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A Randomized Clinical Trial of Exercise and Spinal Manipulation for Patients With Chronic Neck Pain

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Study Design. A randomized, parallel-group, single-blinded clinical trial was performed. After a 1-week baseline period, patients were randomized to 11 weeks of therapy, with posttreatment follow-up assessment 3, 6, and 12 months later.

Objectives. To compare the relative efficacy of rehabilitative neck exercise and spinal manipulation for the management of patients with chronic neck pain.

Summary of Background Data. Mechanical neck pain is a common condition associated with substantial morbidity and cost. Relatively little is known about the efficacy of spinal manipulation and exercise for chronic neck pain. Also, the combination of both therapies has yet to be explored.

Methods. Altogether, 191 patients with chronic mechanical neck pain were randomized to receive 20 sessions of spinal manipulation combined with rehabilitative neck exercise (spinal manipulation with exercise), MedX rehabilitative neck exercise, or spinal manipulation alone. The main outcome measures were patient-rated neck pain, neck disability, functional health status (as measured by Short Form-36 [SF-36]), global improvement, satisfaction with care, and medication use. Range of motion, muscle strength, and muscle endurance were assessed by examiners blinded to patients' treatment assignment.

Results. Clinical and demographic characteristics were similar among groups at baseline. A total of 93% of the patients completed the intervention phase. The response rate for the 12-month follow-up period was 84%. Except for patient satisfaction, where spinal manipulative therapy and exercise were superior to spinal manipulation with ($P = 0.03$), the group differences in patient-rated outcomes after 11 weeks of treatment were not statistically significant ($P = 0.13$). However, the spinal manipulative therapy and exercise group showed greater gains in all measures of strength, endurance, and range of motion than the spinal manipulation group ($P < 0.05$). The spinal manipulation with exercise group also demonstrated more improvement in flexion endurance and in flexion and rotation strength than the MedX group ($P < 0.03$). The MedX exercise group had larger gains in extension strength and flexion–extension range of motion than the spinal manipulation group ($P < 0.05$). During the follow-up year, a greater improvement in patient-rated outcomes were observed for spinal manipulation with exercise and for MedX exercise than for spinal manipulation alone ($P = 0.01$). Both exercise groups showed very similar levels of improvement in patient-rated outcomes, although the spinal manipulation and exercise group reported greater satisfaction with care ($P < 0.01$).

Conclusions. For chronic neck pain, the use of strengthening exercise, whether in combination with spinal manipulation or in the form of a high-technology MedX program, appears to be more beneficial to patients with chronic neck pain than the use of spinal manipulation alone. The effect of low-technology exercise or spinal manipulative therapy alone, as compared with no treatment or placebo, and the optimal dose and relative cost effectiveness of these therapies, need to be evaluated in future studies. [Key words: chiropractic, exercise, manipulation, neck pain, orthopedic, randomized clinical trial] **Spine 2001;26:788–799**

Neck pain is a commonly reported problem that affects 70% of individuals at some time in their lives.[11] At any given time, approximately 10% to 20% of the population reports neck problems.[17,19,20] Because most neck pain has no specific, identifiable cause, it is diagnosed as mechanical neck pain.[3] A large proportion of health care practice is devoted to the care of neck problems,[22,31] and millions of dollars are spent annually on treatment, lost wages, and compensation.[5,35]

Despite the magnitude, costs, and morbidity of neck pain, surprisingly little research has evaluated treatments for patients with neck pain, and little is known about its natural history.[4] Data show cervical zygapophysial joint pain to be common among patients with chronic neck pain,[29] and spinal manipulation is assumed to improve spinal joint dysfunction. Systematic reviews of spinal manipulation for chronic neck pain have concluded that there is limited evidence on the short-term effectiveness of spinal manipulation and insufficient data for conclusions about its long-term effects.[1,7,21]

Prospective studies have suggested that patients with chronic neck pain have weak neck muscles,[33,34] and that neck-strengthening exercises may decrease pain and increase neck range of motion and muscle performance.[18] A recent randomized trial[25] evaluated spinal manipulation, intensive low-technology exercise, and physical therapy for patients with chronic neck pain. No clinically important or statistically significant differences were ob-

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served at 2, 6, and 12 months after treatment. Surprisingly, except for isometric endurance, the exercise group was no better than the other two groups in terms of isometric strength and range of motion.

Longer periods of neck exercise training may be necessary to obtain greater strength gains and improvement in patient-rated outcomes.[25] Therefore, substantial uncertainty still exists regarding the efficacy of spinal manipulation and exercise for chronic neck pain. Also, the effect of both therapies combined, a common approach in clinical practice, is unknown.

The randomized clinical trial reported in this article compared the short- and long-term relative efficacy of three conservative treatment approaches for chronic neck pain: spinal manipulation combined with low-technology rehabilitative neck exercise, high-technology MedX rehabilitative neck exercise, or spinal manipulation alone.

■ Methods

Design. This prospective, parallel-group, randomized clinical trial was conducted in Minneapolis/St. Paul, Minnesota. The study was approved by the local institutional review boards of the participating institutions, and informed consent was obtained from all participants.

Patients. Patients 20 to 65 years of age who had a primary problem of mechanical neck pain that had persisted for 12 weeks or more were eligible for this study. Mechanical neck pain was defined as pain having no specific, identifiable etiology (*i.e.,* infection or inflammation) that could be reproduced by neck movement or provocation tests.[3] Patients were excluded if they had referred neck pain; severe osteopenia; progressive neurologic deficits; vascular disease of the neck or upper extremity; previous cervical spine surgery; current or pending litigation; inability to work because of neck pain, spinal manipulative therapy (SMT), or exercise therapy within 3 months before study entry; or concurrent treatment for neck pain by other health care providers.

Patients were recruited through local newspaper advertisements. Initial screening was accomplished by telephone, and eligible persons attended two baseline evaluation appointments.

Randomization. Eligible patients were randomized to one of the three treatment arms on the basis of a computer-generated list using a 1:1:1 allocation ratio. Before randomization, the group allocation scheme was successfully concealed from investigators, research assistants, patients, and clinicians involved in the study. An independent, professional agent verified the randomization process.

Interventions. To balance for time and attention, all the patients attended 20 one-hour visits during the 11-week study period.

Spinal Manipulation and Low-Technology Exercise (SMT/Exercise). At each visit, patients underwent treatment by one of nine experienced chiropractors (15 minutes), followed by a supervised low-technology rehabilitative exercise session (45 minutes). Short-lever, low-amplitude, high-velocity spinal manipulative therapy was administered to the cervical and thoracic spine.[15] Light soft-tissue massage was used to facilitate treatment, but physical therapy methods were not permitted.

The exercise program for the SMT/exercise group comprised 45-minute supervised sessions of progressive strengthening exercises for the neck and upper body preceded by a short aerobic warm-up of the upper body and light stretching. Upper body strengthening exercises included push-ups and dumbbell shoulder exercises as described by Dyrssen et al.[13] Patients performed two sets of 15 to 30 repetitions, with dumbbell weights varying from 2 to 10 pounds. Lying on a therapy table and wearing a headgear with variable weight attachments (1.25 to 10 pounds) guided by a simple pulley system attached to the table, the patients performed cervical strengthening exercises. Weight resistance was increased gradually over the course of the treatment period.

MedX Exercise. Patients in the MedX group received one-on-one supervision by a physical therapist. Sessions began with stretching, upper body strengthening, and 15 to 20 minutes of aerobic exercise using a dual-action stationary bike. Dynamic progressive resistance exercises were performed on the MedX cervical extension and rotation machines (MedX Corp., Ocala, FL), which allow isolated testing and exercise of the cervical extensors and rotators.[18,32] Resistance was increased periodically, with patients performing approximately 20 repetitions of each exercise.

Spinal Manipulation. Patients in the SMT group received 15-minute treatments of the type described earlier (see description of Spinal Manipulation and Low-Technology Exercise). To minimize differences in potential attention bias, patients in this group also received 45 minutes of detuned (sham) microcurrent therapy after SMT.

All three groups were instructed in the use of a home exercise program consisting of resistive extension as well as flexion and rotation exercises with an inexpensive rubberized tubing device.

Outcome Measures.

Questionnaires. Patient self-report questionnaires were administered twice at baseline, 5 and 11 weeks after the start of treatment, then 3, 6, and 12 months after treatment. Pain, the primary outcome measure, was rated by patients on an 11-box scale: 0 (no symptoms) to 10 (highest severity of pain).[23,24] Disability was measured by the Neck Disability Index (S)[27,37] and functional health status by the Short Form (SF-36).[6,36] The patients rated their improvement using a 9-point ordinal scale. Use of over-the-counter pain medication was assessed by a 5-point scale, with choices ranging from "none" to "every day." Finally, satisfaction with care was assessed by a 7-point scale with choices ranging from "completely satisfied (couldn't be better)" to "completely dissatisfied (couldn't be worse)."

Neck Performance. Cervical muscle strength, endurance, and range of motion were measured twice at baseline, then after 11 weeks of treatment by observers blinded to patient treatment allocation. Cervical isometric muscle strength was measured by computerized load-cell transducer dynamometer (Promotron 3000, Promatek Medical Systems, Joliet, IL). The highest of three trials assessing maximal voluntary contraction for flexion, extension, and rotation was used for analyses.

For cervical endurance testing, patients were placed on a therapy table, prone for extension and supine for flexion, wearing a headgear with an attached weight guided by a simple pulley system attached to the table. Static endurance was measured by elevating the head just free of support and holding it for up to 240 seconds with a weight corresponding to 60% of the maximal voluntary contraction. Dynamic endurance was recorded as the number of repetitions (1 second up and 1 second down in synchrony with a metronome) until failure. The weight attached during dynamic performance was 25% of the maximal voluntary contraction. Active rotation, flexion–extension, and lateral bending ranges of motion were measured with the CA6000 Spine Motion Analyzer (Orthopedic Systems Inc., Haywood, CA).[8,12,26]

Patient Expectation. Before randomization, the patients were asked to indicate their expected response to each of the three possible treatments: 1 (worse), 2 (no change), 3 (better), or 4 (much better).

Statistical Analysis. Factoring in a dropout rate of up to 20%, statistical power was set so there was less than a 20% chance of overlooking at least a medium effect size difference in pain between interventions (considered to be a minimum clinically important difference for the purpose of this study).[9]

Repeated measures analyses of covariance (ANCOVA) were performed for each of the patient-rated outcomes, with adjustment for baseline values when indicated. Patient-rated pain was determined *a priori* to be the main outcome, with all other outcomes regarded as secondary. Repeated measures multivariate analyses of variance (MANOVA) were used as overall tests for treatment differences incorporating the six patient-oriented outcomes for the short and long term.[14] The MANOVA controls for the problem of spurious significant findings resulting from multiple tests. For the short-term outcome, data for weeks 5 and 11 were used. For the long-term outcome, data for weeks 5 and 11 and for months 3, 6, and 12 were used. Change scores (week 11 minus baseline) in objective neck performance data were tested for group differences with analysis of variance (ANOVA). Group differences were determined by the multiple comparison Newman-Keuls test.[14] If normality of data was not established, the data were rank transformed and analyzed using the same parametric analysis.[10]

To account for increasing time intervals between assessments, areas under the curve for all six patient-oriented outcomes were calculated for each patient as recommended by Matthews et al[30]. Effect sizes were calculated to standardize the measurement units of the six outcomes and to help evaluate the importance of the magnitude of group differences in areas under the curve.[9,16] These summary measures were tested for group differences with ANOVA, and 95% confidence intervals were placed on group differences.

All analyses were performed on an intent-to-treat basis unless otherwise specified. To evaluate potential predictors of outcome, a multiple linear regression analysis was performed. A statistician independent of the study site performed the main analyses. Analyses were performed with SPSS for Windows, Version 7.5 (SPSS, Chicago, IL) and Statistica for Windows, Version 5.1 (Statsoft Inc., Tulsa, OK).

Results

Study Sample

Recruitment of patients was conducted over a 22-month period from October 1994 to July 1996. A detailed summary of patient recruitment, participation, and attrition during the study is summarized in Figure 1.[2] Demographic and clinical characteristics of the randomized patients are summarized in Table 1. The random allocation of patients resulted in three groups comparable in all baseline variables. Group means and standard deviations for the patient-rated outcome measures during the intervention and follow-up phases are presented in Table 2.

Short-Term Therapeutic Outcomes

Patient-Rated Outcomes. Substantial improvement over time was observed in all three study groups. However, except for satisfaction with care, there were no clinically important or statistically significant differences between groups. Repeated measures ANOVA incorporating weeks 5 and 11 yielded the following statistics: pain ($F[2,173] = 2.2$, $P = 0.12$; Figure 2), neck disability ($F[2,172] = 0.8$, $P = 0.45$; Figure 3), general health status ($F[2,173] = 0.79$, $P = 0.48$; Figure 4), improvement ($F[2,174] = 1.7$, $P = 0.18$; Figure 5), satisfaction ($F[2,174] = 3.6$, $P = 0.03$; Figure 6), and over-the-counter medication use ($F[2,173] = 0.8$, $P = 0.47$; Figure 7).

As the overall test, repeated measures MANOVA, incorporating all patient-reported outcomes at weeks 5 and 11 into the analysis, showed no statistically significant differences between groups (Wilk's Lambda = 0.90; $F[12,336] = 1.49$, $P = 0.13$). Except for satisfaction with care ($F[2,163] = 3.3$, $P = 0.04$), analysis of the area under the curve also demonstrated no important group differences. These results, summarized in Table 3, indicate that satisfaction with care was significantly higher for SMT with exercise than for SMT alone ($P < 0.05$).

Neck Performance Outcomes. After 11 weeks of treatment, SMT/exercise produced greater gains in strength, endurance, and range of motion than SMT alone ($P < 0.05$). The group treated with SMT/exercise also demonstrated more improvement in flexion endurance and in flexion and rotation strength than the group treated with MedX ($P = 0.03$). Finally, the MedX group showed greater gains in extension strength and flexion–extension range of motion than the SMT group ($P < 0.05$). The change scores for the individual measures are depicted in Table 4.

Long-Term Therapeutic Outcomes

Most of the improvement noted in all outcomes for the three groups at the end of the treatment phase was maintained during the posttreatment follow-up year. There was a group difference in patient-rated pain ($F[2156] = 4.2$, $P = 0.02$; Figure 2) with no group time interaction ($F[8,624] = 0.5$, $P = 0.88$) in favor of the two exercise groups. There was also a group difference in satisfaction

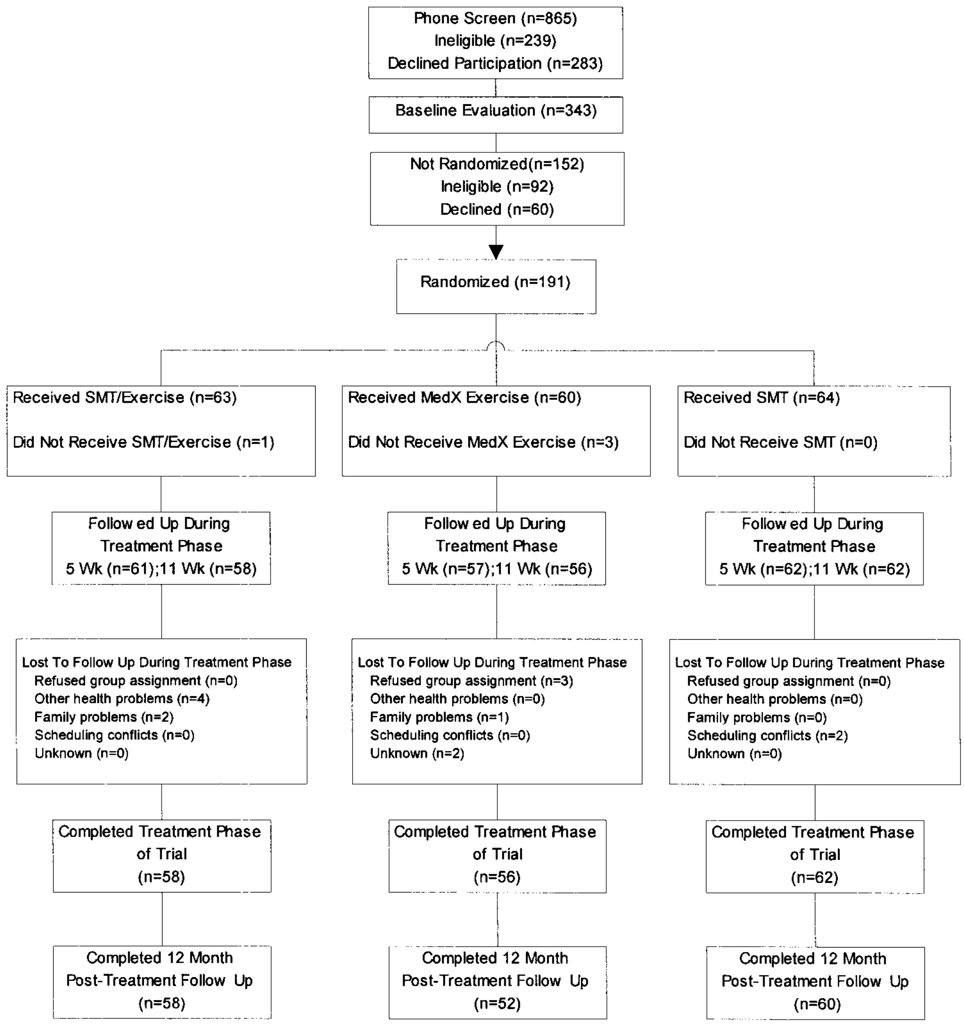

Figure 1. Participant flow and follow-up evaluation.

with care, with SMT/exercise superior to both MedX and SMT ($F[2,158] = 6.7$, $P = 0.002$; Figure 6). The remaining outcomes measures showed no significant group differences for neck disability ($F[2,156] = 2.04$, $P = 0.13$; Figure 3), general health status ($F[2,158] = 2.5$, $P = 0.09$; Figure 4), improvement ($F[2,158] = 2.1$, $P = 0.13$; Figure 5), or medication use ($F[2,157] = 2.3$, $P = 0.10$; Figure 7). There were no important differences for any of the patient-oriented outcomes between patients who regularly performed the recommended home exercises throughout the follow-up year (n = 46) and those who did them only occasionally (n = 51) or did not do them at all (n = 62).

The overall MANOVA test yielded a statistically significant group difference (Wilk's Lambda = 0.85; $F[12,302] = 2.2$, $P < 0.01$), with no group time interaction, and with SMT/exercise superior to SMT. Analyses of group differences for area under the curve were computed using the product of the time differences between measurement points (baseline, weeks 5 and 11, and months 3, 6, and 12) and the mean of these six measurements. The cumulative scores for the three groups showed group differences in pain ($F[2,157] = 3.3$, $P = 0.04$) and satisfaction with care ($F[2,146] = 4.5$, $P < 0.01$), which were consistent with the other statistical analyses. Additionally, these analyses showed that except for satisfaction with care, there were no important differences between SMT/exercise and MedX. Findings showed that SMT/exercise was superior to SMT alone in terms of pain, satisfaction, and improvement, and MedX was superior to SMT in terms of pain (Table 4).

Patient Expectations. The patients in the SMT/exercise group had a median score of 4 (*i.e.*, they expected they would get "much better" as a result of SMT with exercise), whereas the patients in the other two groups had a median score of 3 (*i.e.*, they expected they would get "better" as a result of either MedX or SMT alone). Regression analyses showed that expectation was not a predictor for any of the outcomes.

Missing Data Analysis

For the 11-week intervention phase, 8% of the data was missing. For the posttreatment follow-up year, complete data on all patient-oriented outcomes were available for 83% of the 191 patients randomized into the trial. Using the SPSS Missing Value Analysis 7.5 module and con-

Table 1. Demographic and Baseline Clinical Characteristics

Characteristic	SMT/Exercise	MedX	SMT	All Patients
Number of patients	64	63	64	191
Age (yrs)	45.0 ± 10.5	43.6 ± 10.5	44.3 ± 11.0	44.3 ± 10.6
Gender (% female)	59.4	60.3	57.8	59.2
Height				
Inches	66.4 ± 3.7	66.4 ± 4.4	66.3 ± 4.9	66.4 ± 4.3
cm	168.7 ± 9.4	169.2 ± 11.2	168.4 ± 12.4	168.7 ± 10.9
Weight				
Pounds	171.7 ± 44.3	168.9 ± 28.7	167.4 ± 40.1	169.3 ± 38.1
kg	77.9 ± 20.1	76.6 ± 13.0	75.9 ± 18.2	76.8 ± 17.3
Duration of neck pain (median yrs and range)	6.5 (0.3–29)	5.0 (0.3–24)	5.5 (0.4–34)	5.0 (0.3–34)
Radiation to upper extremity (%)	53.1	50.8	53.1	52.4
Awake at night because of neck pain (%)	73.4	73.0	70.3	72.3
Neck pain associated with trauma				
Automobile accident (%)	31.3	25.4	27.0	27.9
Work or leisure time (%)	18.8	19.0	31.7	23.2
Frequency				
Pain all or most of the time (% of patients)	68.0	63.5	53.9	61.8
Neck pain severity score (0–100 scale)	56.7 ± 15.6	56.9 ± 14.2	56.5 ± 12.8	56.7 ± 14.2
Neck disability score (NDI) (0–100 scale)	27.2 ± 9.0	28.1 ± 10.8	27.6 ± 10.0	27.6 ± 9.9
Global general health status score (SF-36) (0–100 scale)	70.2 ± 13.0	65.4 ± 15.5	69.0 ± 15.8	68.2 ± 14.9
Use of OTC pain-relieving medication during past week (0–4 scale)	1.7 ± 1.6	1.5 ± 1.4	1.3 ± 1.4	1.5 ± 1.5
MMPI raw scores				
Hysteria scale	26.6 ± 5.1	28.1 ± 5.1	27.5 ± 5.4	27.4 ± 5.2
Hypochondriasis scale	9.7 ± 5.0	9.8 ± 5.1	10.2 ± 4.9	9.9 ± 5.0
Lie scale	4.4 ± 2.4	4.8 ± 2.3	4.6 ± 2.3	4.6 ± 2.3
Depression score (CES-D) (0–100 scale)	14.7 ± 11.7	19.2 ± 13.6	18.6 ± 15.3	17.5 ± 13.7
Neck performance				
Static endurance (weight × seconds)				
Flexion	212.1 ± 187.0	213.9 ± 205.1	231.4 ± 202.6	219.3 ± 197.4
Extension	498.4 ± 292.1	585.7 ± 392.3	538.2 ± 343.8	540.7 ± 344.6
Dynamic endurance (weight × max reps.)				
Flexion	69.2 ± 59.7	82.7 ± 82.7	79.8 ± 66.8	77.2 ± 70.3
Extension	150.8 ± 90.9	187.2 ± 120.6	164.6 ± 106.9	167.8 ± 107.5
Isometric strength (pounds)				
Flexion	16.3 ± 9.4	18.2 ± 11.1	18.9 ± 10.5	17.8 ± 10.3
Extension	20.2 ± 10.7	21.6 ± 11.2	21.4 ± 10.5	21.0 ± 10.7
Rotation	8.3 ± 4.8	9.5 ± 5.8	9.3 ± 5.4	9.0 ± 5.3
Range of motion (degrees total)				
Flexion/extension	97.8 ± 16.2	102.3 ± 16.0	101.6 ± 15.7	100.6 ± 16.0
Rotation	129.3 ± 17.4	128.3 ± 20.0	129.2 ± 18.2	128.9 ± 18.5
Lateral bending	68.3 ± 19.0	70.6 ± 18.3	65.2 ± 17.5	68.0 ± 18.3

Note: Values are means and standard deviations unless otherwise noted.
SMT = spinal manipulative therapy; OTC = over the counter; MMPI = Minnesota Multiphasic Personality Inventory; CES-D = Community Epidemiological Scale-Depression.

trolling for early drop-outs, the outcomes were determined to be missing at random in each group, and thus not related to measurement history.[28] The results of the alternative analysis (based on the full data set, with all the missing data entered for all outcomes) did not change the results from the main statistical analyses.

Side Effects

Notable increases in neck or headache pain were reported by 23 patients: eight with SMT/exercise, nine with MedX, and six with SMT alone). Other side effects were: increased radicular pain in one patient with SMT/exercise, and severe thoracic pain in one patient with SMT. The differential number of side effects across treatments was not statistically significant ($\chi^{22} = 1.44$, $P = 0.49$). All of the preceding cases were self-limited, and no permanent injuries occurred.

Discussion

In the short term (during the 11 weeks of intervention), all three treatments were associated with substantial improvement in patient-reported symptoms. There was a tendency for the two exercise groups to perform better than the SMT group in almost all of the patient-rated outcomes, but these differences were not statistically significant, and the authors did not consider them clinically important. The exception was satisfaction with care, which favored SMT with exercise over SMT alone.

In terms of neck performance, however, at least twice as much improvement was observed in the SMT and exercise group as in the SMT group on all measures including range of motion. The SMT and exercise group showed somewhat greater improvement in flexion en-

Table 2. Patient-Rated Outcomes for Those Who Provided Data at All Time Points During the 11-Week Intervention Phase and the 12-Month Posttreatment Follow-up Period

Outcome	No.	Group	Baseline	Week 5	Week 11	Month 3	Month 6	Month 12
Pain								
	55	SMT/Exercise	56.0 ± 15.0	32.7 ± 17.7	23.6 ± 18.0	29.5 ± 20.6	29.5 ± 20.7	31.1 ± 22.7
	49	MedX	57.1 ± 15.0	33.1 ± 17.2	24.1 ± 19.7	25.3 ± 19.8	29.8 ± 21.8	29.8 ± 20.4
	56	SMT	56.6 ± 12.8	38.6 ± 17.1	31.3 ± 21.8	37.3 ± 22.3	35.5 ± 24.2	36.5 ± 22.3
NDI								
	55	SMT/Exercise	26.4 ± 8.5	18.6 ± 9.2	14.1 ± 8.7	14.3 ± 10.7	14.8 ± 10.6	16.1 ± 11.2
	49	MedX	26.7 ± 10.4	17.1 ± 10.3	12.4 ± 9.9	13.7 ± 11.8	15.0 ± 12.6	15.6 ± 13.1
	56	SMT	27.8 ± 10.3	20.2 ± 11.5	15.8 ± 12.3	18.8 ± 13.3	17.7 ± 12.7	19.9 ± 13.1
SF-36								
	55	SMT/Exercise	71.7 ± 11.8	76.5 ± 13.8	81.7 ± 12.0	77.8 ± 14.5	79.0 ± 13.3	76.6 ± 13.9
	50	MedX	69.0 ± 13.1	75.7 ± 11.2	81.0 ± 11.8	80.1 ± 12.5	79.6 ± 12.3	78.0 ± 13.7
	56	SMT	69.1 ± 16.6	73.1 ± 16.6	78.7 ± 16.0	74.6 ± 17.7	73.8 ± 18.3	74.3 ± 17.8
Medication use								
	55	SMT/Exercise	100.4 ± 57.5	87.2 ± 47.9	81.4 ± 42.5	80.3 ± 43.3	84.3 ± 44.6	80.7 ± 45.6
	50	MedX	94.9 ± 51.0	87.2 ± 47.0	92.1 ± 47.6	78.2 ± 41.5	81.5 ± 45.6	79.0 ± 43.3
	56	SMT	90.7 ± 52.5	92.7 ± 49.9	88.3 ± 47.6	92.1 ± 46.9	87.7 ± 47.0	93.1 ± 47.6
Improvement								
	55	SMT/Exercise	NA	82.5 ± 46.5	76.5 ± 42.3	78.1 ± 41.6	76.2 ± 43.1	78.6 ± 45.7
	50	MedX	NA	93.0 ± 48.7	85.8 ± 50.0	77.7 ± 49.0	81.5 ± 49.5	78.2 ± 50.5
	56	SMT	NA	90.5 ± 54.0	98.8 ± 47.9	92.2 ± 44.1	92.6 ± 46.0	91.9 ± 45.0
Satisfaction								
	55	SMT/Exercise	NA	75.7 ± 39.1	76.1 ± 41.6	72.6 ± 41.5	69.2 ± 40.2	67.8 ± 41.4
	50	MedX	NA	87.2 ± 40.8	88.6 ± 42.9	85.7 ± 43.5	89.5 ± 41.7	87.1 ± 45.6
	56	SMT	NA	103.3 ± 48.7	96.9 ± 48.6	92.1 ± 45.5	93.7 ± 46.9	98.8 ± 44.7

Note: Values are means and standard deviations data on medication use, improvement and satisfaction are rank transformed. Except for SF-36 scores, lower scores mean less severity or more improvement. NA = not applicable (This data was collected at weeks 5 and 11 and at months 3, 6 and 12 only), SMT = spinal manipulative therapy, NDI = Neck Disability Index, SF-36 = Short Form 36; NA = not available.

durance and flexion strength than the MedX group. This is understandable because training of the neck flexors in isolation was not part of the MedX protocol. As expected, the MedX group also showed higher gains than the SMT group in most of the measures, with flexion measures as an exception. However, the differences between these two groups were smaller and statistically significant only for extension.

The tendency in the short term for the two exercise groups to perform better in the patient-oriented outcomes than the group treated with SMT alone continued throughout the follow-up year and cumulatively resulted in statistically significant group differences. Given the magnitude of the effect size differences (with the majority approximating a medium effect size of 0.5) and the consistency of group differences in most outcome measures across time, the authors consider these differences to be clinically important. This is especially the case between the SMT and exercise group and the SMT group.

The study by Jordan et al[25] allows for the most meaningful comparison with the current study because it demonstrated similar patient demographics and used comparable interventions and outcome measures. Jordan et al[25]

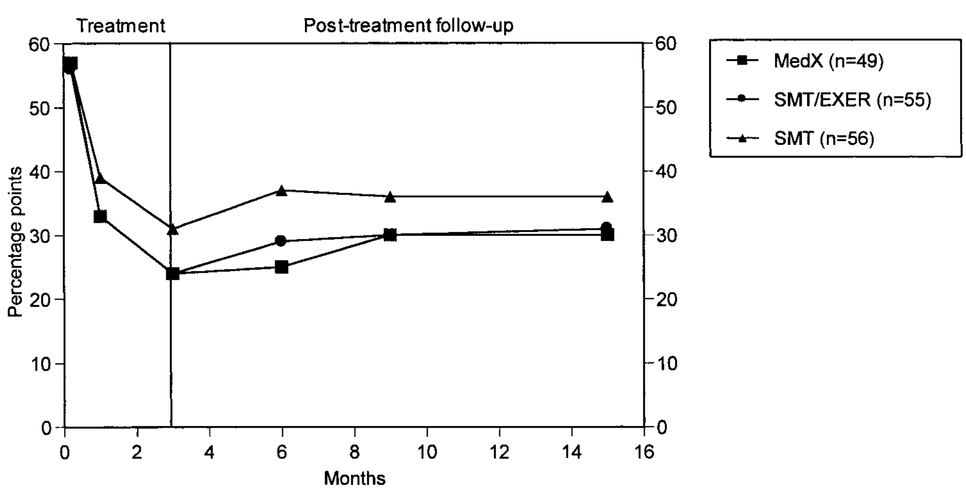

Figure 2. Patient-rated neck pain.

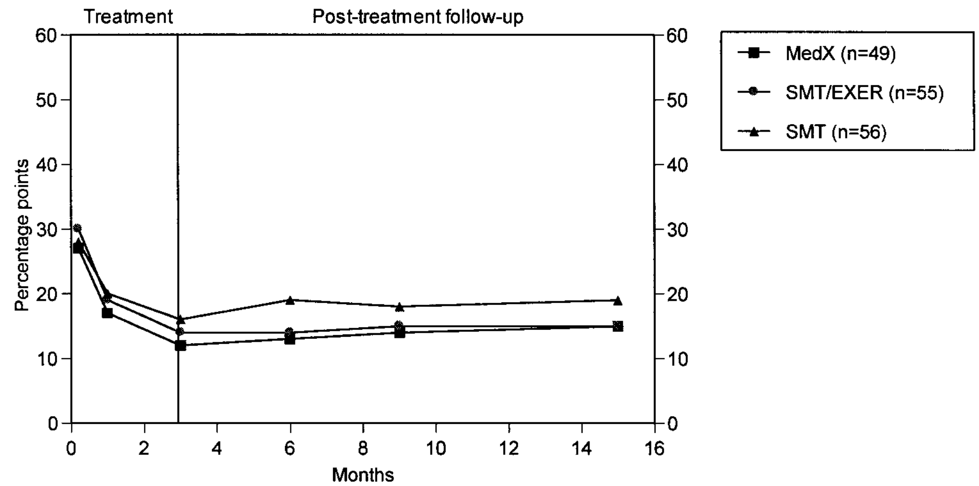

Figure 3. Patient-rated neck disability (NDI).

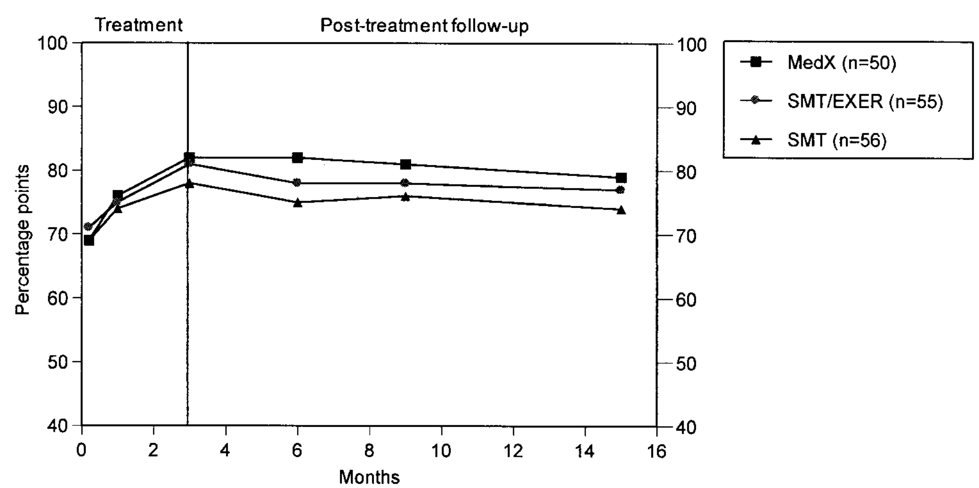

Figure 4. Patient-rated general health status (higher score = better status).

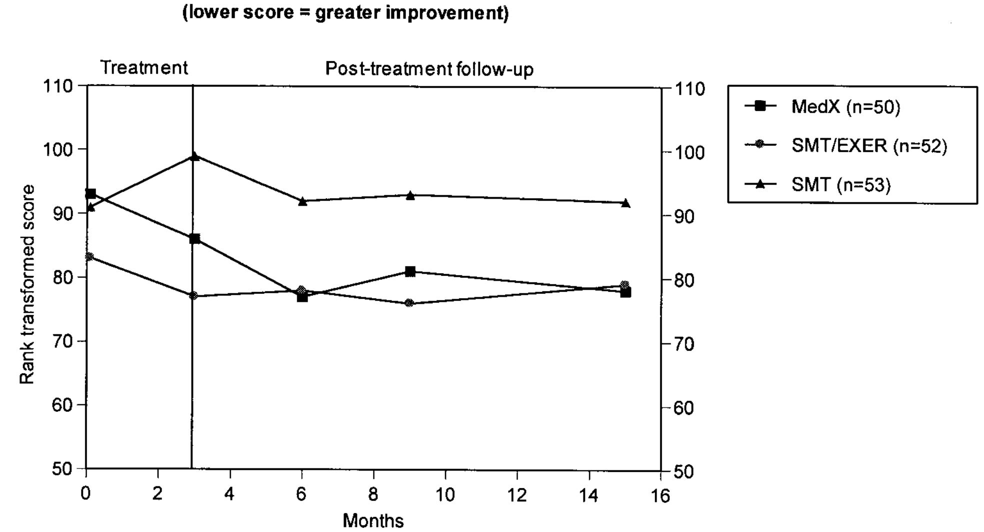

Figure 5. Patient-rated improvement.

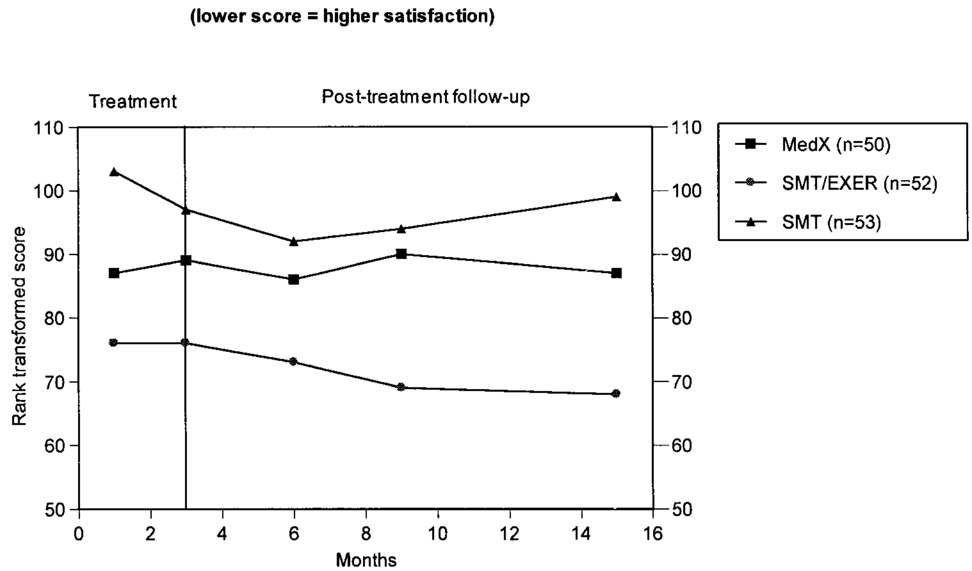

Figure 6. Patient-rated satisfaction with care.

provided their data for this study so direct comparisons of the studies could be performed. Baseline disability scores were similar in both trials. However, patients in the Jordan et al[25] study had lower baseline pain severity. Calculation of within-group effect sizes for both trials showed that a greater magnitude of change in pain and disability occurred in the current study. Therefore, the advantage of the exercise groups over the SMT group in the current study may have resulted because the patients in the exercise groups had more pain and therefore greater room for improvement. Another possible explanation may involve the higher dose of exercise used in the current study, which was about twice that used in the Jordan et al[25] trial.

Some of the improvement in the three groups may be explained by a combination of the natural history, regression to the mean, and the nonspecific effects of patient–provider interaction. Randomization enhances the likelihood of equal distribution among groups of patients experiencing a favorable natural history, or regression to the mean. Therefore, any differences observed between groups are likely because of the treatment encounters.

The design of this study was less than optimal for cost comparisons because it was balanced deliberately in terms of time and attention to best address the relative clinical efficacy of the interventions. Future studies might prospectively address the cost effectiveness of the study treatments when delivered in a fully pragmatic way.

The magnitude of effect exerted by low-technology exercise alone as well as how SMT would fare in relation

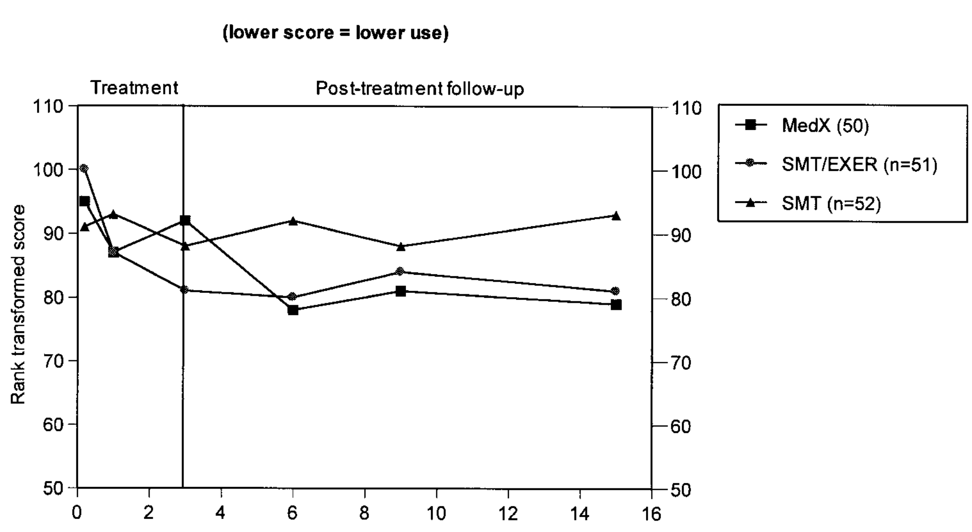

Figure 7. Analgesic medication use.

Table 3. Magnitude of Group Differences (Effect Sizes) Based on Areas Under the Curve Calculations

Outcome Measure	Group Contrast	Short-Term (Week 0–11) Effect Size*†	Short-Term (Week 0–11) 95% CI	Long-Term (Week 0–52) Effect Size*†	Long-Term (Week 0–52) 95% CI
Pain	A *vs* B	0.03	0.41 to −0.35	0.06	0.44 to −0.33
	A *vs* C	−0.25	0.12 to −0.61	***−0.41***	***−0.03 to −0.78***
	B *vs* C	−0.28	0.10 to −0.66	***−0.44***	***−0.06 to −0.83***
NDI	A *vs* B	0.16	0.54 to −0.22	0.05	0.44 to −0.33
	A *vs* C	−0.14	0.22 to −0.51	−0.29	0.08 to −0.67
	B *vs* C	−0.27	0.10 to −0.65	−0.32	0.06 to −0.71
SF-36	A *vs* B	−0.10	0.28 to −0.48	0.06	0.44 to −0.32
	A *vs* C	−0.21	0.15 to −0.58	−0.26	0.11 to −0.63
	B *vs* C	−0.14	0.24 to −0.51	−0.32	0.06 to −0.70
Medication	A *vs* B	0.04	0.42 to −0.34	−0.10	0.28 to −0.48
	A *vs* C	0.01	0.37 to −0.36	***−0.38***	***−0.01 to −0.76***
	B *vs* C	−0.03	0.35 to −0.41	−0.30	0.08 to 0.68
Improvement	A *vs* B	−0.17	0.21 to −0.55	−0.13	0.27 to −0.53
	A *vs* C	−0.18	0.18 to −0.55	***−0.46***	***−0.06 to −0.85***
	B *vs* C	−0.02	0.35 to −0.40	−0.30	0.09 to −0.70
Satisfaction	A *vs* B	−0.25	0.13 to −0.63	***−0.46***	***−0.06 to −0.87***
	A *vs* C	***−0.45***	***−0.09 to −0.82***	***−0.58***	***−0.18 to −0.98***
	B *vs* C	−0.24	0.14 to −0.62	−0.13	0.26 to −0.52

Note: Small, medium, and large effect size differences correspond to 0.2, 0.5, and 0.8, respectively.
* Negative sign in front of effect size differences denotes advantage of first group in group contrast. No sign denotes the opposite.
† Bold and italic effect size differences are significant at an alpha of 0.05.
Group A = SMT and exercise; Group B = MedX exercise; Group C = SMT; CI = confidence interval; NDI = Neck Disability Index; SF-36 = Short Form 36.

to placebo, waiting list, or other type of control remains unknown. This, along with the optimal dose-response for both SMT and neck exercise, needs to be established.

■ Conclusions

With the exception of patient satisfaction, for which SMT with exercise was superior to SMT alone, no clinically important group differences were observed after 11 weeks of treatment. During the follow-up year, there was a cumulative advantage for both SMT with exercise and MedX exercise as compared with SMT alone. Both exercise groups showed very similar improvement for all outcomes, although the SMT with exercise group reported greater satisfaction with care. Overall, the use of strengthening exercise, whether in combination with SMT or in the form of a high-technology MedX program, appears to be more beneficial to patients with chronic neck pain than the use of SMT alone. The optimal dose and relative cost effec-

Table 4. Gains (Change Scores) in Neck Muscle Endurance and Strength and Neck Range of Motion After 11 Weeks of Intervention Compared With Baseline Values

Neck Performance Measure	SMT/Exercise (n = 56–58)	MedX (n = 54–56)	SMT (n = 61)
Static endurance (weight × seconds)			
Flexion	164.9 (117.0 to 212.8)*	66.2 (16.0 to 116.3)	73.7 (28.6 to 119.1)
Extension	284.6 (185.4 to 387.7)†	159.6 (54.5 to 264.8)	145.6 (50.5 to 240.6)
Dynamic endurance (weight × maximum number of repetitions)			
Flexion	89.4 (73.7 to 105.2)*	29.4 (13.1 to 45.7)	20.7 (5.3 to 6.0)
Extension	78.9 (58.9 to 98.9)†	70.2 (50.1 to 90.4)	47.3 (28.0 to 66.6)
Isometric strength (pounds)			
Flexion	8.4 (6.9 to 10.0)*	6.0 (4.8 to 7.6)	4.0 (2.6 to 5.5)
Extension	8.3 (6.3 to 10.2)†	7.6 (5.6 to 9.6)†	2.4 (0.5 to 4.3)
Rotation	4.1 (2.8 to 5.4)*	1.8 (0.5 to 3.1)	1.2 (−0.5 to 2.6)
Range of motion (degrees)			
Flexion/Extension‡	8.3 (5.4 to 11.2)†	6.8 (3.9 to 9.8)†	1.6 (−1.2 to 4.4)
Rotation‡	11.4 (8.5 to 14.2)†	8.1 (5.3 to 11.0)	5.7 (3.0 to 8.4)
Side bending‡	7.8 (5.1 to 10.4)†	5.1 (2.4 to 7.8)	2.2 (−0.4 to 4.7)

Note: Values are expressed as mean change (95% confidence interval).
* Superior to MedX and SMT ($P < 0.05$).
† Superior to SMT ($P < 0.05$).
‡ Total, full cycle.
SMT = spinal manipulative therapy.

tiveness of these therapies need to be evaluated in future studies.

Key Points

- A randomized trial of 191 patients with chronic neck pain compared spinal manipulation combined with low-technology strengthening exercise, high-technology MedX rehabilitative exercise, and spinal manipulation alone.
- The treatment program was 11 weeks in length, and the patients were observed for 1 year.
- After 1 year, strengthening exercise, whether in combination with spinal manipulation or in the form of a high-technology MedX program, was more beneficial than spinal manipulation alone.
- Further research is needed to determine the optimal dose response and cost effectiveness of these therapies.

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Point of View

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There is no doubt that neck pain is prevalent in the general population,[1] or that it results in frequent visits to physicians and therapists of all types, including chiropractors.[2] At the same time, there is substantial disagreement regarding the most effective methods for treating these patients and even about the particular source or sources of pain. This knowledge deficit is particularly problematic considering patients with chronic neck pain who have not improved with a "tincture of time."

The study by Bronfort et al is a very well designed and conducted randomized clinical trial (RCT), as noteworthy for what it does not do as for its main conclusions. First, this trial was not placebo controlled, so no conclusions can be drawn from it regarding the overall effectiveness of treatment. It can support only conclusions based on the relative response in the three patient groups: patients treated with spinal manipulation alone, those managed with spinal manipulation and low-technology neck exercises, and those involved in a high-technology neck rehabilitation exercise program. The fact that all three groups showed impressive improvements in disability scores and pain ratings during the course of treatment cannot be taken as evidence of effectiveness for any of the treatment protocols. Even the fact that these improvements persisted for 12 months cannot indicate that specific interventions were beneficial because there was no control for natural history, regression to the mean, or nonspecific effects of treatment. In fact, it is very tempting to conclude that the great majority of the improvement was not directly related to treatment because all three groups showed almost identical change in all of the main variables. However, as the authors point out, placebo control would be necessary for this to be evaluated properly.

The value of this study lies in the small but significant differences between groups that appeared after the treatment period. For example, when pain ratings are considered, there is a relative benefit for neck exercise alone or neck exercise combined with spinal manipulation as compared with treatment using spinal manipulation alone. This effect was identifiable for months after treatment, arguing that exercises should be incorporated as a regular part of treatment for patients with chronic neck pain.

It also would be tempting to conclude that cervical manipulation did not add anything of value to the improvement of these patients. However, this conclusion is not supported by the experimental design, notwithstanding the fact that the group treated with spinal manipulation alone had slightly but significantly less improvement than the group that also engaged in an exercise program.

Of course, inasmuch as the high-technology exercise group did just as well in all measures as the group treated with spinal manipulation and low-technology exercise, it would be tempting to believe that the main important variable was the exercise. However, the data do not allow such a conclusion, nor do they permit the values of the low- and high-technology exercises to be equated because the low-technology exercise group also receive spinal manipulation.

It is clear that the groups treated with exercise had significant gains in neck strength and endurance of neck muscles. However, as attractive as it might be to regard this increase in muscle strengthening and endurance as the cause of the long-term improvement in symptoms, this is not entirely clear. For example, if strength and condition were the main variables contributing to long-term improvement, it might be expected that patients participating actively in home exercises during the follow-up period would have had significantly better outcomes. However, this was not found to be the case. Therefore, the question of how exercise might influence chronic neck pain remains an open issue.

This study raises other questions. The authors identified a significantly higher level of treatment satisfaction among patients in the exercise with manipulation group than in either the group receiving spinal manipulation or the group using high-technology exercise alone. This difference cannot be attributed simply to differences in treatment response because the two exercise groups had similar responses at all time points. Although the reasons for this difference were not directly tested and therefore are speculative, it certainly could relate to the addition of a "hands-on" component to the treatment protocol.

This study serves to point out certain difficulties in performing RCTs on spinal disorders. Improvement may be spontaneous, or it may be attributable to statistical regression to the mean or other nonspecific treatment-related factors. Therefore, to document any significant treatment-related effect, the experimental population and the therapeutic effects may need to be quite large and homogeneous. These studies also may run into statistical "floor effects" if the amount of spontaneous improvement is high enough.

Additionally, to be effective, RCTs must be narrowly focused, resulting in many unanswered questions at the conclusion of the study. Despite these and other daunting hurdles, well-designed RCTs will remain, for the foreseeable future, the best method for demonstrating treatment effects and comparing treatment protocols for back and neck pain.

Valuable insights may be forthcoming from RCTs, such as the significant advantage of adding exercise to a spinal manipulation treatment protocol for chronic neck pain. At the same time, these studies may raise as many questions as they answer, such as how much of the improvement across treatment groups is the result of nonspecific or placebo effects. Ultimately, it will be necessary to focus these empiric methods on important questions including cost effectiveness, how much treatment is appropriate, whether the beneficial effects of therapies are additive, and whether individuals who are more likely to respond to one treatment or another can be identified.

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