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A Prospective Randomized Three-Week Trial of Spinal Manipulation, Transcutaneous Muscle Stimulation, Massage and Corset in the Treatment of Subacute Low Back Pain

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Study Design. A randomized prospective trial of manipulation, massage, corset and transcutaneous muscle stimulation (TMS) was conducted in patients with subacute low back pain.

Objectives. The authors determined the relative efficacy of chiropractic treatment to massage, corset, and TMS.

Summary of Background Data. Although all of these treatments are used for subacute low back pain treatment, there have been few comparative trials using objective outcome criteria. Patients were enrolled for a period of 3 weeks. They were evaluated once a week by questionnaires, visual analog scale, range of motion, maximum voluntary extension effort, straight leg raising and Biering-Sorensen fatigue test. The dropout rate was highest in the muscle stimulation and corset groups and lowest in the manipulation group. Rates of full compliance did not differ significantly across treatments. A measure of patient confidence was greatest in the manipulation group.

Results. After 3 weeks, the manipulation group scored the greatest improvements in flexion and pain while the massage group had the best extension effort and fatigue time, and the muscle stimulation group the best extension.

Conclusion. None of the changes in physical outcome measures (range of motion, fatigue, strength or pain) were significantly different between any of the groups. [Key words: manipulation, low back pain, massage, corset, transcutaneous muscle stimulation] **Spine 1994;19:2571–2577**

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Low back pain (LBP) remains a problem at epidemic proportion and, despite the multiplicity of treatments available for low back pain, a clear choice of treatment has not emerged.[7] Spinal manipulation has been the subject of extensive reviews,[3,7] with varying conclusions regarding its efficacy. Nevertheless, there is now relative agreement that manipulation has a role in the treatment of LBP. Manipulation provided more immediate relief and more rapid return to pre-episode status than other forms of care.[1,3,11,15] Other studies have demonstrated that manipulation is as effective as other forms of conservative therapy.[5,13,16,25] Most reviewers agree that any long-term benefits of manipulation have yet to be conclusively demonstrated.

In the past few years, various controlled studies of manipulation have been conducted.[12,17,22,24] Waagen et al[24] reported, unfortunately in a small sample size, that patients who received manipulations experienced a greater relief from LBP than those who received a sham manual treatment. Recently, in chronic LBP patients, Meade et al[19] compared chiropractic manipulation with hospital treatment (largely Maitland mobilization or exercise) in chronic LBP patients in a multicentered trial in the UK. Both groups improved but the chiropractic group showed 7% more improvement in the Oswestry score as compared with the hospital treatment group.

There are problems in some of the previous studies.[7] These include the following limitations:

1. Inclusion-exclusion criteria are either too broadly or narrowly defined.
2. The outcome measures have poor or unmeasured reliability and/or validity.
3. Controls do not account for the hands-on (possible placebo) effect of manipulation.
4. The manipulation is poorly described and not carried out by a practitioner of the art.

5. Many trials have poor design and potential Type II errors, in both data acquisition and analysis.
6. Manipulation is often mixed with other treatments.
7. Poor or inadequate randomization procedures are present.
8. Poor patient compliance or attrition rate existed.
9. Nonblinded assessment was used.

Of common treatment methods, Perry,[21] in 1970, found that 99% of orthopedic surgeons had prescribed an orthosis at some time for their LBP patients. It is, however, not known whether these patterns still exist. Ahlgren and Hansen[1] conducted a survey of randomly selected patients for whom a corset had been prescribed 4 years previously and found that 50% were still using their corset. Nachemson et al[20] found that corsets have an unpredictable effect on lumbar motion. It is uncertain whether orthoses have other beneficial effects such as increased warmth, or that they simply make the patient more aware of potentially harmful spinal movements. Larsson et al[18] showed that "auto-traction" is superior to either corset or sham treatment in LBP and sciatica, but that the effect is short-lived.

Transcutaneous muscle stimulation (TMS) has been widely used as a means of preventing disuse atrophy.[9] TMS of the extremities significantly improves muscle function[8] and muscle working capacity.[2] However, TMS has yet to be tested in a well-designed, randomized, prospective trial.

Massage, although not widely employed as a treatment, has been used in other controlled studies as[10] a "hands on" placebo.

In this study we randomly assigned patients into one of the four treatment groups: manipulation, soft tissue massage, transcutaneous muscle stimulation, or corset.

■ Hypotheses

This study attempted to determine the relative efficacy of chiropractic manipulation in the treatment of low back pain, as compared with soft tissue massage, transcutaneous muscle stimulation (TMS), or use of a lumbosacral corset. Hypotheses to be tested include the following:

1. There is no difference in patient-reported pain relief or other physical outcome measures, after a three-week intervention, between patients treated with spinal manipulation and those treated with one of three other methods (soft tissue massage, transcutaneous muscle stimulation and use of a lumbosacral corset.
2. There will be less fatigue and greater isometric strength of the erector spinae muscles in patients with TMS compared with the other treatments after three weeks of intervention.
3. Range of motion will increase with manipulation, decrease with corsets, and remain unchanged with the other treatments after a 3-week intervention.

■ Materials and Methods

Subjects. All patients signed a consent form and had all procedures explained by a video tape. Using a power analysis to detect particular outcome differences with a significance level of 5% and using preliminary data to assess natural outcome variation, it was decided to target for a primary (manipulation) group of 60 with comparison groups of 30 subjects each.

The experimental subjects were chosen from those attending the Whittier Health Center at the Los Angeles College of Chiropractic. The numbers recruited were supplemented by additional advertising. The inclusion/exclusion criteria were as follows:

1. Ages 18 to 55, inclusive.
2. General health good (self-report).
3. Not known to be pregnant.
4. LBP between 3 weeks and 6 months duration (this episode). Must have been free of LBP a minimum of 3 weeks before this episode.
5. No sciatica. We define sciatica as pain radiating below the knee, a positive straight leg raising test and neurologic deficit (numbness, weakness, or reflex change) including patients with buttock and upper thigh pain.
6. No neurologic deficits such as loss of sensation, strength and reflex.
7. No previous vertebral fracture, tumor, infection or spondyloarthropathy.
8. No previous back surgery.
9. Davenport weight index (wt/ht^2, units kg and m) not greater than 33.
10. No previous manipulation therapy (this episode).
11. No conditions potentially aggravated by electrical devices, i.e., heart pacemaker.
12. No workmen's compensation or disability insurance issues.
13. Willing to travel to the facility for treatments and to be randomized.

Once the consent form was signed, the patient was screened by a standard physical examination and two-view radiographs (anterior-posterior and lateral). The patient who met the inclusion/exclusion criteria was then assigned a number according to a block-style randomization scheme. Because twice as many patients would be randomized to the spinal manipulation condition as to the other three treatments, blocks of 10 patients were used. The blocking guarantees that the desired balance among treatments will be achieved after every 10 patients enter the trial so that temporal shifts in the patient pool will have minimal effects on treatment comparisons. Separate such randomizations were conducted for episode length groups (3 weeks to 3 months/3 months to 12 months) and work status groups (employed or student/unemployed) to ensure treatment balance for these three covariates. The treatment was assigned by providing the subject's age, sex, and length of episode information to an administrative assistant, who would then refer to the appropriate randomization chart. These charts were not available to the clinicians providing

Table 1.

Visit Group	Manipulation	Massage	TMS	Corset	Totals
1, 2, 3, 4	53 (76%)	27 (73%)	18 (64%)	23 (79%)	121
1, 4 at least	13	4	4	2	23
1, 2, 3 only	1	2	2	0	5
1, 3 only	0	0	0	0	0
1, 2 only	2	1	1	1	5
1 only	1 (1%)	3 (8%)	3 (11%)	3 (10%)	10
Totals	70	37	28	29	164

treatment. Once assigned to a treatment, the standard physical examination was conducted.

Of the 164 subjects in this study, 62% were male and 65% had attended college or a professional school after high school. The median age was 32, with 72% under 40, and 8% in their fifties. The preponderance (81%) had a job or were self-employed, and 82% were nonsmokers. For about one quarter (28%) of the subjects, this was the first time they had experienced low back pain. Back pain first became a problem for 29% of the subjects within the 6 months before their clinic visit, for 35% it had first occurred between 6 months and 2 years previously, and for 36% it had first occurred more than 2 years ago.

Assessment Procedures. Two research clinicians, trained in the standardized testing protocol and blinded with respect to the treatment group, administered: (1) a visual analog scale to assess recent pain and a visual analog scale to assess patient confidence; (2) a modified Schober test and a straight leg raising test; (3) time recorded during a Sorensen fatigue test; 4) the median center frequency shift of the muscle activity recorded during the Sorensen test; and (5) a Maximum Voluntary Extension Effort in the standing position. These measures were repeated during each week of the study. These two clinicians were not involved with treatment at all.

Visual Analog Scales. The visual pain analog scale was a 10-cm line with anchor words "no pain" at one end and "worst pain" at the other. The subject was asked to rate intensity of pain over the past week. Values are reported on a 0–100 (Table 3) numerical scale. The confidence visual analog scale was such that a 10-cm line was used to rate their confidence in the care they were receiving. The anchor words were "very sure it will *not* work" and "very sure it *will* work." Values are reported on a 0–100 scale.

Table 2.

Mean Confidence that Treatment Will Work (0–10 scale) and Follow-up Rating of Effectiveness

Treatment	Statistics	Visit 1	Visit 2	Visit 3	Visit 4
Manipulation	Mean	7.70	7.97	8.38	8.61
	n	69	62	58	66
	sd	1.68	1.85	1.40	1.63
Massage	Mean	6.92	7.19	7.35	7.23
	n	36	32	31	31
	sd	2.03	2.25	2.47	3.01
TMS	Mean	6.41	6.33	6.38	6.86
	n	27	21	21	21
	sd	1.39	2.54	2.69	2.43
Corset	Mean	5.97	5.52	5.17	5.28
	n	29	25	24	25
	sd	2.54	2.71	2.87	3.35

Table 3.

Differenced Outcome	Statistics	Manipulation	Massage	TMS	Corset
Flexion	Mean Diff	**B**.38*	−.08	−.02	.33
(cm)	n	66	34	23	25
	SD Diff	1.25	1.20	.82	.93
Extension	Mean Diff	−.29*	−.32*	**B**.63*	−.27
(cm)	n	66	34	23	25
	SD Diff	.59	.63	.89	.72
MVEE	Mean Diff	23.1*	**B**23.7*	20.6*	11.6*
(% chg)	n	65	34	23	25
	SD Diff	38.3	25.0	33.2	22.4
Pain VAS	Mean Diff	**B**−24.1*	−17.2*	−9.6	−15.9*
(0–100)	n	65	32	22	25
	SD Diff	27.0	25.1	30.0	27.0
Sorensen	Mean Diff	19.5*	**B**19.9*	6.3	−1.5
Time	n	66	29	22	24
(sec)	SD Diff	53.5	34.8	27.2	45.4
Sorensen	Mean Diff	−.01	.10	.02	B−.19
Slope	n	59	26	20	24
(MF sec)	SD Diff	.26	.68	.16	.96

* Indicates that the average change was significantgly differentg from 0 using a paired t test ($P < .05$) separately for each treatment.
"**B**" Indicates the most effective treatment among the four, although no differences among treatments are statistically significant.

Range of Motion. Range of motion was assessed by the modified Schober examination. For the Schober method, while the patient stood, ink skin marks were made at the midline at the level of the posterior superior iliac spine (PSIS), the second 5 cm below the first, and the third 10 cm above the first. The patient was asked to stand with knees locked and to bend forward as far as possible while the pelvis was stabilized. Once full flexion was achieved, the distance between the upper and lower skin markers was measured. The patient was then asked to bend backward as far as possible, again restraining the pelvis to vertical, and the distance between the marks was measured again.

Maximum Voluntary Extension Effort (MVEE). The level of the MVEE was recorded in the standing position with the pelvis stabilized in a specially designed frame.[10] A shoulder harness was worn with the point of attachment at the midsternum. A load cell was connected to the harness by means of a rope, while the patient was standing erect. The subject was asked to pull against the rope as hard as possible and to hold the pull for one to two seconds so that an accurate reading from the load cell could be obtained (Figure 1). The second of two trials results were utilized. The percentage change in the MVEE at different visits was used for comparisons.

Sorensen Fatigue Test.[4] The patient had a pair of EMG-monitoring electrodes placed on the back at the level of L3–L4 3 cm from the midline on the right side, directly over the erector spinae muscle. A ground electrode was placed over the right iliac crest. The subject was instructed to lie prone on a specially designed exam table. Three restraining straps were placed across the buttocks, the mid thighs and the mid calves to prevent the patient from rocking forward. With arms flat

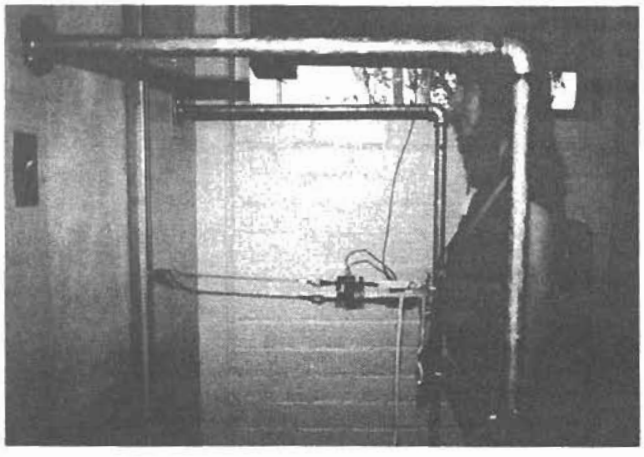

Figure 1. The standing subject was asked to pull against the rope as hard as possible and to hold the pull for one to two seconds so that an accurate reading from the load cell could be obtained.

against the body, the patient was asked to lift the upper body off the table and to hold it up horizontally for as long as possible. The muscle activity and the time to fatigue in seconds were recorded (Figure 2).

Median Frequency. The median frequency (MF) from the muscle activity of the Sorensen test was measured using a software-based waveform analyzer. The EMG signal was amplified, then filtered (anti-alias filtering with F = 200 Hz). This signal was then manipulated in digital form by a microcomputer which automatically sampled data through an analog to digital (A/D) converter at 512 Hz. Sampling time was 2 seconds, with 1,024 points taken for the fast Fourier transform (FFT). The median frequency (MF) was calculated every six seconds and the rate of shift calculated as an index of fatigue by linear regression. An increase in the slope of the MF indicated that the patient had improved endurance.[6]

Interventions. Those people involved in the treatment of the study sample were essentially masked as to the results of evaluations since the amount of interaction allowed with each patient during treatment sessions was strictly limited to treatment.

Five licensed chiropractors delivered the manipulations to the patients. Two licensed massage therapists, serving as chiropractic interns, delivered all soft tissue massage treatments. Another trained chiropractor instructed and monitored the use of corset and TMS units for the patients. A brief explanation of each treatment protocol follows.

Spinal Manipulation. The patient was placed in a comfortable side-lying position with the side of the manipulable lesion most superior from the table surface. The physician performing the manipulative procedure stabilized the patient in the side-lying position by placing their noncontact hand on the patient's shoulder that was not in contact with the table. The patient's leg that was not in contact with the table was in a flexed position (hip and knee flexed). A thigh-to-thigh contact was made between the patient and the physician and a downward pressure was exerted by the physician to move the joint through its physiologic range of motion. Once the end of physiologic range of motion was achieved, a dynamic short lever, high velocity, and low amplitude thrust was applied exerting a force on the lumbar spine and/or the sacroiliac joint. The detection of movement by the physician administering the therapy served as evidence of a satisfactory maneuver. This maneuver was performed unilaterally or bilaterally at each treatment session as determined by the treating physician. The frequency of treatment sessions was nominally three times per week for three weeks. Full compliance was defined as receiving three or more sessions per week, with partial compliance defined as one or two sessions per week and no compliance recorded if there were no sessions.

Soft Tissue Massage. Soft tissue massage of the effleurage variety was conducted with the patient in the prone position on a standard chiropractic treatment table. The treating massage therapist stood to the side and with a smooth nonforceful motion, rubbed the skin of the back from the buttocks to the shoulders in a rhythmic fashion. The time for this treatment did not exceed 15 minutes and the number of treatment sessions for the 3-week trial period was nominally the same as that of the chiropractic manipulation, i.e., three times per week for 3 weeks. Compliance was recorded as above.

Transcutaneous Muscle Stimulation (TMS). Patients were fitted with a Myocare PLUS (3M, Minneapolis, MN) muscle stimulating unit that was programmed for continuous use. The wave form was biphasic pulse rate was 37 pps with a duration of 225 OS. The amplitude was set at a maximum of 91 mA, but the patient was able to adjust this from 0 to 100 percent. The pulse ramped up in 2 seconds, then held for six seconds before it ramped off in 2 seconds. There was a pause of 6 seconds before the next cycle.

Four TMS electrodes were placed on the back in the area around the pain. Placement of the electrodes was linear, one pair on either side of the spine. The amplitude was adjusted by the patient to a level that maintained the sensation as high as possible, while at the same time maintaining comfort. The

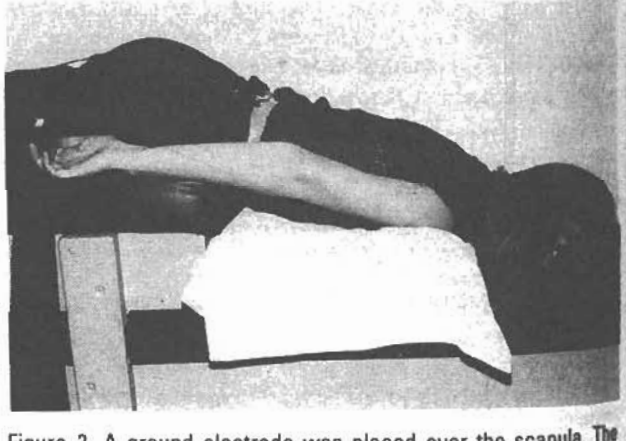

Figure 2. A ground electrode was placed over the scapula. The subject was instructed to lie prone on a specially designed exam table. Three restraining straps were placed across the lower extremities to prevent the patient from rocking forward. With arms flat against the body, the patient was asked to lift the upper body off the table and to hold it up horizontally for as long as possible. The muscle activity and the time to fatigue in seconds were recorded.

patient was requested to wear the TMS unit for a cumulative total of at least 8 hours per day. The unit should be turned on for a minimum of 1 hour at a time. The number and length of rest periods is unconstrained, as is the total number of hours the unit is worn per 24-hour period. Treatment compliance was measured by an internal compliance meter. The patient was told to discontinue use if they experienced extreme discomfort. Each patient was scheduled to return once a week for 3 weeks. The clinician checked if the patient used the unit correctly and then printed out the compliance report from the meter on each follow-up visit. Full compliance was a minimum of 7 hours per day on average, partial compliance was a minimum of 4 up to 7 hours per day and no compliance was less than 4 hours per day.

Corset. Patients were measured and fitted for a Freeman Lumbosacral Corset by a trained clinician on the initial office visit. The Freeman Corset is a canvas corset with metal stays in the back. The patient was instructed to wear the corset during waking hours, except while bathing. The patient removed the corset for a maximum of 10 minutes at a time, up to three times per day. Each patient was scheduled to return once a week for 3 weeks. The clinician checked if the patient used the corset properly on each follow-up visit. Patient compliance was measured by a diary maintained by the subject with the same hourly usage figures defining compliance as for TMS.

Subjects. There were ultimately 70 patients randomized to the spinal manipulation group and an average of 31 patients assigned to each of the other three conditions, yielding a total of 164 patients. Eighty-eight percent of these completed both the baseline and third week evaluations.

Results

Compliance

Eighty-eight percent of the original patients completed at least the baseline (evaluation 1) and the third weekly visit (evaluation 4), enabling a computation of differences in response from baseline to the end of the three weeks of treatment. The dropout rate was highest in the Corset, TMS and Massage groups, and lowest in the Chiropractic group. Table 1 shows the pattern of dropouts and visit completion for the 164 patients included in the study.

The rates for completing all four visits are not significantly different (64% to 79% among the treatment groups), but are lowest in the TMS group. The dropout rates after first, second or third visits were not significantly different and were lowest in the manipulation group (6% versus 14%–21% for others). The chi-square tests performed here as well as the later statistical analyses were performed in SAS.[21]

Compliance in following each treatment's regimen was rated as "not complying," "partially complied," or "fully complied" at each of the return visits. There was not a statistically significant difference in compliance rates among the four treatments. At the fourth evaluation, the percentages fully complying were 38% for manipulation and 47% for massage, 50% for TMS, and 65% for corset. For the TMS, 27% of the 22 rated did not comply at all, and for manipulation, 21% did not comply, while for massage, 10% did not and for corset only 6% did not comply at all.

Baseline Comparability of Patients

Since patients were randomly assigned to their treatment groups, one would expect comparability between groups with regard to all the variables measured at baseline. Testing of the primary outcome factors at baseline, as well as certain other background factors (e.g., number of previous LBP incidents, length of current LBP episode, job status, pain level) indicate that there were no statistically significant differences among treatment groups, except in one case. The mean confidence (from 0 to 10) that their proposed care would work was significantly higher at the first visit in the manipulation group (7.7) than in the TMS (6.4) or corset (6.0) groups, based on Tukey's studentized range test for means ($P < .05$).

Differences at Later Visits

All the primary outcome variables, including compliance, were tested for statistically significant differences among treatment groups at each of visits two, three and four. The only response indicating differences is the question that asks them "How sure are you that the care you are receiving will reduce your low back pain?" As noted above, the mean confidence in their treatment working was significantly different for certain of the four treatments even at the first visit. Table 2 gives these means, the number of subjects responding (n) and the standard deviation (SD) at each of the four visits, calculated for all respondents available at each visit.

During the four evaluation visits, the treatments ranked in order of confidence as listed in the table. Manipulation received significantly higher confidence than the corset or TMS at all four visits (Studentized range test at each visit, $P < .05$).[23] Massage was also significantly higher than the corset at visits two through four. The mean confidence scores tended to increase from visits one to four, except in the case of the corset where they declined.

An additional comparative analysis was done based on the changes in confidence levels from visit 1 to visit 4, which allows control for the initially different confidence levels between individuals and treatment groups. A one-way analysis of variance of these change scores showed that there was an overall difference among the treatment groups ($P = .03$). Multiple pairwise comparisons among the groups showed that the corset group had significantly lower changes in confidence than either the manipulation group ($P = .004$) or the massage group ($P = .03$). We have analyzed the other primary outcome measures by subtracting the baseline value from the visit four value of each primary outcome (Table 3). Note that a significant mean increase in flexion only occurred for manipulation, although the statistical

power to detect a 10% change in flexion exceeded .995 for each of the treatments. Extension flexibility significantly improved in all treatments except the corset. Thus the third hypothesis, which partly stated that there would be significantly increased range of motion with manipulation, is supported. The corset did not cause decreased range of motion as conjectured. Most other treatments also increased ROM which was different than our hypothesis.[3] MVEE increased significantly in all four groups. Hypothesis 2, that TMS patients have greater strength than the other treatments, was not supported. There were significant drops in the VAS for pain for all treatments but TMS. The Sorensen time to fatigue significantly increased with manipulation or massage, but not with TMS or corsets, while no significant changes were seen with the Sorensen fatigue index (slope). Thus TMS patients did not fatigue less than other treatments (hypothesis 2).

Despite some significant changes occurring within separate treatment groups for the 3-week study, there were no significant differences established between treatments. Analysis of the differenced scores (Table 3) via a "one way analysis of variance" or Dunnett's Multiple Comparisons of the other treatments to manipulation, at the 5% significance level, revealed no significant contrasts among the four treatments. An alternative analysis of covariance for the visit 4 outcomes, with visit 1 results as the covariate, also revealed no significant differences between treatments.

In comparisons among treatments for the various outcomes we calculated the approximate statistical power available, using for illustration a two sample *t*-test contrasting the mean difference score for manipulation with the mean difference score for another treatment. This used the actual sample sizes available and an estimate of pooled standard deviation for the difference scores. The power available was less than 20% if the goal were to establish significance for a real contrast of 25% in another treatment difference effect compared to that seen in manipulation's mean difference. This low power is due to the relatively large natural patient variability in these outcomes.

■ Discussion

There are no significant differences between treatment methods in the objective scores of spinal function and pain score which we utilized, supporting the primary null hypothesis of this study. However, the present study found that a measure of patient confidence in their treatment was greatest in the manipulation group. The recent data on psychosocial factors in the genesis of low back pain would suggest that there are potential benefits in patient expectation and satisfaction in the outcome. It is also possible, but not proven, that the success of manipulation may lay in the "hands-on" approach. It is noteworthy that differences were found between all treatments using the Oswestry and Roland-Morris questionnaires.[14] Although we have attempted to obviate the objections to previous studies[7] we may have engendered a bias due to the study being conducted at a clinic attached to a chiropractic college and the means of patient recruitment. We acknowledge the potential bias and note that this study could now be conducted in an orthopedic setting where the patient expectations will differ; however, wherever the setting, the argument of patient bias may still arise.

In terms of future trial planning, it is worth noting that the statistical power was at least 80% in this size study for detecting 10% changes in mean response within treatments for the outcomes of flexion or extension. Larger changes (25%) were detectable (80% power) in VAS pain or MVEE. Sorensen time, and particularly the slope index, had the least relative power.

In terms of nine specific concerns raised by Deyo[7]:

1. We developed inclusion-exclusion criteria that are reasonably broad for studying subacute idiopathic low back pain.
2. We selected physical outcomes that have been studied elsewhere and found to be useful.
3. We included a massage treatment to serve as a possible placebo for the manipulation group.
4. We employed professional chiropractors to give treatments.
5. The randomized trial studied here avoided patient selection biases and was large enough to have adequate power in detecting important changes within methods. Substantially larger numbers of subjects would be required to find significant differences between the methods for the sizes of effects seen here for the manipulation treatment.
6. Chiropractic manipulation was not used as just one part of a multi-pronged treatment approach.
7. Patients were randomized to receive one of the four possible treatments.
8. Eighty-eight percent of the patients completed the full 3-week study.
9. Assessment outcomes were blinded and specifically selected to minimize measurement subjectivity by the assessors.

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