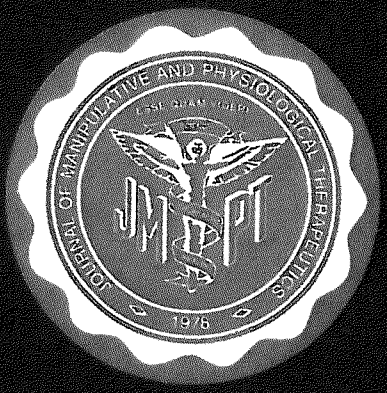
JOURNAL OF MANIPULATIVE AND PHYSIOLOGICAL THERAPEUTICS



Dedicated to the Advancement of Chiropractic Health Care Principles and Practice

Volume 29

Number 7

September 2006

ISSN 0161-4754

National University of Health Sciences

The Official Scientific Journal of the American Chiropractic Association

Comparison of Bioenergetic Synchronization Technique and Customary Chiropractic Care for Older Adults With Chronic Musculoskeletal Pain

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Abstract

Objective: The aim of the study was to compare the clinical outcomes of 2 approaches to chiropractic care for patients with chronic musculoskeletal pain. Included were the approach most commonly used by doctors of chiropractic (diversified technique spinal manipulation) and a nonmanipulative mind-body approach (Bioenergetic Synchronization Technique). This clinical experiment tested the null hypothesis that there is no clinically or statistically significant difference in effect between the 2 approaches.

Methods: The study was conducted in the research clinic of the Parker College of Chiropractic. Patients were initially recruited by contacting a previously developed pool used for studies related to fall prevention in the elderly. Eighty-one patients (74 females; median age, 66 years) were enrolled and 78 (96%) completed the study. The primary end point was the end of a 3-week nontreatment interval after a 4-week treatment period. An intention-to-treat analysis was used; all patients who completed assessments were included whether or not they were compliant with the treatment protocol. A sample size of 55 per group was estimated to be necessary to detect a clinically significant (6-point) between-group difference in the Pain Disability Index (PDI). The primary outcome, the mean between-group difference between PDI scores at visit 1 and the exit visit, was tested with a 2-tailed t test for independent samples.

Results: Mean improvements in the PDI from visit 1 to the exit visit were 6.9 points in the Bioenergetic Synchronization Technique group (n = 40) and 6.4 in the diversified technique group (n = 38); the between-groups difference was not statistically or clinically significant (95% confidence interval, −4.7 to 5.8).

Conclusions: For this particular group of patients, both groups demonstrated similar improvement scores on the PDI; the study's null hypothesis was not rejected. (J Manipulative Physiol Ther 2006;29:540-549)

Key Indexing Terms: *Chiropractic; Randomized Controlled Trials; Manipulation; Spinal; Pain*

The profession of chiropractic is closely associated with the procedure of spinal manipulation.[1] Spinal manipulative therapy (SMT), in turn, is closely identified with the high-velocity, low-amplitude (HVLA) procedure often referred to as "diversified technique" (DT), which is the most common procedure used by chiropractors. However, many chiropractors use other manipulative or adjustive techniques.[2] Some of these procedures involve very little biomechanical force.[3,4] This may, in some circumstances, be an accommodation to patients' preferences or presentations that contraindicate the use of HVLA techniques. Chiropractors also use an array of nonadjustive physical modalities such as ultrasound and interferential current, and counsel patients on lifestyle and health behavior.[2] An additional aspect of chiropractic practice, which is often overlooked or discounted, is the doctor-patient interaction itself, which, like that of other complementary and alternative professions, has been hypothesized by medical anthropologists to play an important role in the healing encounter.[5-7]

At this time, the relative contribution to treatment outcomes of the various aspects of the clinical encounter, including application of biomechanical force, has not been thoroughly explored. However, several randomized

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Paper submitted September 13, 2005; in revised form October 17, 2005; accepted October 31, 2005.
0161-4754/$32.00

doi:10.1016/j.jmpt.2006.06.026

controlled trials (RCTs) investigating SMT for patients with nonmusculoskeletal conditions have found that comparison treatments using lower amounts of biomechanical force and/or low-velocity manual procedures have produced similar clinical outcomes to those of the "active" treatment using HVLA SMT.[8-10] From such findings, one might infer that aspects in addition to specific biomechanical force may contribute to treatment effects.[11]

Based on the positive results of a preliminary, single-group study[3] investigating a nonmanipulative mind-body approach, Bio-Energetic Synchronization Technique (BT), used by chiropractors and other health professionals, this study was designed to compare the outcomes of patients with chronic musculoskeletal pain, measured 3 weeks after the end of treatment, receiving either DT SMT or BT.

Methods

Study Design

This study compared the treatment effect of BT and customary chiropractic care (DT) in a sample of patients with chronic musculoskeletal pain. The primary end point was the end of a 3-week nontreatment interval that followed a 4-week treatment period. The null hypothesis was that there is no clinically or statistically significant difference in effect between the 2 techniques.

Study Population

The study was conducted in the research clinic of the Parker College of Chiropractic (Dallas, Tex) and was approved by the college's institutional review board before patient recruitment. Clinic personnel were trained in administration of informed consent and the reporting of adverse events. Patients were initially recruited by contacting a previously developed pool used for studies related to fall prevention in the elderly.[12] Based on records of people who had expressed interest in participating in future studies, along with the results of previous recruitment efforts, it was estimated that 4 months would be adequate to recruit the required sample (see description of sample size below), and resources were dedicated for this recruitment and enrollment period. Additional means were (1) presentations to local groups, such as senior centers and chronic pain support groups; (2) an ad in a local senior newspaper; and (3) a radio ad, produced and run free of charge as a public service announcement by a former clinic patient. Men and women of all ethnic backgrounds were eligible. No one was excluded on the basis of disability.

Inclusion Criteria

Inclusion criteria consisted of (1) being 18 years or older; (2) having chronic musculoskeletal pain, with the onset at least 3 months before baseline visit, by patient self-report; and (3) being able to speak and understand English adequately to complete study forms (literacy was not required).

Exclusion Criteria

Exclusion criteria consisted of (1) pregnancy, because of possible exposure to diagnostic x-rays; (2) contraindications to manipulation, such as presence of fractures or other abnormalities identified by history, physical examination, or x-rays, as determined by the examining clinician; (3) pain due to cancer or other nonmusculoskeletal-related conditions; (4) litigation for a health-related claim (in process or pending); (5) chiropractic care within the last month, by self-report; and (6) unwilling to postpone use of all other types of manual therapy except those provided (including chiropractic, physical therapy, and massage) for the duration of the study.

Study Protocol

Volunteers were screened over the phone or at off-site events. If eligible at screening, they were scheduled for eligibility verification (visit 0), where the coordinator confirmed eligibility, explained the study, and obtained informed consent. Volunteers completed visit 0 forms before screening for final eligibility determined through the history and physical examination, and, if indicated, x-rays. If no exclusions were determined, the patient was randomly assigned to a treatment group.

Randomization

Treatment allocation was determined through dynamic randomization, using a minimization algorithm to allocate patients on the basis of visit 0 Pain Disability Index (PDI) score (30+/<30), sex (M/F), and age (65+/<65 years).[13] The cut point of 30 for the PDI was based on previous studies of similar populations and was selected to ensure that each group was balanced in terms of disability levels.[11,14] The age cut point was based on our expected recruitment pool, which we expected to be primarily elderly.

Interventions

Both groups' clinicians were experienced, licensed doctors of chiropractic. Three clinicians provided care to the BT group. The primary clinician was the originator of the technique, had 40 years experience as a chiropractor and more than 30 years with BT; he provided most of the BT care. The other 2 BT clinicians had 20 and 10 years of experience with BT, and provided care when the primary clinician was not available. One clinician with 18 years of experience in private practice and in a chiropractic college teaching clinic with DT provided care to the DT group.

At the time informed consent was administered, patients were asked if they had ever received chiropractic care and

were also shown photographs illustrating BT and DT. They were asked if they thought they had ever experienced each of those techniques.

Bioenergetic Synchronization Technique

Bioenergetic Synchronization Technique might be described as a mind-body approach rather than a manipulative technique. It includes light touch, verbal suggestions on positive thinking, group lectures on self-empowerment, lifestyle and nutrition, and provision of specific nutritional supplements. Two striking differences between the recommended delivery of BT and customary chiropractic practice are (1) use of several closely spaced intensive sessions rather than short multiple visits over a longer period and (2) interventions delivered in a group setting rather than a one-on-one doctor-patient visit. The technique has been described in greater detail elsewhere.[3]

Diversified Technique: Usual and Customary Chiropractic Care

The intervention in this group was designed to represent the customary procedures used by most chiropractors.[2] The primary procedure was spinal manipulation using DT; ancillary procedures permitted were soft tissue treatment, heat, ultrasound, and/or interferential current, as well as advice on exercise and/or nutrition. Areas of the spine manipulated and use of ancillary procedures were determined by this group's clinician's judgment on the basis of the physical examination and history, x-rays, and static and motion palpation.

Other Aspects of the Clinical Encounter

Other important nonspecific aspects of the clinical encounter were equalized, where possible, between groups, and were assessed in both groups. These included the following:

1. *Clinician expectation of improvement* was assessed with a form completed by primary clinicians after each patient's first treatment.
2. *Patient expectation of improvement* was assessed as described in the Additional Assessment Instruments section.
3. *Patient's previous experience with chiropractic.* Patients with chiropractic experience more than 1 month before visit 0 were eligible; the research assistant recorded information about their previous experiences.
4. *Rapport.* Patients in both groups interacted with all clinic personnel except for the treating chiropractors, who interacted only with their group's patients.
5. *Attention and time spent.* Because of the management schedule of BT, visit frequency and duration were not equivalent between groups. To aid in assessing its possible contribution, the research assistant recorded total time spent with all patients.
6. *Features of the office setting and environment.* These were equalized because of the use of a single site and assessed through the "Evaluation of Clinical Services" form described below.

Frequency and Duration of Treatment

The treatment period was 4 weeks. This period was determined by results of previous studies and consensus of the treating clinicians.[14] Visit frequency and duration were determined by the standard protocols for each technique and by the doctors' clinical assessment of each patient's needs. A nontreatment assessment visit was scheduled for patients in both groups 3 weeks after their last treatment.

Bio-Energetic Synchronization Technique was delivered as follows: 3 consecutive or closely spaced (all within a single week) days (1-2 hours for days 1 and 3, and 4-6 hours for day 2), with additional follow-up visits if needed over a 4-week period. Nutritional supplements were provided free of charge to patients if the clinician determined that they were indicated.

Diversified technique was delivered as follows: 8 to 12 visits for hands-on chiropractic care (10-15 minutes per treatment visit) over a 4-week period, with frequency and ancillary procedures (heat/cold, ultrasound, and interferential current) determined by the clinician.

Operational Definition of Compliance

For the BT group, patients were considered "compliant" if they completed 2 of the scheduled visits for the first treatment week and missed no more than 1 additional treatment visit. For DT, patients were considered "compliant" if they missed no more than 1 scheduled treatment visit in any given week, not to exceed 3 total missed treatment visits in the study.

Co-Interventions and Attrition

A research assistant interviewed patients at the exit visit concerning co-interventions. Procedures were used to minimize attrition, including reminder phone calls and assistance with transportation.

Data Collection: Assessment Methods and Instruments

Assessments were made to test the study hypothesis and to assess equivalence of groups. Where available, instruments with documented reliability, validity, and clinical responsiveness were used. Data were collected via

patient self-report, clinic staff interviews of patients, and observations made by clinic staff (such as records of time spent). For patients who were unable to read and write, clinic personnel read and explained the forms and recorded the patients' verbal responses.

Hypothesis Testing

The primary outcome was the change in the PDI from visit 1 (before any contact with the treating chiropractor) to the exit visit (3 weeks after the last treatment visit). From previous studies, a clinically significant difference in the PDI was estimated to be 6 points.[11,14] The PDI is a 7-item self-report instrument using a 10-point Likert scale per item (scores range from 0 to 70), developed in 1981 for chronic pain.[15] Its reliability and validity have been well documented, and it has been shown to have a significant correlation with direct measures of physical performance such as exercises stressing the low back in patients with chronic back pain.[15,16]

Additional Assessment Instruments

Along with patient demographics, health history, and health habits, several instruments were used to assess equivalence of groups, as presented below.

- *The Beck Depression Inventory (BDI).* The 13-item version, which has demonstrated adequate reliability and validity, is scored using an ordinal scale of 0 to 3. Scores of 0 to 4 indicate no or minimal depression; 5 to 7, mild depression; 8 to 15, moderate depression; and 16 or higher, severe depression.[17]
- *Patient expectation of improvement.* A 10-cm visual analog scale anchored by "very sure it will not work" and "very sure it will work" was completed at visit 0 before group assignment, visit 1 before treatment, and visit 1 immediately after treatment.[11]
- *Evaluation of clinic services.* A 7-item questionnaire adapted from one used in previous studies[11,18] included questions on clinic facilities, interpersonal aspects of the clinical encounter, satisfaction with outcomes of care, and a question generally rating the chiropractic care, adapted from a chiropractic patient satisfaction questionnaire.[19]

Data Collection: Schedule of Assessment Administration

All assessment forms were administered at the eligibility verification visit (visit 0) after informed consent, before treatment or contact with the clinician on visit 1, at the end of week 4 (before treatment or at a nontreatment visit), and 3 weeks from the last treatment visit (exit visit), at which time no treatment was scheduled. Assessments were administered at both visits 0 and 1 because of the lapse of time between them.

Blinding

Patients were told that they would be randomly assigned to 1 of 2 different schedules and approaches to chiropractic care. Because of the considerable difference in these 2 approaches, especially in regard to scheduling, the nontreating clinic personnel could not be blinded to patients' group assignment. However, the principal investigator and biostatistical consultant were blinded to patients' treatment group assignment throughout the data analysis.

Sample Size and Statistical Analysis

The sample size calculation was based on an estimate of the variability of the PDI from previous studies (SD, 10.8).[11,18] A sample size of 104 was calculated to have 80% power to detect the minimal clinically important difference of 6 points between groups. Based on previous studies,[11,18] 6% attrition was estimated, resulting in the total sample size estimate of 110 (55 patients per treatment group).

The hypothesis was tested with a 2-tailed t test for independent samples of the mean between-group difference between PDI scores at visit 1 and the exit visit. An intention-to-treat analysis was used in which all patients who completed the PDI at visit 1 and the exit visit were included in the analysis whether or not they were compliant with their group's treatment protocol.

Descriptive statistics were compiled on patient characteristics at baseline for each treatment group to assess comparability of groups, using a 2-tailed χ^2 test for categorical variables and independent-sample t test for continuous variables.

Results

Recruitment and Enrollment

Patients were recruited from March to June 2005. As shown in Fig 1, approximately the same number of potential patients was recruited from former studies and screenings as from new recruitment efforts at senior centers and health fairs (90 and 98, respectively). Nearly half of these (46%) were subsequently eligible and interested in enrolling in the study.

Because of transportation and scheduling difficulties, 11 patients (5 in the BT group and 6 in the DT group) who were unable to schedule separately from their spouse, relative, or friend were assigned to the group to which that person had been randomly assigned. Thus, 11 (12%) patients of the total 91 were not randomly assigned.

Because of scheduling complexities, patients were randomly assigned to groups at the eligibility visit, visit 0, although the study did not begin until visit 1. The interval between visits 0 and 1 averaged 11 days for BT and 9 days for DT. Of the 91 eligible patients, 46 were assigned to the BT group and 45 to the DT group. Ten eligible patients chose not to enroll in the study so did not continue to visit 1

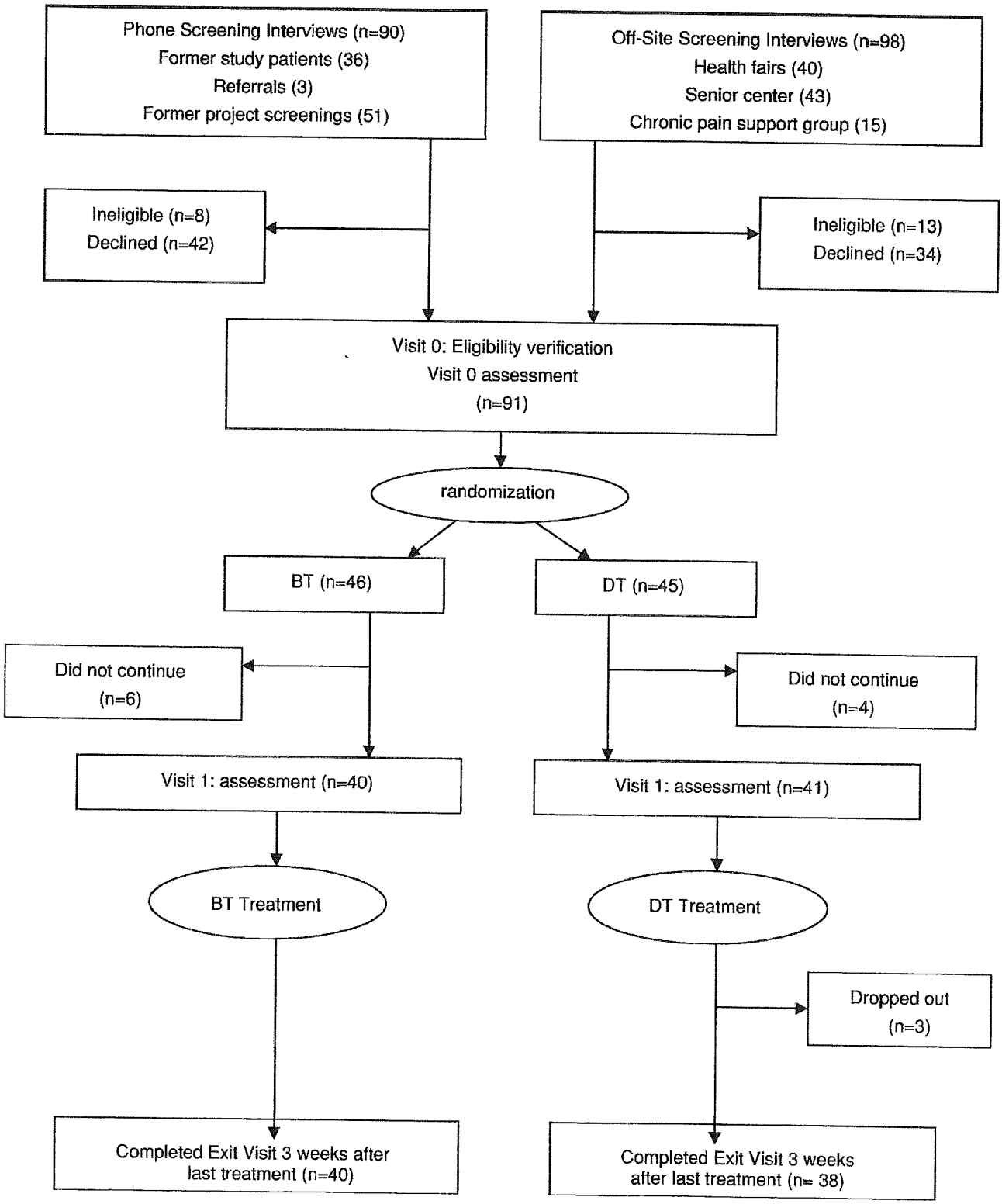

Fig 1. *Study flow chart.*

Table 1. *Comparison of baseline characteristics of patients who dropped out before treatment vs patients who began treatment*

	Eligible; did not enroll (n = 10)	Eligible; enrolled (n = 81)	Total (n = 91)
Female	90	74	76
Age, y—median (range)	48 (27-77)	66 (19-85)	65 (19-85)
Race/ethnicity*			
Asian	10	0	1
Black/African American	20	30	29
Hispanic	10	14	13
Mixed race	10	3	3
White	50	54	54
Any previous chiropractic experience	60	54	55
Ever received BT	10	21	20
Ever received diversified	20	43	40
Preference for any chiropractic technique	10	11	11
PDI scores in points—median (range)	25.5 (0-57)	23.0 (0-25)	23.0 (0-57)
BDI scores in points[a]—median (range)	5.5 (0-25)	4.0 (0-26)	4.0 (0-26)

All numbers are proportions unless otherwise specified. Differences among categories for each item did not approach statistical significance unless so noted. There were no significant differences between enrolled/not enrolled patients for education, employment, or marital status.

[a] Beck Depression Inventory scores of 0 to 4 indicate no or minimal depression; 5 to 7, mild depression.

* $P = .04$ (Pearson χ^2 test).

Table 2. *Patient demographics and report of previous chiropractic experience by treatment group assignment*

	BT group (n = 40)	DT group (n = 41)	Total (n = 81)
Sex			
Female (%)	78	71	74
Male	20	29	24
Age (y)	64 (mean)	58 (mean)	61 (mean)
	68 (median)	63 (median)	66 (median)
	23-85	19-83	19-85
	(range)	(range)	(range)
Race/ethnicity			
Black/African American	28	32	30
Hispanic	23	5	14
Mixed race	3	2	3
White	48	61	54
Education (highest level)			
No high school diploma	26	12	19
High school diploma only	16	20	18
Some college	34	32	33
College degree	8	20	11
Postgraduate degree	16	17	17
Previous chiropractic experience			
Ever received chiropractic care	55	54	54
Ever received BT	26	17	21
Ever received DT	41	44	43

All numbers are proportions unless otherwise specified. Totals may not equal 100% due to rounding. Neither parametric nor nonparametric tests for differences among categories for each item were statistically significant unless so noted.

(6 in BT; 4 in DT) (Fig 1). As shown in Table 1, there were no significant differences, between those who continued to enrollment and those who did not, in demographics except for race and no significant differences in previous chiropractic experience or baseline outcome measure scores. A total of 81 patients were enrolled in the study.

Attrition

Three patients (4%) dropped out after visit 1 (0 in the BT and 3 in the DT group). Their visit 0 and visit 1 PDI scores were, respectively, 8 and 11, 22 and 28, 0 and 0. The patients with higher PDI scores dropped out because of unwillingness to make multiple visits; the patient with 0 PDI scores could not be contacted. A total of 78 patients (40 in BT and 38 in DT) completed all intake and exit assessments.

Compliance

Compliance with treatment visit frequency. Of the 40 BT patients, 5 were noncompliant, although all received some treatment and completed all assessments. One completed her exit visit assessments by mail. Reasons for noncompliance were marital problems (2), transportation difficulties (2), and did not wish to receive further treatment (1 patient who completed 2 treatment visits only). Of the 38 patients who completed treatment in DT, 3 were noncompliant; their reasons were gall bladder surgery (1), have moved (1), or they felt better (1).

Compliance with nonuse of co-interventions. One patient (DT) reported chiropractic care elsewhere in the nontreatment interval before the exit visit, for a recent work injury. His PDI scores at the 4 assessments were 36, 36, 38, and 38. Two patients (BT) reported having received a massage in the nontreatment interval. Their PDI scores were 23, 11, 10, 7 and 6, 26, 1, 0.

Adverse Events

No adverse events (defined as any symptom that arose within 24 hours of the treatment session and lasted over 24 hours after its onset) were reported in either group.

Table 3. *Patients' report of baseline symptoms, reported medication use, and expectations of treatment, by treatment group assignment (n = 81)*

	BT Group (n = 40)	DT Group (n = 41)	Total (n = 81)
Chief location of chronic pain			
Back	43	51	47
Neck	18	22	20
Nonspinal joints	40	26	33
Time in years since first onset			
Mean/median	11.3/9.5	10.2/5.0	10.8/6.0
Range	4 mo–48 y	3 mo–50 y	3 mo–50 y
PDI (mean/median)	24.2/22	24.0/23.0	24.2/23.0
BDI (mean/median)[a]	5.7/3.5	4.9/5.0	5.3/4.0
Expectation of improvement[b]			
Visit 0	7.6	7.6	7.6
Visit 1, before treatment (n = 81)	7.5	7.4	7.4
Visit 1, after treatment (n = 81)	7.9	8.2	8.1

All numbers are proportions unless otherwise specified. Totals may not equal 100% due to rounding. Statistical tests for differences among categories for each item did not approach statistical significance unless so noted.

[a] Beck Depression Inventory scores of 0 to 4 indicate no or minimal depression; 5 to 7, mild depression.

[b] Higher scores indicate higher expectation of the treatment working.

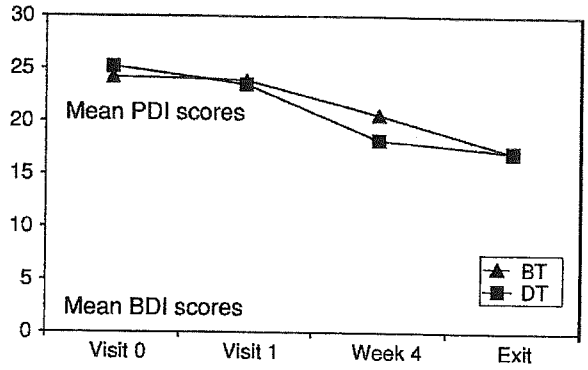

Fig 2. *Mean PDI scores over time, by group.*

Table 4. *Mean changes in PDI scores from visit 1 to exit visit, by group*

	BT group (n = 40)	DT group (n = 38)	Mean between-group difference (95% confidence interval)
Change in PDI score	6.9	6.4	0.6 (−4.7 to 5.8)

Patient Baseline Characteristics

Table 2 summarizes the 81 patients' characteristics at baseline, by group. The typical study patient was an elderly female (median, 66 years). Slightly over half were white, 30% African American, and 14% Hispanic. There were no statistically significant between-groups differences in racial/ethnic distribution. Overall, 24% of patients were unemployed. Although between-group differences in employment did not reach statistical significance, there were more retirees in the BT group and more full-time workers in the DT group. Over half of patients in both groups had received chiropractic care at some time in the past, with 21% reporting (based on the photos shown to them) they had received BT and 43% DT. The only statistically significant difference noted in baseline characteristics was patients' reported preference for a particular type of chiropractic adjustments: 21% of BT and 2% of DT said they had a preference, with the remainder in both groups reporting no preference.

In both groups, most patients reported chronic pain in multiple areas of their body, with back pain being their primary complaint (Table 3). There were no significant between-groups differences in patients' baseline symptoms, reported medication use, or expectations of improvement. Patients in both groups had uniformly high expectations for treatment outcomes, which were observed to increase slightly after their first treatment visit, somewhat but not significantly more in DT.

Delivery of Interventions

For the DT group, patients who completed the study had an average of 8 treatment visits of 10 minutes' duration each, for a total of 1.3 hours total contact time with the treating doctor. All patients received DT manipulation at each visit. Only 1 patient received any physical modalities; he received ultrasound on 1 visit and interferential current on 3 visits (in addition to manipulation).

For the BT group, patients who completed the study attended group sessions as follows: day 1, 2 hours; day 2, 5 hours; day 3, 2 hours; 1 follow-up visit 1 week later, 2 hours; and 1 visit 4 weeks after visit 1, 2 hours. This was a total of 13 hours spent in group sessions with the treating doctor; no individual sessions occurred.

Clinician expectations for patients' improvement differed significantly ($P = .00$). The BT primary clinician expected all patients to improve completely and have other effects in addition to chronic pain reduction. The DT clinician expected 27% of his patients to improve a little, 68% a lot, 5% completely, and expected 15% to have other effects in addition to chronic pain reduction.

Outcomes

Pain Disability Index and Beck Depression Inventory. The PDI mean scores for each group at the 4 assessment visits are shown in Fig 2. There was almost no change in the PDI in the nontreatment interval between visit 0 and visit 1. Comparing

Table 5. *Patients' evaluation of clinical services, by group (n = 78)*

	BT group (n = 40)	DT group (n = 38)	Total (n = 78)
Convenience of location (%)	48	47	47
Technical skills/competence			
Clinic staff	58	66	62
Treating doctor	48	61	54
Attention to what you had to say			
Clinic staff	65	61	63
Treating doctor	58	62	60
Time spent with			
Clinic staff	60	58	59
Treating doctor	48	58	53
Helpfulness of instruction/education you received			
Clinic staff	55	42	49
Treating doctor	48	50	49
Outcomes of care (how much you were helped)			
Excellent	28	16	22
Very good	30	58	44
Good	23	21	22
Fair	15	5	10
Poor	5	0	3
Rating of care you received (0 = worst chiropractic care; 10 is best chiropractic care)			
9-10	48	61	54
7-8	25	29	27
5-6	15	11	13
3-4	5	0	3
0-2	8	0	4

All numbers are proportion of patients responding "excellent" unless otherwise specified. Statistical tests for differences among categories for each item did not approach statistical significance unless so noted.

patients whose baseline PDI scores improved 6 points or less to those whose scores improved more than 6 points, baseline PDI scores were almost identical (24.5 vs 24.9). Diversified technique patient scores dropped by more than those of BT patients at the end-of-treatment visit, but by the third week of the nontreatment follow-up period, scores for both groups were similar. The BDI scores showed a tendency to decrease over the 4 assessments as well.

There was no statistically or clinically significant between-group difference in the mean change in PDI scores from visit 1 to the exit visit 3 weeks after the conclusion of treatment (Table 4). The proportion of patients in each group whose PDI scores improved 6 points or more from visit 0 to exit did not differ significantly (48% in BT and 55% in DT; $P = .49$). There were 10 patients in each group whose PDI score improvement was in the 75th percentile (an improvement of 13 points or greater).

Evaluation of clinical services. As shown in Table 5, patients in both groups rated the interpersonal aspects of their clinical experience highly; there were no significant between-group differences, although 48% of the DT group (compared with 61% of the BT group) rated their chiropractic care 9 to 10. However, both groups rated their outcomes of care lower than the interpersonal aspects of their experience. Although the between-groups difference in outcomes did not appear to be significant, 20% of the BT group and 5% of the DT group rated the outcomes of their care "fair" or "poor," and 28% of the BT group and 16% of the DT group rated their outcomes as excellent.

Discussion

Before interpreting the findings of this study, it is necessary to consider its limitations. First, we were not able to recruit the sample size of 104, the necessary number estimated to avoid a type II error. It is possible that with a larger sample size, greater improvement in one treatment group might have been apparent. Second, 12% of patients were not randomly allocated to treatment group because of transportation problems, which introduces a selection bias. This limitation is mitigated by the similarity of the 2 groups at baseline; their demographics and assessment scores were quite similar. Third, outcomes were only assessed after a 3-week nontreatment interval, so no conclusions can be made about longer-term results. Fourth, having the clinic staff read and explain forms to patients with low literacy might have introduced an unknown level of response bias.

Fifth, although our recruitment strategy was extraordinarily efficient and cost-effective, relying primarily on personal contact, it is possible that this may have resulted in patients who were favorably disposed toward the study, regardless of group assignment. The fact that 55% of patients had experienced chiropractic in the past is a related issue. However, it should be noted that there did not appear to be a difference between groups in terms of previous experience with our clinic or chiropractic in general. Sixth, it is possible that the clinicians were not representative of their respective approaches to care. The BT primary clinician was not only the originator of the technique, but also had more than 30 years' experience in providing it. Furthermore, in general use, BT may not be routinely administered according to the schedule used in this study (intensive group settings). The DT clinician, although highly experienced with 18 years of practice, still had much less experience than the BT primary clinician. He also used fewer ancillary procedures than is common in general chiropractic practice and so the results may not be generalizable.[2] Finally, and probably the most important, the differences between the 2 groups in terms of biomechanics, time spent, and treatment schedule posed a challenge to the design of a RCT, which usually assumes that a single factor varies between groups. In this RCT, we took the pragmatic approach that the "single" factor was an entire treatment gestalt, or package. Thus, we cannot draw any conclusions about the many factors present in both treatment packages that might have contributed to patients' improvement. We also cannot draw conclusions about the possible impact of factors (such as time spent) that differed between packages.

Because patients in both groups demonstrated similar improvement scores on the PDI, the study's null hypothesis was not rejected. It is possible that aspects of the clinical encounter common to both interventions contributed to patients' improvements. Patients' high rating of their clinical experience would suggest that this should be a consideration. It is interesting to note that although the clinicians' expectations of improvement differed dramatically by group, the differences in patients' expectations, outcomes, and satisfaction did not.

Our chiropractic patient population was unusual.[20] It had greater racial/ethnic diversity; it was skewed toward older patients; and it had a higher proportion of patients with low levels of education. Thus, one must be cautious in generalizing these results.

Conclusion

This study introduces questions about the possible contribution of factors other than biomechanical force to the observed beneficial effects of chiropractic care. More in-depth studies, perhaps incorporating sociological and psychological perspectives, are warranted to explore the nuances of the therapeutic encounter in chiropractic and other complementary and alternative therapies in which physical touch and specific belief systems may play a role.

Practical Applications

- Two disparate approaches to nonpharmacologic treatment of patients with chronic pain both produced clinically meaningful and statistically significant improvements in the PDI in this patient sample.
- Multiple factors may contribute to treatment effects in therapeutic encounters.

Acknowledgment

The authors acknowledge Maria Dominguez for her efforts in assisting with this study and Claudia Der-Martirosian, PhD, for her expertise with the statistical analysis. The authors thank the doctors who provided care for the patients in the study: Milton T. Morter, Jr, DC; Jack Crawford, DC; Thomas Redenbaugh, DC; and Walter Parish, DC. We thank Celia Maguire, DC, and John Norfleet for facilitating interns' involvement in patient interviews, physical examinations, and x-rays. This project was supported by in-kind contributions (personnel and facilities) from Parker College of Chiropractic and partially funded by a grant from Morter Health Systems. The funding organizations had no influence upon the study design; data collection or analysis; interpretation of the results; writing of the manuscript; or to the decision to submit the manuscript for publication. The principal author was an employee of Parker Research Institute during the design phase of the project and served as an independent consultant unaffiliated with Parker Research Institute during the data analysis and manuscript preparation. Milton T. Morter, Jr, DC, his position at Morter Health Systems, served as one of the primary treating clinicians for this study, but was not involved in the study design, data collection, interpretation of results, or manuscript preparation.

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