rehabilitative Services. The Institutional Review Board of the University of Arizona at Tucson approved the present study. Informed consent was obtained from study participants.

Eligibility criteria for the present study included any child aged 11 months through 12 years who had been diagnosed as having spastic cerebral palsy. For the purpose of this study, cerebral palsy was defined as a nonprogressive, static encephalopathic condition, secondary to an insult to the CNS that occurred during the time of gestation or within the first 5 years of life, resulting in a motor disturbance. Children were also eligible if they had a mixed type of cerebral palsy, with features of spasticity and athetosis (ie, nonpurposeful writhing movements)—provided that the spasticity component was predominant. A moderate to severe level of spasticity, as defined by a score of 2 or greater on the Modified Ashworth Scale,^{14,15} was required for inclusion in this study.

Patients using any of the following therapies were excluded from the present study: current use of a baclofen pump, injections of botulinum toxin during the study period or within 4 months of entering the study, or any orthopedic or neurosurgical procedure during the study period.

Researchers recruited patients primarily through posted fliers and on-site enrollment at cerebral palsy clinics, as well as letters of invitation to the offices of physicians and allied health professionals in the Tucson region. Secondary recruitment efforts were directed at cerebral palsy clinics in the Phoenix, Ariz, region and at clinics practicing alternative therapies for improving motor function.

Families of enrolled children agreed not to alter the doses of any muscle relaxants that their children were currently using and to continue their children's other standard therapies for the duration of the study. Families also agreed to postpone any invasive procedures for patients until the study interventions were completed. Finally, families were asked not to use any other complementary or alternative therapies intended to change muscle tone or coordination or to improve motor function. Such therapies included conductive education, hippotherapy (ie, therapeutic horseback riding), hyperbaric oxygen therapy, hypnosis, music therapy, yoga, and any acupuncture or OMT that was not a part of the study.

Baseline Assessment

After enrollment, each child received a baseline assessment consisting of multiple measures of motor function and quality of life, including the Gross Motor Function Classification System (GMFCS),¹⁶ Gross Motor Function Measurement (GMFM-

88),¹⁷⁻¹⁹ Functional Independence Measure for Children (WeeFIM),²⁰ and Pediatric Evaluation of Disability Inventory (PEDI).²⁰ Descriptions of these measuring instruments, which were repeated for patient evaluation and outcome variable collection at the midpoint of the study (12 weeks) and the end of the study (24 weeks), are given in *Figure 1*.

After baseline assessment, children were randomly assigned, by age and motor disability severity as determined by GMFCS, to one of three treatment arms: OMT, acupuncture, or wait-list control group.

Measuring Instruments for Outcome Variables

A blinded physical therapist who was well-experienced in examining and treating children with cerebral palsy administered the GMFCS, GMFM-88, and PEDI based on direct observation and the observations of the children's parents or guardians. A research assistant completed the WeeFIM. The GMFCS, GMFM-88, PEDI, and WeeFIM were used to collect data for the six primary outcome variables of GMFCS, GMFM total percent, PEDI mobility, PEDI self-care, WeeFIM mobility, and WeeFIM self-care.

Data for five secondary outcome variables were collected by a blinded physical therapist, a blinded osteopathic physician (K.W.), and the children's parents or guardians. The phys-

ical therapist conducted assessments with two Modified Ashworth Scales, which were used for measuring tone of the biceps and hamstring muscles.^{14,15} The osteopathic physician used a visual analog scale to evaluate any change in the level of spasticity or any change in body alignment or symmetry. Each child's parent or guardian was asked to use a visual analog scale to rate the current severity of the child's spasticity, compared with the usual level of the child's spasticity. Active and passive range of motion of multiple joints were also measured by the physical therapists.

As previously mentioned, study protocol called for these evaluations of outcome variables to be completed at baseline, midway through the 24 weeks of treatment, and at the conclusion of the treatments.

Random Assignment

The random allocation sequence for assigning study participants to the intervention groups and the control group was generated using a draw technique, with blocking stratification based on age and severity of spasticity. Weighting yielded the following four groups:

- age <5 years and GMFCS Levels I-II
- age <5 years and GMFCS Levels III-V
- age ≥5 years and GMFCS Levels I-II
- age ≥5 years and GMFCS Levels III-V

Next, groups of sequence draws were completed in blocks of four coin draws weighted 50% control and 50% intervention—which were weighted equally between intervention types, yielding 25% OMT and 25% acupuncture.

The final allocation document was housed with the study's data manager on a password-protected computer and was not made available to any other study personnel until enrollment had ceased. The study's biostatistician generated the allocation sequence before the start date of enrollment and had no involvement in the recruitment, enrollment, allocation, treatment, or assessment of the study participants.

With the exception of the data manager, all study personnel were blinded to the allocation sequence and were not made aware of the allocation for each child until after all enrollment documents were signed and the child was listed as enrolled in the study. At that point, the allocation of each new enrollee was provided to the project manager to allow her to set up the necessary appointments for the child. The project manager also oversaw consenting requirements and data collection for each participant and was required to provide each participant's name, age, GMFCS level, and enrollment date to the data manager for study arm assignment.

Blinding of study staff varied by status. Examiners were blinded to group allocation of each participant throughout the entire study. Families were counseled on the importance of this fact so as not to reveal any information about inter-

- **Gross Motor Function Classification System (GMFCS)**—Subjective measure that classifies the motor involvement of children with cerebral palsy on the basis of functional abilities and need for assistive technology and wheeled mobility. It is classified in five levels, from Level I (least severe) to Level V (most severe).
- **Gross Motor Function Measurement (GMFM-88)**—Objective clinical measure for evaluating change in gross motor function in children with cerebral palsy. There are 88 tasks, scored on a scale of 0 (most severe) to 3 (least severe), consisting of such activities as lying, rolling up, walking, running, and jumping.
- **Functional Independence Measure for Children (WeeFIM)**—Standardized measure of functional independence to assess the overall effectiveness of rehabilitation programs for individual children or groups of children.
- **Pediatric Evaluation of Disability Inventory (PEDI)**—Subjective descriptive measure of a child's functional performance at a given point in time and divided into three domains: self-care, mobility, and social function.

Figure 1. Standardized outcome measures used in pilot study of effectiveness of osteopathic manipulative treatment or acupuncture in the treatment of children with moderate to severe spastic cerebral palsy.

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vention type to the examiners. The project manager was blinded until after participant enrollment. The data manager was not blinded at any stage and ensured adherence to random assignment for patients and blinding for project staff.

Intervention Groups and Controls

■ **Osteopathic Manipulative Treatment**—Three osteopathic physicians who were all members of the American Academy of Osteopathy and the Cranial Academy participated in the osteopathic structural examination and OMT protocols of the present study. Two of the osteopathic physician examiners were board-certified by the American Osteopathic Board of Neuromusculoskeletal Medicine as specialists in osteopathic manipulative medicine, and the other examiner was board-certified by the American Osteopathic Board of Family Physicians. Two of the examiners had been in practice for more than 20 years, while the other had been practicing for 12 years.

To address concerns regarding reliability of independent examinations, two instruction sessions covering the examination and treatment protocols were held with the three osteopathic physicians involved in the present study. In one of these sessions, each examiner independently screened five children serving as volunteer subjects. Findings were recorded. Interobserver reliability was found to be good, with the only difference among the three examiners being the direction for which the torsion pattern of cranial strain was named. After the instruction sessions, all examiners agreed to follow osteopathic medical convention and name the direction of the torsion pattern according to the side of the high wing of the sphenoid bone.

All enrolled children were examined by the same independent osteopathic physician examiner at baseline and at 12 weeks and 24 weeks. This examiner was blinded as to which treatment arm of the study each child was in. The osteopathic structural examination performed by this osteopathic physician reflected the 10 body regions identified by the International Classification of Diseases, Clinical Modification (ICD-9-CM) codes for describing somatic dysfunction (ie, head, cervical region, thoracic region, lumbar region, sacrum, pelvis, rib cage, upper extremities, lower extremities, abdominal-visceral region).²¹ Findings were documented on the Osteopathic Research Data Form. At each patient visit during the study period, a visual analog scale was completed by the osteopathic physician examiner and by the parent or guardian to subjectively assess the overall severity of the child's spasticity.

In each treatment session, the treating osteopathic physician completed the osteopathic structural examination of each of the 10 body regions and recorded his or her findings on the same data form used by the examining osteopathic physician. This protocol allowed confirmation of osteopathic findings by an examiner who was blinded to the status of the children in the study (ie, OMT, acupuncture, wait-list control). It also allowed us to study the natural history of unmanaged

somatic dysfunction in the wait-list control group and to determine if osteopathic findings would change after either the OMT or acupuncture treatment. The treating osteopathic physician, based on his or her structural findings, treated the child in whichever sequence he or she deemed appropriate for that visit. Osteopathic manipulative treatment was limited to the use of direct or indirect techniques of osteopathy in the cranial field, myofascial release, or both. By definition, direct techniques provide a change in the body by working against a barrier of resistance in the tissue, and indirect techniques provide a change in the body by moving tissue away from a barrier, allowing the vectors of force within the tissue to reach a new point of balance.²² During prestudy discussions with our osteopathic advisors, these techniques were determined to be the most appropriate OMT techniques for the patient population of the present study.

The treating osteopathic physician initially recorded which technique was used for each of the 10 regions. At subsequent visits, the same osteopathic physician reassessed the child to guide further treatment. On certain follow-up visits, the osteopathic physician recorded findings only for those regions that he or she treated in that visit.

Each child was scheduled to be treated with OMT for 10 sessions of decreasing frequency over a 24-week period: weeks 1-4, once every week (4 treatments); weeks 5-8, once every other week (2 treatments); and weeks 9-24, once every month (4 treatments). Each treatment session lasted 30 to 60 minutes, guided by the tolerance and response of the child to a given intervention.

■ **Acupuncture**—To determine each child's affected motor areas, an independent acupuncturist evaluator interviewed the child's parent or guardian and, when appropriate, the child, completing a systematic review of symptoms at the initial visit. A brief review of these symptoms was repeated by this evaluator at each subsequent visit to note any changes that had occurred since the previous visit. All acupuncture therapy was performed by one community acupuncturist according to the methods of the Shanghai College of Traditional Chinese Medicine.²³ This treating acupuncturist was a graduate of a 4-year accredited program and had board certification in his specialty and 3 years of clinical experience before the study.

Each child was treated with a combination of scalp, body, and auricular acupuncture techniques that were specific to affected areas and inclusive of both sides of the body. Acupuncture was performed with needles inserted into the scalp, contralateral to the affected side, and into both sides of the body, according to pattern differentiation. Local points were targeted to relieve spasticity in the affected areas. Once inserted, the needles were stimulated manually, left in place, and stimulated again before they were withdrawn.

Each child was scheduled to receive 30 sessions of acupuncture therapy at decreasing intervals over a 24-week

period: weeks 1-4, three times every week (12 treatments); weeks 5-8, twice every week (8 treatments); weeks 9-12, once every week (4 treatments); and weeks 13-24, once every other week (6 treatments). Each acupuncture therapy session lasted as long as 30 minutes.

■ **Wait-List Controls**—During the 24 weeks of the present study, student volunteers were scheduled to spend 11 hours of nonspecific, nontherapeutic “play” time, in individualized sessions, with the children who had been randomly assigned to the control arm. The nontherapeutic play had two purposes: to control for the effect of attention in the intervention arms, and to offer families of participants an interim benefit of time spent with their children. A duration of 11 hours was selected for the control arm to approximate the time children spent in the OMT arm (10 sessions of 60 minutes each, for a total of 10 hours) and the time children spent in the acupuncture arm (30 sessions of 30 minutes each, for a total of 15 hours).

As an incentive for control group participants to remain in the study, all control subjects were randomly reassigned into a treatment arm after completion of their control measures. This random reassignment involved the same sequence draw strategy previously described in the “Random Assignment” section with equal weighting between intervention types.

Statistical Analyses

Data were analyzed using hierarchical multiple regressions for each of the 11 individual outcome variables. Because there were no differences among assessments taken from the left or right side of the body, the results are reported only from the left side. Imputation procedures were used for the few cases with missing data. Imputation is a standard strategy for estimating missing values for a variable in order to execute analyses of a complete data set.

We executed hierarchical linear regression models for the 11 outcome variables using the Statistical Package for the Social Sciences (version 11.0; SPSS Inc, Chicago, Ill). The dependent variables were the outcome scores at 24 weeks. The independent variables, in their order of entry, were as follows: the pretreatment score (to control for baseline severity); the patient’s age (to control for maturation); the number of months from baseline to final assessment (to control for variable time to assessment); and the number of treatments (testing the dose effect for each treatment). To represent estimates of the standardized strength of a given treatment’s effect on an outcome measure, β coefficients were generated for each outcome variable.

Results

Ninety children were assessed for eligibility in the present study, and 76 were initially enrolled. Before random assignment, however, 13 families withdrew from the study, and 8 families elected to have their children placed in a special

group to receive a combination of OMT and acupuncture. Thus, these children did not participate in random assignment, and the results of their evaluations are not included in this report.

The remaining 55 children were randomly assigned. Thirty-three of the children were directly assigned into intervention arms, with 15 children placing in the OMT arm and 18 children placing in the acupuncture arm. The other 22 children were randomly assigned into the wait-list control arm, and 20 of these individuals were later randomly reassigned into intervention arms, with 11 going to the OMT arm and 9 going to the acupuncture arm. Thus, the 55 children actually represent 75 cases. Among these cases, a total of 55 had sufficient data points to include in the final analysis: 19 in the OMT arm, 19 in the acupuncture arm, and 17 in the wait-list control arm. Compliance with the nonintervention play in the control arm did not meet acceptable limits. An algorithm representing the flow of cases in the study protocol is shown in *Figure 2*.

Table 1 displays the baseline demographics and GMFCS severity levels for the 55 children included in the analysis. There were no statistically significant differences for these baseline variables between the control arm and each of the intervention arms. Of the 55 children in the analyzed cases, 38 (69%) were boys. All children were between the ages of 20 months and 12 years. Only 3 children (5%) were younger than 24 months. Forty-three children (78%) were aged 4 years or older. The ethnic mix of the children in the present study—mostly white or Hispanic, with some African American and Native American—was an accurate reflection of the diversity of the population in the Tucson metropolitan area (*Table 1*).

A pediatric neurologist confirmed the diagnosis of spastic cerebral palsy in all children enrolled in the present study. The etiology of the CNS insult in this cohort was multifactorial. The severity of the motor disturbances ranged from GMFCS Level I (mildest) to GMFCS Level V (most severe). Among the cases in the analyses, 21 (38%) were classified as GMFCS Level I, II, or III, and 34 (62%) were GMFCS Level IV or V (*Table 1*).

Hierarchical Regression for Outcome Variables

The average pretreatment and posttreatment scores for each of the 11 outcome variables in the two intervention groups and the control group are shown in *Table 2*. The β coefficients for the individual outcome variables, representing estimates of the standardized strength of the effect of given treatments on outcome measures, are presented in *Table 3*.

The data in *Table 2* and *Table 3* indicate that the number of OMT sessions was associated with statistically significant changes in two of the outcome variables: the GMFM total percent score and the WeeFIM mobility score ($P < .05$). For the acupuncture treatment group, by contrast, the number of therapy sessions was not significantly associated with any of the outcome variables.

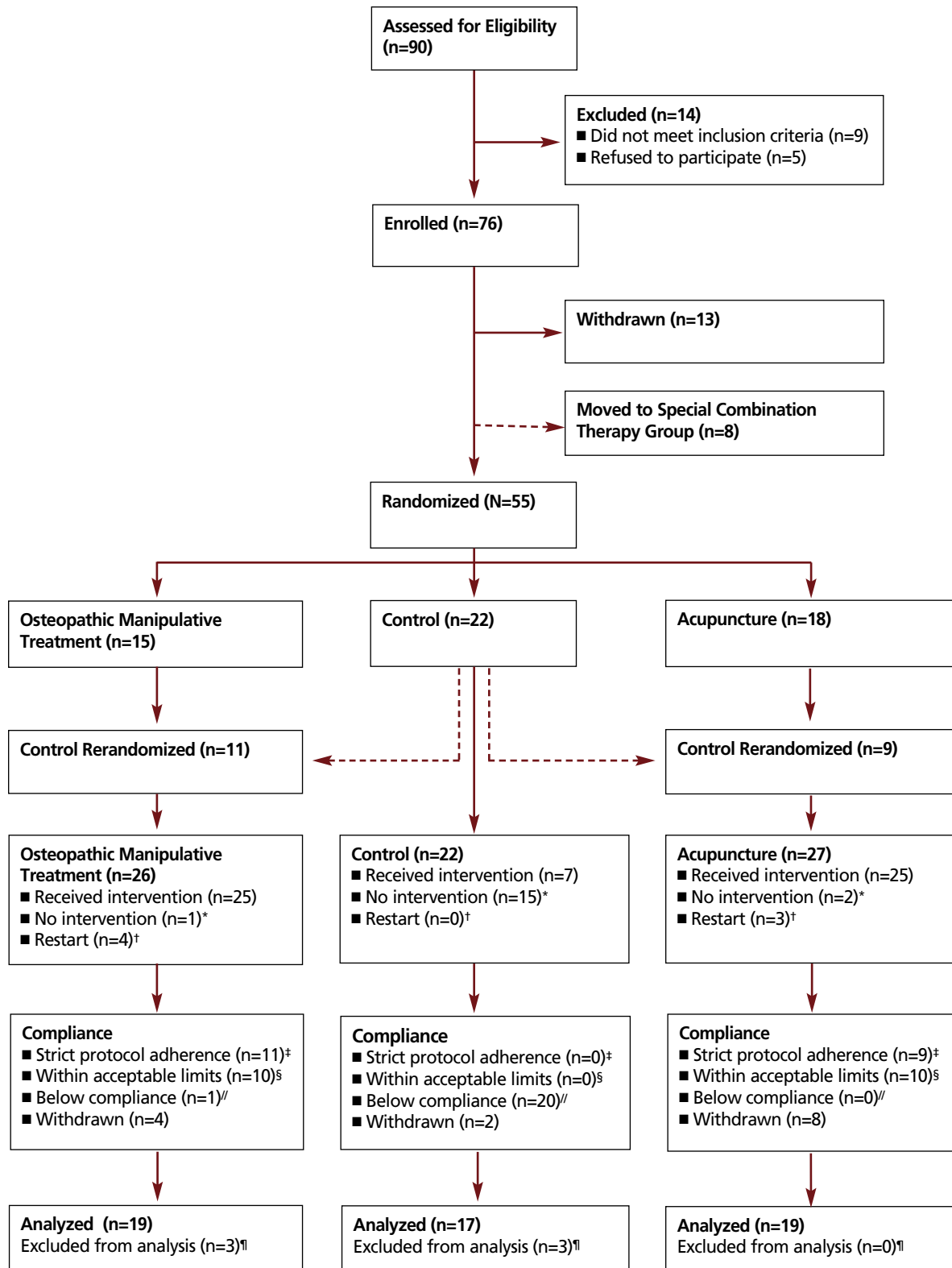


Table 1 Baseline Characteristics and GMFCS Levels of Children in Spastic Cerebral Palsy Pilot Study (N=55)*			
Characteristic	Study Group, No. (%)†		
	OMT (n=19)	Acupuncture (n=19)	Control (n=17)
■ Sex			
□ Boys	13 (68.4)	13 (68.4)	12 (70.6)
□ Girls	6 (31.6)	6 (31.6)	5 (29.4)
■ Age, y			
□ 1-2	0 (0)	1 (5.3)	2 (11.8)
□ >2-4	7 (36.8)	0 (0)	2 (11.8)
□ >4-8	6 (31.6)	13 (68.4)	7 (41.2)
□ >8-12	6 (31.6)	5 (26.3)	6 (35.2)
■ Ethnicity			
□ White	12 (63.2)	8 (42.1)	8 (47.1)
□ Hispanic	7 (36.8)	10 (52.6)	7 (41.2)
□ African American	0 (0)	0 (0)	1 (5.9)
□ Native American	0 (0)	1 (5.3)	1 (5.9)
■ GMFCS Level			
□ I	4 (21.1)	5 (26.3)	2 (11.8)
□ II	2 (10.5)	2 (10.5)	2 (11.8)
□ III	3 (15.8)	1 (5.9)	0 (0)
□ IV	1 (5.3)	4 (21.1)	1 (5.9)
□ V	9 (47.4)	7 (36.8)	12 (70.6)

* Children who were randomly reassigned into an intervention group after their time in the wait-list control group are counted in both the intervention data and control data as cases.
† Some percentages do not total 100 because of rounding.

Abbreviations: GMFCS, Gross Motor Function Classification System; OMT, osteopathic manipulative treatment.

The β coefficients in *Table 3* reveal that the rate of change of the GMFM total percent score was .39 SD units per one SD unit of change in the number of treatments, after holding constant the other variables in the model (ie, pretreatment score, age, months from baseline to final assessment). The rate of change of the WeeFIM mobility score was .28 SD units per

one SD unit of change in the number of treatments, after holding constant the other variables in the model.

Comment

Data analyses for the present pilot study involved 55 cases. The purpose of the analyses was to determine the effectiveness of OMT or acupuncture as complementary treatment for decreasing the degree of muscle tension and improving motor functionality in children with spastic cerebral palsy.

Regarding whether the complementary use of OMT was more effective than standard therapy alone for reducing muscle spasticity in children with cerebral palsy, we found that when OMT was added to the therapeutic regimen of patients and the results were compared with the children in the control group, OMT did indeed show an added benefit for improving the child's gross motor function (as indicated by GMFM total percent score and WeeFIM mobility score).

Regarding whether the complementary use of acupuncture was more effective than standard therapy alone for reducing muscle spasticity in children with cerebral palsy, we found that the acupuncture protocol used in the present pilot study failed to show any statistically significant additional

Figure 2. Flow of cases in study protocol for pilot study of effectiveness of osteopathic manipulative treatment or acupuncture in the treatment of children with moderate to severe spastic cerebral palsy. *Children who were randomly assigned, subsequently failed to meet any appointments, received no intervention, and were later withdrawn; †Children who missed scheduled appointments and were lost to follow-up, requested to be restarted in their respective therapeutic arm; ‡Child completed all treatment visits and all three assessments; §Child completed 80% or more of treatment visits and all three assessments; ¶Child completed less than 80% of treatment visits and fewer than three assessments; ¶¶The six cases excluded from analysis missed baseline or final assessment, had assessments done but lacked crucial data elements for analysis, or did not have acceptable compliance.

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Table 2
Mean Pretreatment and Posttreatment Scores of Children in Spastic Cerebral Palsy Pilot Study, by Outcome Variable (N=55)

Variable	Study Group, Mean Score (SD)					
	OMT		Acupuncture		Control	
	Baseline	Posttreatment	Baseline	Posttreatment	Baseline	Posttreatment
■ Primary Outcome Variables						
□ GMFCS*	3.5 (1.7)	3.4 (1.8)	3.3 (1.7)	3.2 (1.8)	4.1 (1.5)	4.2 (1.3)
□ GMFM total percent [†]	48.2 (33.8)	58.0 (32.3)	48.2 (36.0)	50.9 (37.9)	32.2 (31.4)	33.5 (31.2)
□ PEDI mobility [‡]	25.3 (20.5)	28.7 (21.0)	27.1 (21.8)	27.7 (22.3)	18.6 (20.1)	18.6 (20.2)
□ PEDI self-care [‡]	28.7 (25.2)	31.7 (26.5)	29.3 (22.9)	30.8 (23.1)	20.1 (20.3)	19.5 (20.4)
□ WeeFIM mobility [§]	14.2 (10.4)	15.9 (10.1)	13.9 (10.3)	14.6 (11.2)	11.2 (10.8)	10.7 (9.3)
□ WeeFIM self-care [§]	23.3 (18.2)	24.3 (18.5)	21.1 (16.9)	22.2 (17.6)	15.8 (15.0)	16.3 (15.1)
■ Secondary Outcome Variables						
□ DO rating of spasticity ^{//}	59.0 (22.6)	48.8 (25.7)	65.8 (24.0)	57.1 (24.8)	73.3 (22.1)	69.5 (21.6)
□ MAS biceps [¶]	1.4 (1.5)	1.7 (1.6)	1.7 (1.4)	1.9 (1.9)	2.5 (1.2)	1.9 (1.4)
□ MAS hamstring [¶]	2.2 (1.5)	2.1 (1.4)	2.3 (1.5)	2.5 (1.9)	2.6 (1.5)	2.3 (1.2)
□ Parent or guardian rating of arched back [#]	28.2 (30.5)	25.1 (26.4)	28.9 (25.5)	30.1 (27.9)	27.8 (30.1)	29.0 (23.8)
□ Parent or guardian rating of startle reflex [#]	31.7 (32.5)	29.0 (30.3)	51.1 (30.7)	31.2 (33.9)	54.3 (42.0)	46.0 (30.5)
<p>* Gross Motor Function Classification System (GMFCS) based on scale of 1 (least severe) to 5 (most severe). [†] Gross Motor Function Measurement (GMFM) total percent based on scale of 0 (most severe) to 100 (least severe). [‡] Pediatric Evaluation of Disability Inventory (PEDI) based on subjective descriptive measure of a child's functional performance at a given point in time. [§] Functional Independence Measure for Children (WeeFIM) based on standardized measure of functional independence to assess overall effectiveness of rehabilitation programs. ^{//} Osteopathic physician (DO) rating based on visual log scale of 0 (least severe) to 100 (most severe). [¶] Modified Ashworth Scale (MAS) rating based on scale of 0 (least severe) to 4 (most severe). [#] Parent or guardian rating based on visual log scale of 0 (least severe) to 100 (most severe).</p>						
Abbreviation: OMT, osteopathic manipulative treatment.						

benefit when added to the patient's standard therapeutic regimen.

In terms of which treatment is more effective in reducing spasticity in children with cerebral palsy, this pilot study suggests that OMT is more effective than acupuncture. However, final judgment on this point must be reserved for a larger and more definitive investigation.

Regarding whether there was a difference in compliance or tolerance between the intervention groups, this study required a substantial time commitment from the families involved, and, as a result, strict adherence to the protocol as written was difficult for several of the families. Although the children in the active intervention arms received most of their scheduled treatments, the control group did not have any cases within acceptable limits for compliance.

In terms of the most appropriate outcome measures to use in future research involving children with cerebral palsy, the GMFM proved useful in the present study and is now widely

used in studies designed to evaluate the effectiveness of therapeutic interventions. The WeeFIM is more useful as a tool for program design than for determining the effectiveness of a short-term intervention. Passive range of motion in children who have spastic cerebral palsy and limited cognitive abilities is difficult to measure unless there are physical therapists engaged in the measurements. The Modified Ashworth Scale proved to be too subjective to be of value in this regard.

When we examined posttreatment changes in the individual outcome variables, OMT was associated with statistically significant changes ($P < .05$) in 2 of the 11 outcome variables—the total percent score of GMFM and the mobility domain of WeeFIM, both of which are measures of gross motor function (Table 3). Although this was a pilot study and any analysis should be considered preliminary, a statistically significant positive effect found in two independent traditional outcome variables that measure gross motor function may be interpreted as confirmation of a finding.

Table 3
Hierarchical Regression Analyses for the Effect of OMT and Acupuncture on Outcome Variables of Children in Spastic Cerebral Palsy Pilot Study, Adjusted for Number of Treatments (N=55)

Variable	Treatment Modality, β^*	
	OMT	Acupuncture
■ Primary Outcome Variables		
□ GMFCS	-.27	-.31
□ GMFM total percent	.39 [†]	.24
□ PEDI mobility	.26	.20
□ PEDI self-care	.25	.22
□ WeeFIM mobility	.28 [†]	.18
□ WeeFIM self-care	.23	.17
■ Secondary Outcome Variables		
□ DO rating of spasticity	-.44	-.24
□ MAS biceps	.09	.01
□ MAS hamstring	-.13	.08
□ Parent or guardian rating of arched back	-.10	0
□ Parent or guardian rating of startle reflex	-.27	-.22

* The β coefficient represents an estimate of the standardized strength of the effect of a given treatment on an outcome measure, given as the number of SD units per one SD unit of change in number of treatments, with other variables held constant (ie, pretreatment score, age, months from baseline to final assessment).
[†] $P < .05$

Abbreviations: DO, osteopathic physician; GMFCS, Gross Motor Function Classification System; GMFM, Gross Motor Function Measurement; MAS, Modified Ashworth Scale; OMT, osteopathic manipulative treatment; PEDI, Pediatric Evaluation of Disability Inventory; WeeFIM, Functional Independence Measure for Children.

Intervention using acupuncture therapy was not associated with a significant change in any of the individual outcome variables. The mean change in GMFM for children who received no treatment was an increase of 1.3%; for the children in the OMT group, an increase of 9.8%; and for the children in the acupuncture group, an increase of 2.7%. As depicted in Table 4, the GMFM improvement found in the noninvasive, OMT group in the present study compares favorably with other studies using different interventions, some of which were invasive (eg, selective dorsal rhizotomy).²⁴⁻³⁴

The children in the two intervention arms received most of their scheduled treatments. However, families in the wait-list control arm took part in only a few of the scheduled “play” visits. This study required a substantial time commitment from the families involved, and strict adherence to the protocol was difficult for several of the families. If a case received 80% or more of the scheduled treatments per arm and if all three assessments were performed, the patient was considered to

have completed treatment within acceptable limits. Using this standard, 21 (81%) of 26 OMT patient and 19 (70%) of 27 acupuncture patients completed the assigned visits—compared with the control group, which did not have any cases within acceptable limits for compliance.

Limitations

The present study design was far too ambitious given the limited budget, which led to the need to use volunteers to assist with the protocol for the control arm and prevented reimbursement of families for their time. The study also involved an excess of outcome variables, demanding more time and commitment than the majority of the participants could provide.

Some of the secondary outcome variables evaluated in this study could have been eliminated. The Modified Ashworth Scale did not prove to be a consistent and reproducible measure. The visual log scale of degree of spasticity, as assessed by the child’s parent or guardian, was meant to reflect the “average” level, because relying on the last evaluation was believed to be too subjective. The range of motion data were not included in the analyses because the data collected were not reliable.

Relying on children with limited cognitive abilities to cooperate and follow the instructions of the present study was problematic. The degree of spasticity and control over muscle tightness in the children varied from time to time, and there was a substantial amount of missing data for the children who had the most severe degrees of impairment. It was also difficult to determine accurate measurements for some of the passive range of motion outcomes. One physical therapist working alone attempted to measure the degree to which the joint could be flexed or extended. Often the child was uncooperative, or a sudden loud noise would startle the child and spasticity would ensue, making it difficult to obtain accuracy or consistency throughout the measurements.

Osteopathic physicians and practitioners of traditional Chinese medicine are taught to use a holistic approach in determining the individualized treatment for each particular patient visit. This approach made it difficult for these practitioners to strictly follow a prescribed standardized research protocol. Thus, reassessments of patients at each visit might have resulted in a varying emphasis or sequence of treatment.

Both osteopathic physicians³ and acupuncturists^{10,11} have proposed that the greatest benefit of their therapies for patients with cerebral palsy will be seen in children younger than 2 years of age and in children with limited neurologic involvement. Only three of the children included in the present analysis were younger than 2 years at the time they began treatment. Most of the children were at an age when the brain is no longer developing at a rapid pace and when plasticity is presumed to be reduced. Yet, from an osteopathic perspective, improved circulation with increased oxygenation and removal

Table 4
Comparison of Studies of Children With Cerebral Palsy Using GMFM-88 as Outcome Measure

Study	Subjects, N	GMFCS	Intervention	Mean Change in GMFM-88, %
Duncan et al (2008)	55	I-V	OMT Acupuncture	9.8 2.7
Bower et al ²⁴ (2001)	27 28	I-III	Routine PT* Intensive PT [†]	3.1 5.9
Hodgkinson et al ²⁵ (1997)	18	NA	SDR	3.2
Ketelaar et al ²⁶ (2001)	55	NA	Functional therapy Pharmaceutical	5.9 [‡] 3.1 [‡]
Kondo et al ²⁷ (2004)	25	I-IV	Muscle release [§]	3.9
Krach et al ²⁸ (2005)	31	I-V	CIBI	14.3 (all children) 22.9 (age <8 y)
McLaughlin et al ²⁹ (1994)	10 24	NA	SDR	9.0 9.8
McLaughlin et al ³⁰ (1998)	38	NA	SDR + physiotherapy ^{//} Physiotherapy alone ^{//}	6.9 [¶] 5.9 [¶]
Slawek et al ³¹ (2003)	14	NA	BTX-A	11.3
Steinbok et al ³² (1997)	28	NA	SDR + physiotherapy [#] Physiotherapy alone [#]	11.3 ^{**} 5.2 ^{**}
van Schie et al ³³ (2005)	9	II-III	SDR	8.8
Wright et al ³⁴ (1998)	24	I-III	SDR + PT + OT ^{††} PT + OT ^{††}	12.1 ^{**} 4.4 ^{**}

* Six hours of routine physical therapy over 3 months.
 † Forty-four hours of intensive physical therapy over 3 months.
 ‡ Evaluation at 6-month follow-up.
 § Muscle release at 6-month postsurgery.
 // One hundred forty-five hours of selective dorsal rhizotomy (SDR) and physiotherapy alone over 6 months.
 ¶ Evaluation at 12-month follow-up.
 # Two hours per week of SDR and physiotherapy alone over 3 months or 6 months.
 ** Evaluation at 9-month follow-up.
 †† Two hours per week of SDR, physical therapy (PT), and occupational therapy (OT) or PT and OT over 12 months.
 ‡‡ Evaluation at 9-month follow-up.

Abbreviations: BTX-A, botulinum toxin type A injections; CIBI, continuous intrathecal baclofen infusion; GMFCS, Gross Motor Function Classification System; GMFM-88, Gross Motor Function Measurement (based on 88 tasks); NA, not available; OMT, osteopathic manipulative treatment.

of waste products (and perhaps proinflammatory cytokines) result from OMT. Thus, it is speculative, but plausible, that increased circulation to the “idling neurons” of the less plastic brains of older children could improve neurologic and motor function.

Thirty-four (62%) of the children included in the present analysis had severe neurologic involvement (ie, GMFCS Level IV or V). The frequency of severely involved children in this study was higher than would be expected in the general

population of children with cerebral palsy. In a population-based sample of 408 school-aged children with cerebral palsy, Kennes et al³⁵ found the following distribution of GMFCS levels: Level I, 27.5%; Level II, 11.5%; Level III, 19.9%; Level IV, 20.1%; and Level V, 21.1%. The charts developed by Rosenbaum et al³⁶ predict eventual gross motor functioning based on age and GMFCS level—revealing that changes in GMFM scores stabilized at a younger age at each increasing level of GMFCS.

Part of the value of the present study was the opportunity for collaboration and interaction among practitioners from diverse fields, including osteopathic physicians, allopathic physicians, acupuncturists, physical therapists, statisticians, and other research personnel. One area in which researchers in complementary and alternative medicine will likely continue to struggle is the merging of the desire of allopathic researchers for reproducible treatment protocols with the desire of alternative clinicians for freedom to treat the patient as a whole. Taking into consideration the lessons learned in the present study, we suggest that any subsequent investigative protocol use fewer outcome variables, a substantially reduced patient and family burden, and patients who are younger and less severely involved neurologically.

Conclusions

This pilot clinical trial of complementary treatments for children with spastic cerebral palsy was somewhat problematic, but it produced encouraging and intriguing results—and the process was extremely informative. Although this was a pilot study with a small sample size, the results indicated substantial functional improvement in children with modest to severe spastic cerebral palsy who received OMT. The results also allowed a subjective appraisal of the multiple outcome variables initially selected.

The findings of the present study can be used to guide future research into the effectiveness of OMT and acupuncture for the treatment of children with spastic cerebral palsy.

Acknowledgments

We are extremely grateful to all the children and their families who gave us so much of their time and energy to help complete this investigation. The statistical analyses of data were completed by the Biostatistics Unit of the Pediatric Complementary & Alternative Medicine Center at the University of Arizona College of Medicine in Tucson. We would like to thank Sanford "Sandy" Newmark, MD, one of the evaluators; Theresa Cisler, DO, and Christian K. Peters, DO, treating osteopathic physicians; Philip E. Greenman, DO, and Viola Frymann, DO, osteopathic medicine advisors; Joseph Balensi, MS, LAc, acupuncturist; and Helene Sorkin, LAc, traditional Chinese medicine healer; Dorsett Edmunds, MA, PT, and Cristina Santos, LPT, physical therapists who completed the monumental task of patient evaluation; and Beverly Blashill Jutry, study coordinator. Finally, our data management team, including Kathleen Pettit and Russ Roberge, did an outstanding job.

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(continued)

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I asked of my own reason if there was not a cloud of water in the human body that could be caused to drop its dews, put out the fires of fever, and save the forests of life that were being burned every fall season.

Andrew Taylor Still, MD, DO
“The Wisdom of Nature” from *Philosophy of Osteopathy* (1899)