



The Effectiveness of Chiropractic Management of Fibromyalgia Patients: A Pilot Study

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ABSTRACT

Objective: To demonstrate the effectiveness of chiropractic management for fibromyalgia patients using reported pain levels, cervical and lumbar ranges of motion, strength, flexibility, tender points, myalgic score and perceived functional ability as outcome measures.

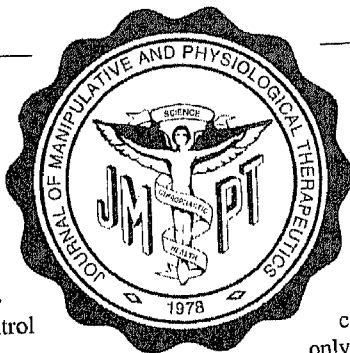
Design: A. Preliminary randomized control crossover trial. B. Before and after design.

Patients: Twenty-one rheumatology patients (25–70 yr).

Chiropractic Interventions: Treatment consisted of 4 wk of spinal manipulation, soft tissue therapy and passive stretching at the chiropractors' discretion.

Control Intervention: Chiropractic management withheld for 4 wk with continuation of prescribed medication.

Main Outcome Measures: Changes in scores on the Oswestry



Pain Disability Index, Neck Disability Index, Visual Analogue Scale, straight leg raise and lumbar and cervical ranges of motion were observed.

Results: Chiropractic management improved patients' cervical and lumbar ranges of motion, straight leg raise and reported pain levels. These changes were judged to be clinically important within the confines of our sample only.

Conclusions: Further study with a sample size of 81 (for 80% power at $\alpha \leq .05$) is recommended to determine if these findings are generalizable to the target population of fibromyalgia sufferers. (*J Manipulative Physiol Ther* 1997; 20:389–99).

Key Indexing Terms: Chiropractic; Fibromyalgia; Fibrositis; Physical Therapy; Randomized Controlled Trial

INTRODUCTION

Fibromyalgia syndrome is characterized by chronic diffuse musculoskeletal aching for greater than 3 months accompanied by multiple soft-tissue tender points in the absence of an underlying organic pathology or significant concomitant neuromusculoskeletal disease. Pain is considered widespread when all of the following are present: pain on the left side of the body, pain on the right side of the body, pain above the waist and pain below the waist. In addition, axial skeletal pain (cervical spine, anterior chest, thoracic spine or low back) must be present (1). The condition is frequently associated with stiffness, generalized fatigue, unrestorative sleep, paresthesias, headaches, dysmenorrhea, irritable bowel symptoms and a swollen feeling in the tissues (2). In 1990, the American College of Rheumatology established a new criterion for the classification of fibromyalgia. In a sample of 558 rheumatic disease patients who had other rheumatic conditions included

in the differential diagnosis of fibromyalgia, the new classification proved to have a sensitivity of 88.4% and a specificity of 81.1% (1), thus raising fibromyalgia to a recognizable syndrome.

Approximately 90% of fibromyalgia patients are women (3). Symptoms usually begin at 40 to 50 yr of age. The average symptom duration is 6–7 yr at the time of first visit to a rheumatology clinic (3). It seems that for most patients, symptoms began gradually and unexpectedly in adulthood; however, many report a history of symptoms beginning after trauma (whiplash), acute sprain, muscle spasm, nerve root irritation or lumbosacral strain that progresses to persistent and severe pain around the affected joints and muscles (4).

After low back pain and cervical spine conditions, fibromyalgia represents one of the most common disorders of the musculoskeletal system. Although its exact prevalence is unknown, it has been estimated that approximately 3 to 6 million individuals in the United States suffer from it (5, 6). It accounts for 2% of family medicine visits (7), 10% of general internal medicine referrals (8, 9) and 20% of referrals to rheumatologists (8, 10–12). The differences in prevalence are attributable to demographic factors, methods of data collection and referral bias. Yet the condition has been considered the third most prevalent rheumatologic disorder, thus justifying the current research trend in this direction.

Fibromyalgia is a chronic disease of varying severity, with symptoms that usually persist for a least 3 yr after diagnosis despite medical therapy (13, 14). Symptom remissions are rare;

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Paper submitted February 3, 1995; in revised form October 11, 1996 and January 21, 1997.

Funding was provided by Canadian Memorial Chiropractic College and North York Rehabilitation Center.

when they occur, they are often transitory. One longitudinal survey suggests a complete remission rate of approximately 5% (15). The prognosis is good when onset of symptoms is clearly defined, history of symptoms is short (less than 1 yr) and the patient is young, with mild symptoms early in the illness (16). Factors related to poor prognosis include a long history of symptoms and patient inability to take responsibility for his or her well being (16). It seems that once they have manifested, fibromyalgia symptoms are likely to persist to a detectable degree over the course of the patient's life (6).

Unlike any known diseases, fibromyalgia lacks a reproducible pathophysiologic abnormality and remains an aggregate of derived symptoms and signs not (as yet) attributable to any identifiable etiology. Potential contributing factors studies include muscle abnormalities (17, 18), alpha rhythm intrusion in non-rapid eye movement sleep (17), neurohormonal and neurotransmitter aberrations (17, 19–26), psychological disturbance (27, 28), genetic predisposition (29, 30), deconditioning (31), autonomic dysfunction (32) and muscle strength deficits (33). Other authors have suggested that mechanical dysfunction (34–37) and myofascial pain syndromes (MPS) (38–41) are two factors that deserve more attention. As Smythe states, the location of pain is often determined by mechanical problems in the lower neck and lower back (40).

The myofascial component of fibromyalgia has more support in the literature (38). Bennett believes that fibromyalgia and MPS are two separate entities (39). It is evident, however, that MPS in separate regions resembles fibromyalgia. Furthermore, it is not uncommon to see a patient with an initially well-defined MPS progress over time to a profile identical to that of fibromyalgia (39). Bennett believes that myofascial trigger points are, in fact, latent trigger points that become symptomatic as a result of enhanced pain perception. This opinion is shared by Smythe and Simons, who argue that tender points may in fact be areas of referred pain (40, 41).

Research efforts over the last decade have attempted to define the proper therapeutic intervention to improve patient symptomatology, but no cohesive approach or grand paradigm has emerged to date. Current management of fibromyalgia consists of drug therapy alone or in combination with a cardiovascular training program, cognitive behavioral therapy or electromyographic biofeedback training (31, 42–56). Numerous randomized controlled clinical trials have now been completed indicating the short-term efficacy of amitriptyline and cyclobenzaprine in improving sleep difficulties, pain levels, fatigue and tender point score. However, medication seems to have little effect on the natural history of fibromyalgia, and only 30–50% of fibromyalgia patients have had a clinically meaningful improvement (15). Unproven therapeutic interventions, such as massage and manipulation, are widely accepted and therefore need to be studied in controlled trials (15).

Treatment of chronic fibrositis using manipulation was reported in the literature as early as 1936 (57). Today, there are several authors who advocate the use of chiropractic manipulation as an effective form of treatment for fibromyalgia patients (34, 35, 58–62). Wolfe found that 48.7% of fibromyalgia

patients surveyed received chiropractic manipulations as a form of treatment, with 45.9% reporting a moderate to great improvement (60).

The rationale for the use of chiropractic manipulation in the management of fibromyalgia includes the following:

1. *Inhibition of pain:* Articular capsules of the spinal facet joints are densely populated with mechanoreceptors; thus, increased proprioceptive input in the form of spinal mobility tends to decrease the central transmission of pain from adjacent spinal structures (63–67). A chiropractic manipulative thrust may induce normalization of hyperactive pain reflex generator mechanisms via normal central nervous system regulatory mechanisms (68). Vernon hypothesizes further that spinal manipulation activates the endogenous opioid anti-nociceptive systems, elevating the plasma beta-endorphin levels (69). Also, the pressure pain thresholds of paraspinal musculature (cervical) are subsequently significantly increased by manipulation (70).
2. *Relaxation of paraspinal muscles:* Manipulation will cause stretching of the apophyseal joint capsules, reflexly inhibiting facilitated motor neuron pools responsible for increased muscle tone (71). Manipulation will stretch intrafusal fibers and cause intense discharge in the Golgi tendon organs, restoring normal afferent and efferent impulses in the joint proprioceptive system and musculature (72). Shambaugh showed a 25% reduction of muscle electrical activity subsequent to a spinal manipulation (73).
3. *Breaking of articular adhesions:* In chronic cases, there is a shortening of periarticular connective tissue, and intra-articular adhesions may form (74). Manipulation may stretch or break these adhesions.
4. *Increased range of motion:* In acute and chronic spinal pain, joint movement is restricted and can be relieved by manipulation (75). Cassidy et al. showed that spinal manipulation of the cervical spine increased the cervical range of motion (67, 76). Lewit also demonstrated that manipulation can increase intersegmental joint play and restore spinal mobility (77).

Chiropractic management of fibromyalgia may also entail the application of other potentially useful techniques. Soft tissue massage with analgesic creams (78) is a passive technique that is useful for breaking up the facilitatory cycle or alter the spinal pain feedback loops (segmental modulation) and central modulation of pain (13, 15, 34, 61, 79, 80). Spray and stretch, another counter-irritant technique, has also been demonstrated to be an effective treatment for myofascial pain (13, 16, 35, 59, 61, 81). Ethyl chloride spray has been documented in the literature as a potent topical anesthetic for fibrositic muscle (82).

Our primary objective was to evaluate the effectiveness of chiropractic management on a sample of fibromyalgia patients (referred from a rheumatologist) in a randomized controlled cross-over trial and before/after design combination. Specifically, we wanted to determine the effects of chiropractic man-

agement on fibromyalgia patients, as measured by subjective pain levels (using the Visual Analogue Scale, pain diagram, tender point analysis and total myalgic score), perceived functional ability (as measured by the Oswestry Disability Index and Neck Disability Index), cervical and lumbar range of motion, flexibility (as measured by a "sit and reach" test and straight leg raise) and strength (grip strength, upper and lower body strength). Our research hypothesis was that chiropractic management will significantly improve reported pain levels, cervical and lumbar ranges of motion and perceived functional ability compared with the control group (p with Bonferroni correction $\leq .005$). Clinically significant improvement was defined as an improvement greater than 25%.

MATERIALS AND METHODS

Patient Selection

All fibromyalgia patients (not meeting the exclusion criteria) currently attending a university-based rheumatology clinic, were initially telephoned by the physician to invite their participation in this clinical trial. Fifty-three of the 100 patients telephoned indicated initial interest in the study. Baseline data for the nonparticipating patients, including their reasons for refusal, was not collected. These 53 patients were telephoned by the study organizers to provide more information. Twenty-one patients agreed to participate, a percentage recruitment of 37%. The majority of the 32 patients who declined felt the distance was too far to travel or they could not commit the time.

These 21 patients were between the ages of 18 and 70 (inclusive) and fulfilled the American College of Rheumatology's 1990 criteria for the classification of fibromyalgia (as ensured by the referring physician). Patients were excluded from participating in the study for any of the following reasons: (1) comorbidity, such as neurological, traumatic, muscular, infectious, osseous or endocrinological condition, that may prevent attendance at chiropractic appointments; (2) inability to read and speak English fluently, (3) concurrent rheumatic disease (except osteoarthritis) and (4) newly prescribed medication (less than 8 wk), including NSAIDs, hypnotics and/or antidepressants. For ethical reasons, patients were allowed to take their prescribed medications (of > 8 wk's standing) during the study period.

Study Design

The study consisted of two groups, a "waiting list" control (group 1) and a chiropractic treatment group (group 2). Each participant was assigned an odd or even number from a random numbers table. Group 2 (even numbers) received chiropractic care for 4 wk, whereas group 1 (odd numbers) was put on a waiting list for 4 wk. Because of ethical constraints and the referring practitioner's request, group 1 received chiropractic care at the end of 4 wk after being assessed; at this cross-over stage, group 1 is then referred to as group 3. Therefore group 1 data after 4 wk trial was used as group 3 baseline data. The portion of the study comparing group 1 against group 3 had no concurrent control group and thus formed a before/after design.

The testing of all patients was done at the beginning of the study, at the end of 4 wk and, for group 3, at the end of week 8. The testing consisted of weight, height, blood pressure and heart rate measurements, tender point analysis, ranges of motion of the cervical and lumbar spine, "sit and reach" testing, straight leg raise and strength testing; the testing was performed by two independent assessors who were blind to which group the patients were allocated. Each assessor performed the same components of the evaluation each time.

Tender point analysis. Standard tender point locations, as determined by the ACR 1990 Criteria (1) were evaluated with enough pressure "to blanch the fingernail" (4 kg of pressure). To be considered positive, the patient's response had to be that it is "painful" and not just "tender." Similar pressure applied to control points (e.g., forehead) should not be painful. Tender point count was computed by summing the number of assessed tender points (max. 18). Total myalgic scores were determined using the protocol designed by Carette et al. (2, 43). Six paired points (right and left) were used: occipital groove, midpoint of the upper fold of the trapezius, supraspinatus at origin (medial border of scapula), second costochondral junction, 2 cm distal of the lateral epicondyle and over the medial fat pad of the knee. Pain thresholds over these points were measured using a pressure algometer (11-kg scale) at a rate of about 1 kg/sec. Patients were asked to tell the examiner when "pressure" changed to "pain." Excellent reproducibility and reliability of the pressure threshold measurements have been demonstrated in the literature (83, 84).

Ranges of motion of the cervical and lumbar spine. Cervical range of motion was measured in three planes using the CROM unit. Youdas et al. assessed the accuracy of the CROM instrument in all three planes and concluded the device was accurate because of small median differences (85). Two studies determined the intraclass correlation coefficients (ICC) for intra-examiner reliability [neck flexion (.63-.91), neck extension (.82-.94), left lateral flexion (.84-.90), right lateral flexion (.79-.89), left rotation (.84-.90) and right rotation (.62-.85)] (85, 86). Agreement coefficients of .80 to 1.0 are generally considered clinically acceptable. Interexaminer reliability was high for neck extension (ICC = .90) and good for neck flexion (ICC = .83), left lateral flexion (ICC = .89), right lateral flexion (ICC = .87) and right rotation (ICC = .82). Left rotation showed fair reliability (ICC = .66) (85).

Lumbar range of motion (flexion, extension, lateral flexion) was documented using a double inclinometer (Dualer). This provides a simple technique for assessing disability and measuring progress in rehabilitation (87). Rondinelli et al. determined that intraexaminer reliability of double inclinometry was moderate (ICC = .83) and the interexaminer reliability was only fair (ICC = .69) (88). Other authors have reported a high reliability in quantifying functional improvement in patients (87, 89, 90).

Sit and reach testing. The sit and reach test was performed as described in the Canada Fitness Testing Procedure (91). The mean of three tests was calculated. This test is a reliable

measure of flexibility, with an intraclass test-retest agreement coefficient of .83 (91).

Straight leg raise. Bilateral straight leg raise was measured with a single digital inclinometer (Dualer) while the patient was supine. The accuracy and repeatability are $\pm 1^\circ$ (92).

Strength testing. Grip strength was measured by a JAMAR five-handle position grip test. Standardized patient positioning as set forth by the American Society of Hand Therapists was followed (93). Each patient was seated, with his or her shoulder adducted and neutrally rotated, elbow flexed at 90° and the wrist pronated 90° . Each hand was tested alternately on each of the five handle positions. Accuracy was measured at $\pm 3\%$ with a test-retest reliability (using the Pearson Product-Moment Correlation Coefficient) of $r = .80$ (94). Fike et al. concluded that this device was useful for establishing a baseline and for monitoring progress measurements (95).

Isometric force produced by the musculature of the back, leg, chest and shoulders was tested by the JAMAR Back-Leg-Chest Dynamometer. It has an accuracy of $100 \text{ kg} \pm 0.5 \text{ kg}$. Both leg and high near lift were performed three times.

Initially, all patients filled out an informed consent form (in accordance with the Helsinki Declaration of 1975) and a case data sheet (demographic data, including medication history). In addition, all of the subjects filled out the following forms at 0, 4 and 8 wk.

- **Visual Analogue Scale:** This consisted of a 100-mm line on which patients marked their estimated pain at that particular time. Values were expressed in millimeters with higher numbers indicating higher degrees of pain intensity. Many sources have found this measurement valid and reliable (96–99), especially with fibromyalgia patients (100).
- **Pain Diagram:** The area of the body in which pain was occurring at the time of the assessment was marked by each patient on a diagram depicting front and rear human body outlines.
- **Oswestry Disability Index (ODI):** This questionnaire is divided into 10 sections that assess limitations of various activities of daily living. Each section has 6 statements. The subject marks the statement that best describes her limitations. Each section is scored from zero to five, five representing the greatest disability. The scores are summed up giving a total out of 50. Test-retest procedures used by Fairbank et al. to assess the Oswestry questionnaire achieved a correlation coefficient of .99 ($p < .001$) between the two tests (101). This suggests that the questionnaire should consistently give the same scores at different occasions if the condition has not changed; therefore, it would be useful for monitoring patient progress (101).
- **Neck Pain Disability Index (NDI):** The NDI is a variation on the Oswestry questionnaire, with statements more pertinent to disability of daily activities because of neck pain or dysfunction. Evaluation of the NDI for reliability and validity was performed by Vernon and Mior (102). Test-retest reliability achieved good statistical significance (Pearson's $r = .89$, $p < .05$). Validity was judged to be

acceptable and the index was found to be sensitive to changes in severity over time (102).

Description of Program

The program took place at a chiropractic clinic and rehabilitation center. Group 2 was told that they would be receiving chiropractic care for 4 wk. The patients were randomly assigned to a chiropractor (there were two different chiropractors providing treatment).

The treating chiropractor performed an initial history and examination, which included neurological, orthopedic and chiropractic examination as required. After completion of the initial examination, the treatment began. Treatment was administered three to five times a week for 4 wk. The treatment consisted of the following:

- **Soft tissue massage:** Soft tissue massage using a counter-irritant DEEP COLD or Glenalgescic Cream was performed over the involved hypertonic musculature. The most commonly involved muscles include: scalenes, posterior cervical, trapezius and lumbar paraspinal muscles.
- **Soft tissue stretching:** Passive assisted stretching and Fluorimethane spray and stretch techniques (81) were done on the following muscles, as indicated: scalenes, posterior cervical muscles, quadratus lumborum and lumbar and mid-thoracic paraspinals. In particular, Fluorimethane spray was used over the scalene muscles for the first three to six treatments.
- **Spinal manipulation:** Manipulation of the spinal joints was graded in velocity and amplitude. Initially, the velocity was slower and amplitude minimal to avoid aggravation of myofascial tissues. Indication for a manipulation was determined by a "hard-end" feel.
- **Education:** The patients were educated as to aggravating factors (i.e., cold, excessive exertion, alcohol, caffeine, repetitive strain, etc.), proper sleep habits, good body mechanics for daily activities, natural history, origin and mechanism of their symptoms and prognosis.

There was no use of such modalities as ultrasound and interferential therapy on the patients because of the diffuse nature of the condition. Each patient was treated individually so that each treatment regime was not identical.

Statistical Analysis

Descriptive statistics (mean and standard deviation) of the initial presenting demographic data (age, sex, marital status, household size, employment, education, number of years fibromyalgia diagnosed, number of years the patient had symptoms and number of professionals consulted) and baseline outcome measures (height, weight, blood pressure, heart rate, cervical range of motion (flexion, extension, lateral flexion and rotation), lumbar range of motion (flexion, extension and lateral flexion), tender point score, total myalgic score, straight leg raise, sit and reach test, grip strength, high near lift, leg lift, Oswestry Disability Index, Neck Disability Index, Visual Analogue Scale and pain diagram) were calculated from the data for each group. The change in each outcome measure was

determined in all groups after 4 wk. Repeated measures analyses of variance (ANOVA) were also used here to test for statistically significant differences between pre- and post-treatment within each of the three groups ($p \leq .005$). Initially, an alpha level of .10 was judged as acceptable for the purposes of our study. We tested 28 outcome measures (of which several were similar variations of each other); in addition, because the Bonferroni correction tends to overcompensate for the number of comparisons made, we calculated the corrected alpha level of .005 as follows: .10 of 20 (comparisons). Group 3 data were combined with the group 2 data after an inspection of the descriptive statistics (mean \pm SD) and ANOVA indicated no clinically significant differences in the initial outcome measures between groups 2 and 3. The results were reanalyzed using an unpaired t test at the Bonferroni corrected significance level of $p \leq .005$ to compare differences between the control group and the chiropractic intervention group with the combined data of groups 2 and 3.

RESULTS

Nineteen of the 21 patients completed the trial; nine patients were in the control group and 10 patients were in the chiropractic care group. Nine patients from the control group then received chiropractic care. Two patients of the original control group failed to complete the entire protocol; one patient moved out of the city and couldn't be located; the other patient did not complete the second assessment because of the distance she had to travel.

The average (\pm standard deviation) number of chiropractic treatments rendered was 15.1 (\pm 3.70) for group 2 and 10.78 (\pm 4.81) for group 3. The resulting p value is .044. Some of the demographic data of the three groups is summarized in Table 1. The resulting p values for each variable in Table 1 indicate no statistically significant differences between any of the three groups. Clinically significant differences were noted in the number of years diagnosed, number of years with symptoms and weight.

The ANOVAs on the baseline outcome measures for all three groups were not statistically significant. However observation of the mean and standard deviation of cervical rotation (group 1, 55.33 \pm 12.49; group 2, 60.40 \pm 8.37; group 3, 45.33 \pm 13.68) indicates a trend toward clinically significant differences. Group 2's mean low back disability was moderate (37.60 \pm 17.41), whereas group 1 and group 3's mean disability was categorized as severe (53.67 \pm 13.64, 53.78 \pm 8.86). A clinically significant difference of approximately 20 percentiles was noted in high near lift measurements between group 2 (12.3 \pm 8.88) and groups 1 and 3 (4.00 \pm 4.69, 4.11 \pm 4.65). There are no other clinically significant differences between any of the groups, although it seems that group 2 patients have a slightly greater range of motion, increased spinal flexibility (sit and reach and straight leg raise) and strength (high near lift, leg lift and grip strength) and decreased perceived functional disability, reported pain levels and number of tender points.

Summarized in Table 2 are the post-treatment changes in the outcome measures for groups 1 and 2 after 4 wk [in the

Table 1. Comparison of the initial presenting case data. Values are presented as mean \pm standard deviation.

Variable	Group 1 <i>n</i> = 9	Group 2 <i>n</i> = 10	Group 3 <i>n</i> = 9
Age (yr)	48.78 \pm 7.69	49.10 \pm 10.10	48.78 \pm 7.69
Yr diagnosed	3.67 \pm 3.20	2.00 \pm 1.76	3.67 \pm 3.20
Yr of symptoms	7.71 \pm 5.12	8.90 \pm 9.11	7.71 \pm 5.12
Number of professionals consulted	3.78 \pm 1.30	3.20 \pm 1.99	3.78 \pm 1.30
Height (inches)	61.33 \pm 2.74	61.22 \pm 3.60	61.33 \pm 2.74
Weight (lbs)	149.22 \pm 17.83	160.50 \pm 67.92	150.25 \pm 24.00

(precrossover) randomized control trial portion of the study]. No statistically significant differences between the groups were achieved. A clinically significant difference was noted in right straight leg raise ($p = .109$), with mean between-group differences of 23.10 degrees (25.67%). A statistically insignificant although clinical trend of improvement was noted in cervical extension [13.2° (18.9%)], cervical right lateral flexion [4.60° (18.4%)] and left straight leg raise [13° (14.4%)]. A clinical trend of improvement (17.3 mm on a 100-mm Visual Analogue Scale) was also noted in pain levels, which is a clinically significant improvement in 40% of the patients.

Summarized in Table 3 are the post-treatment changes in the outcome measures for groups 1 and 3. This is part 2 of the study. Within-group (paired) statistical significance (not clinical significance) was achieved in cervical right lateral flexion ($p = .001$) and cervical right rotation ($p = .000$). Clinically significant improvement was noted in lumbar extension ($p = .356$), with a mean between group difference of 6.56° (26.2%). A clinical trend of improvement in cervical flexion [9.30° (15.5%)], cervical extension [7.89° (11.3%)], cervical left lateral flexion [8.56° (19%)], left cervical rotation [7.78° (9.7%)], lumbar flexion [8.4° (14%)], lumbar left lateral flexion [4.78° (19%)], reported pain levels [13.22 mm (13.22%)], left straight leg raise [13.89° (15.4%)] and right straight leg raise [19.11° (21.2%)] was observed.

The initial outcome measures were analyzed for statistically significant differences between groups 2 and 3, as discussed above. Clinically significant differences existed in cervical right rotation, right lumbar lateral flexion high near left maximum and average and Oswestry Disability Index.

Groups 2 and 3 were combined because of the lack of major statistically and clinically significant differences between the groups. The analysis of this new group combination in comparison with the changes in the control group data is displayed in Table 4. Statistically significant differences (without clinically significant differences) were noted in right cervical lateral flexion ($p = .001$) and right cervical rotation ($p = .000$). A clinical trend of improvement was noted in cervical extension [10.68° (15.3%)], reported pain levels (as measured by the Visual Analogue Scale [17.3 mm (17.3%)], left straight leg raise [18.74° (20.8%)] and right straight leg raise [15.90° (17.7%)].

Table 2. Comparison of the post-treatment changes in the outcome measures of groups 1 and 2 after 4 wk. Values are presented as mean \pm standard deviation.

Variable	Group 1 n = 9	Group 2 n = 10	p Value 1 vs. 2
Cervical flexion (0–60°)	-6.30 \pm 12.08	4.00 \pm 13.23	.155
Cervical extension (0–70°)	-4.22 \pm 14.89	13.20 \pm 17.24	.024
Cervical right lateral flexion (0–45°)	-4.89 \pm 7.29	4.60 \pm 10.58	.025
Cervical left lateral flexion (0–45°)	-3.89 \pm 10.34	3.00 \pm 10.93	.141
Cervical right rotation (0–80°)	-12.22 \pm 8.51	1.00 \pm 8.01	.020
Cervical left rotation (0–80°)	-7.11 \pm 21.72	2.90 \pm 9.49	.161
Lumbar flexion (0–60°)	-8.56 \pm 15.77	5.70 \pm 15.46	.042
Lumbar extension (0–25°)	1.33 \pm 9.03	5.20 \pm 5.47	.481
Lumbar left lateral flexion (0–25°)	-5.22 \pm 9.08	1.70 \pm 8.43	.106
Lumbar right lateral flexion (0–25°)	-1.11 \pm 4.81	1.10 \pm 4.98	.298
VAS (0–100 mm)	-4.00 \pm 18.76	17.30 \pm 30.55	.073
Oswestry (0–100%)	-0.11 \pm 14.22	2.30 \pm 12.38	.677
ODI Rating (0–10)	0.50 \pm 2.33	0.70 \pm 3.40	.883
NDI (0–100%)	0.44 \pm 5.27	6.20 \pm 12.20	.158
NDI Rating (0–10)	0.83 \pm 2.14	1.50 \pm 3.38	.643
Tender points right (0–9)	-0.56 \pm 2.35	-0.90 \pm 1.85	.725
Tender points left (0–9)	0.44 \pm 0.73	-0.30 \pm 1.16	.847
Tender point total (0–18)	-1.00 \pm 2.69	-1.40 \pm 2.55	.777
Myalgic score (0–132 kg)	-0.78 \pm 5.43	-0.90 \pm 5.17	.979
Straight leg raise right (0–90°)	1.89 \pm 24.27	23.10 \pm 37.33	.109
Straight leg raise left (0–90°)	-6.00 \pm 23.64	13.00 \pm 21.20	.066
Sit and reach (cm)	-0.67 \pm 5.22	-0.20 \pm 5.39	.858
Grip strength right (kg)	-0.33 \pm 2.60	1.30 \pm 3.34	.260
Grip strength left (kg)	-0.56 \pm 3.25	1.80 \pm 2.74	.151
High near lift maximum (kg)	0.33 \pm 2.96	1.20 \pm 7.89	.743
High near lift average (kg)	0.11 \pm 2.52	0.70 \pm 7.18	.802
Leg lift maximum (kg)	0.11 \pm 6.33	-1.60 \pm 9.66	.633
Leg lift average (kg)	0.56 \pm 5.55	-1.70 \pm 9.13	.499

Sample size estimates were performed with alpha = .05 [1/2 (two primary outcome measures)] and power = .80 on the following outcome measures (deemed most relevant for measuring the improvement levels in fibromyalgia patients): cervical range of motion (requires a sample size of 75 per group), lumbar range of motion (sample size of 81 per group), Visual Analogue Scale (sample size of 34 per group). Therefore, further study incorporating two of these outcome measures would require a minimum of 81 subjects per group.

DISCUSSION

Chiropractic management addresses both peripheral mechanisms of pain transmission and cognitive or central mechanisms of pain control (endogenous pain modulating systems), which is crucial in treating chronic pain syndromes. In our management plan, we addressed the spinal joint dysfunction with spinal manipulation and the myofascial component with soft tissue massage and stretching techniques (premanipulative techniques). Spinal manipulation, as previously stated, affects the muscle spindle apparatus (through stimulation of mechanoreceptors, enhancing spinal gating mechanisms) and thereby reduces pain, increases range of motion and reduces myofascial hypertonicity. We propose that a reduction in the pain levels (as reported on the Visual Analogue Scale) will improve sleep quality and, more indirectly, fatigue. Pain and stiffness sites correlate with each other. Thus, a reduction in the levels of perceived pain coupled with increased spinal mobility (with manipulation) will probably reduce perceived level of stiffness

and improve overall function. As the term “syndrome” dictates, we have addressed the constellation of symptoms, such as pain, fatigue, stiffness and nonrestorative sleep. Education was implemented into the plan of management to empower the patient to take an active role in lifestyle modification.

The results suggest that chiropractic management may improve cervical range of motion, lumbar range of motion, spinal flexibility (as measured by the straight leg raise) and reported pain levels in a representative sample of patients with fibromyalgia attending a rheumatology clinic. Although only right cervical lateral flexion and rotation improved to a statistically significant degree, the other outcome measures above showed potential for improving clinically. This was also found by Simms et al. in their development of preliminary criteria for response to treatment in fibromyalgia syndrome (103). Improvements in “pain level” did not discriminate as well as other outcome measures between two groups of patients (103).

We attempted to ensure that we did not overlook any potentially important outcome measures to detect an objective improvement in our patients. We reasoned that this would enable us to determine which outcome measures are most relevant for future studies. It may be that those outcome measures not showing statistically or clinically significant improvement are possibly less sensitive and/or intrinsically slower to change over time and require a longer time frame than that was used in this study. We had hypothesized that “perceived functional ability” (as measured by the Oswestry Disability and Neck Disability Indexes) would improve with

Table 3. Comparison of the post-treatment changes in the outcome measures of groups 1 and 3 after 4 wk. Values are presented as mean \pm standard deviation.

Variable	Group 1 n = 9	Group 3 n = 9	p Value 1 vs. 2
Cervical flexion (0-60°)	-6.30 \pm 12.08	9.30 \pm 15.76	.023
Cervical extension (0-70°)	-4.22 \pm 14.89	7.89 \pm 14.87	.116
Cervical right lateral flexion (0-45°) ^a	-4.89 \pm 7.29	10.22 \pm 7.45	.001
Cervical left lateral flexion (0-45°)	-3.89 \pm 10.34	8.56 \pm 7.96	.013
Cervical right rotation (0-80°) ^a	-12.22 \pm 8.51	12.00 \pm 16.52	.000
Cervical left rotation (0-80°)	-7.11 \pm 21.72	7.78 \pm 11.80	.218
Lumbar flexion (0-60°)	-8.60 \pm 15.77	8.40 \pm 11.61	.019
Lumbar extension (0-25°)	1.33 \pm 9.03	6.56 \pm 17.83	.356
Lumbar left lateral flexion (0-25°)	-5.22 \pm 9.08	4.78 \pm 9.49	.026
Lumbar right lateral flexion (0-25°)	-1.11 \pm 4.81	-2.33 \pm 3.61	.572
VAS (0-100 mm)	-4.00 \pm 18.76	13.22 \pm 22.80	.153
Oswestry (0-100%)	-0.11 \pm 14.22	-1.11 \pm 10.45	.866
ODI rating (0-10)	0.50 \pm 2.33	1.33 \pm 2.50	.550
NDI (0-100%)	0.44 \pm 5.27	3.11 \pm 5.99	.517
NDI rating (0-10)	0.83 \pm 2.14	1.11 \pm 2.26	.850
Tender points right (0-9)	-0.56 \pm 2.35	0.22 \pm 2.11	.440
Tender points left (0-9)	-0.44 \pm 0.73	0.89 \pm 2.47	.092
Tender points total (0-18)	-1.00 \pm 2.69	1.11 \pm 3.79	.153
Myalgic score (0-132 kg)	-0.78 \pm 5.43	4.78 \pm 16.32	.259
Straight leg raise left (0-90°)	1.89 \pm 24.27	13.89 \pm 15.84	.368
Straight leg raise right (0-90°)	-6.00 \pm 23.64	19.11 \pm 19.40	.020
Sit and reach (cm)	-0.67 \pm 5.22	4.22 \pm 6.24	.077
Grip strength right (kg)	-0.33 \pm 2.60	0.33 \pm 3.24	.651
Grip strength left (kg)	-0.56 \pm 3.25	2.00 \pm 4.30	.130
High near lift maximum (kg)	0.33 \pm 2.96	2.11 \pm 4.76	.514
High near lift average (kg)	0.11 \pm 2.52	2.22 \pm 3.93	.384
Leg lift maximum (kg)	0.11 \pm 6.33	2.56 \pm 6.37	.507
Leg lift average (kg)	0.56 \pm 5.55	2.11 \pm 5.93	.648

^a These changes were statistically significant.

chiropractic management. This result was not demonstrated and might be explained to some degree by the intrinsic differences in the three treatment groups' baseline measures. More likely, however, is the possibility that improvements in function require a longer time frame (greater than 4 wk) and more active approach (functional restoration program) than that provided by our study.

It is possible that concurrent medication may account in part for our observed results. However we feel that this is not a significant factor, because all medications (as ensured by the referring rheumatologist) were stabilized for at least 8 wk before entering our study. Chiropractic management was not received by any patient for a period of 6 months before commencement of the study (except for one patient in the control group who discontinued care 1 wk before the study), thereby ensuring no carry-over effect from this intervention.

Two chiropractors operating out of the same clinic administered the chiropractic care. Patients received care from both chiropractors during the course of their treatment. This would minimize differences in chiropractic technique between practitioners. In further studies, we recommend checking for variance in treatment style, so that one group of patients receives care from only one conveniently located practitioner. The patients were not all assessed on the same day (a span of two or three days in a row), therefore avoiding assessor fatigue.

Despite an overall clinical impression in favor of chiropractic management for the fibromyalgia patient, there are inherent

methodological problems in this study. The small sample size resulted in several instances of Type II Error. Sample size estimate for the most promising outcome measures of cervical range of motion, lumbar range of motion and visual analogue scale, were calculated using a power = 80% and an alpha = .05. These outcome measures yielded the largest sample size of 81 per treatment group. In addition, the self-selection of patients to the study introduces a bias, but this cannot be avoided because of the nature of the proposed treatment.

A before/after design was used for a portion of this study, so that patients served as their own waiting list controls. This design is weaker than the randomized control trial design, because it does not factor out natural history and placebo effects. However, the natural history of fibromyalgia is one of an unremitting course, stable over time with generally no change in symptoms and is therefore judged not to be a factor in this study. For this reason, and because we felt it was necessary to provide all patients with our proposed treatment, we accepted this design. In addition, chronic pain (fibromyalgia) patients respond well to short-term treatment (placebo effect, etc.), but in this particular study, the baseline data indicates that these patients have all received numerous types of treatment before commencing the study; thus, the placebo effect is less of an issue.

There was no long-term follow up of these patients, because all patients received a rehabilitation program (involving aero-

Table 4. Comparison of the post-treatment changes in the outcome measures of the combined chiropractic groups after 4 wk. Values are presented as mean ± standard deviation.

Variable	Group 1 n = 9	Group 2 & 3 n = 19	p Value 1 vs. 2 & 3
Cervical flexion (0–60°)	-6.33 ± 12.083	6.53 ± 14.33	.023
Cervical extension (0–70°)	-4.22 ± 14.89	10.68 ± 15.95	.027
Cervical right lateral flexion (0–45°) ^a	-4.88 ± 7.29	7.26 ± 9.43	.001
Cervical left lateral flexion (0–45°)	-3.89 ± 10.34	5.63 ± 9.80	.035
Cervical right rotation (0–80°) ^a	-12.22 ± 8.51	6.21 ± 13.61	.000
Cervical left rotation (0–80°)	-7.11 ± 21.72	5.21 ± 10.64	.138
Lumbar flexion (0–60°)	-8.56 ± 15.77	7.00 ± 13.47	.023
Lumbar extension (0–25°)	1.33 ± 9.03	5.84 ± 12.52	.291
Lumbar left lateral flexion (0–25°)	-5.52 ± 9.08	3.16 ± 8.83	.036
Lumbar right lateral flexion (0–25°)	-1.11 ± 4.81	-0.53 ± 4.61	.765
VAS (0–100 mm)	-4.00 ± 18.76	17.30 ± 30.55	.073
Oswestry (0–100%)	-0.11 ± 14.22	0.684 ± 11.32	.885
ODI rating (0–10)	0.50 ± 2.33	1.00 ± 2.94	.645
NDI (0–100%)	0.44 ± 5.27	4.74 ± 9.64	.141
NDI rating (0–10)	0.83 ± 2.14	1.32 ± 2.83	.666
Tender points right (0–9)	-0.56 ± 2.35	-0.37 ± 2.01	.840
Tender points left (0–9)	-0.44 ± 0.73	0.26 ± 1.94	.175
Tender point total (0–18)	-1.00 ± 2.69	-0.21 ± 3.36	.512
Myalgic score (0–132 kg)	-0.78 ± 5.43	1.79 ± 11.84	.439
Straight leg raise left (0–90°)	1.89 ± 24.27	18.74 ± 28.82	.124
Straight leg raise right (0–90°)	-6.00 ± 23.64	15.90 ± 20.04	.031
Sit and reach (cm)	-0.67 ± 5.22	1.90 ± 6.08	.266
Grip strength right (kg)	-0.33 ± 2.60	0.84 ± 3.24	.315
Grip strength left (kg)	-0.56 ± 3.25	1.90 ± 3.46	.086
High near lift maximum (kg)	0.33 ± 2.96	1.63 ± 6.43	.471
High near lift average (kg)	0.11 ± 2.52	1.42 ± 5.77	.411
Leg lift maximum (kg)	0.11 ± 6.33	0.37 ± 8.32	.929
Leg lift average (kg)	0.56 ± 5.59	0.11 ± 7.82	.863

^a These changes were statistically significant.

bic exercise, stretching, strengthening and patient education) following the prescribed 4 wk of chiropractic management.

Nevertheless, despite random allocation to a group, group 2 patients would seem, from their initial baseline outcome measures, to be clinically less severe than the other groups. This could account, in part, for the improvement noted after 4 wk of treatment, yet Group 2 patients also received fewer treatments. In addition, the nonparticipants should have baseline outcome measures established to dictate a representative population from the rheumatology clinic and proper comparison.

Another limitation of this study is the apparent lack of effect of chiropractic on the clinical signs defining fibromyalgia. Chiropractic management generally did not seem to have a clinically important effect on the number of tender points or total myalgic score.

The symptoms of fibromyalgia patients are often worse in the winter months in northern regions or in periods of extreme cold (104). This factor was not controlled for (because of time constraints) and we may have dampened our results by commencing the study in November. This would be a future consideration in timing the study. In sampling patients from only one rheumatologist, a referral bias may have occurred. However, because our referring rheumatologist has a special interest in the study of fibromyalgia, we received patients from various demographic areas and this may have given us an acceptable and representative sample.

In summary, it seems reasonable to suggest that chiropractic management should be included (in some capacity) in the treatment of the fibromyalgia patient. A short course of chiropractic treatment (4–8 wk) may offer the fibromyalgia patient some pain relief, increased range of motion in their cervical and lumbar spines and an improvement in their overall level of flexibility. It is fair to say, then, that chiropractic management seems to improve function and not just pain, even in the chronic pain (fibromyalgia) patient. However, chiropractic care (solely) does not seem to offer a “break-through” or is not a panacea for the treatment of fibromyalgia. It is reasonable to offer the fibromyalgia patient a short course of comprehensive chiropractic care initially as an important component of their multidisciplinary treatment approach. The manual therapy (passive treatment) offered by chiropractors should facilitate the fibromyalgia patient’s progression into a functional restoration program.

The fibromyalgia patient is commonly pain-focused and self-limiting in their behavior. It is important for chiropractors to realize this and attempt to defocus them from their pain and attempt to improve their function. The fibromyalgia patient should be encouraged to reintegrate themselves into a more productive lifestyle. They should also be encouraged to become more independent in their pain management. However, supportive chiropractic care may have a role in the long-term management of the patient.

CONCLUSION

This study suggests that chiropractic management may be beneficial in the treatment of fibromyalgia patients, specifically in improving their range of motion, general flexibility and reported pain levels. This pilot study isolated the outcome measures that are most likely to demonstrate improvement in fibromyalgia patients. We recommend further investigation into this area using a minimum sample size of 81 patients per treatment group, several referral bases and stratification for expected prognosis (i.e., age, initial severity level, duration of symptoms, etc.). We also recommend implementing this study at various seasons of the year and incorporating a longer follow-up period (which precludes crossing subjects over between interventions).

ACKNOWLEDGMENTS

We would like to thank M. Bell, M.D., for her cooperation and organization of the sample of fibromyalgia patients. We appreciate the help we received from Alison Venables; she was forever adapting to our requests. A special thank-you to Leslie Horowitz, D.C., Morris Gasparin, D.C., Edward Fillion, D.C. and Kevin Sayeau, C.A., for their effort and assistance and to Carol Hagino for her expertise.

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