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Two-Year Follow-up of a Randomized Clinical Trial of Spinal Manipulation and Two Types of Exercise for Patients with Chronic Neck Pain

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Study Design. Randomized clinical trial.

Objectives. To compare the effects of spinal manipulation combined with low-tech rehabilitative exercise, MedX rehabilitative exercise, or spinal manipulation alone in patient self-reported outcomes over a two-year follow-up period.

Summary of Background Data. There have been few randomized clinical trials of spinal manipulation and rehabilitative exercise for patients with neck pain, and most have only reported short-term outcomes.

Methods. One hundred ninety-one patients with chronic neck pain were randomized to 11 weeks of one of the three treatments. Patient self-report questionnaires measuring pain, disability, general health status, improvement, satisfaction, and OTC medication use were collected after 5 and 11 weeks of treatment and 3, 6, 12, and 24 months after treatment. Data were analyzed taking into account all time points using repeated measures analyses.

Results. Ninety-three percent (178) of randomized patients completed the 11-week intervention phase, and 76% (145) provided data at all evaluation time points over the two-year follow-up period. A difference in patient-rated pain with no group-time interaction was observed in favor of the two exercise groups [$F(_{2141}) = 3.2$; $P = 0.04$]. There was also a group difference in satisfaction with care [$F(_{2143}) = 7.7$; $P = 0.001$], with spinal manipulation combined with low-tech rehabilitative exercise superior to MedX rehabilitative exercise ($P = 0.02$) and spinal manipulation alone ($P < 0.001$). No significant group differences were found for neck disability, general health status, improvement, and OTC medication use, although the trend over time was in favor of the two exercise groups.

Conclusion. The results of this study demonstrate an advantage of spinal manipulation combined with low-tech rehabilitative exercise and MedX rehabilitative exercise *versus* spinal manipulation alone over two years and are similar in magnitude to those observed after one-year follow-up. These results suggest that treatments including supervised rehabilitative exercise should be considered for chronic neck pain sufferers. Further studies are needed to examine the cost effectiveness of these therapies and how spinal manipulation compares to no treatment or minimal intervention. [Key words: chiropractic, exercise, manipulation, neck pain, orthopedic, randomized clinical trial] **Spine 2002;27:2383–2389**

Compared to low back pain, neck pain has been poorly researched, even though it affects a large number of individuals and has an important socioeconomic impact. Surveys in Canada and Finland have found that neck pain afflicts approximately 70% of adults at some point in their lives.[8,25] Approximately 10% of respondents in a Canadian study reported having high neck pain levels, and an additional 5% were severely disabled because of neck pain.[8] Almost 14% of respondents to Norwegian and Finnish surveys reported having neck pain that was chronic in nature.[2,13]

A recent systematic review of the literature of common, nonsurgical treatments found few randomized clinical trials on neck pain that were of high methodologic quality. Furthermore, most reported only short-term outcomes, with only 2 of 27 having at least a 1-year follow-up period.[20]

We conducted a randomized clinical trial comparing commonly used treatments for chronic neck pain: 1) spinal manipulation with low-tech rehabilitative exercise (SMT/Exercise); 2) high-tech MedX rehabilitative exercise (MedX); and 3) spinal manipulation (SMT) alone. The two exercise groups were significantly better than the SMT group in terms of strength and range of motion after 11 weeks of treatment and in patient-rated outcomes one year after treatment. These results have been presented in a previous publication.[3] The current paper describes the results of the two-year follow-up and addresses the hypothesis that the advantage observed over one year in both exercise groups would be sustained two years posttreatment.

Materials and Methods

Design. This prospective, parallel-group randomized clinical trial was conducted at the Wolfe-Harris Center for Clinical Studies at Northwestern Health Sciences University in Bloomington, Minnesota, and the Physician's Neck and Back Clinic in Roseville, Minnesota. The study was approved by the Institutional Review Boards of Northwestern Health Sciences Univer-

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sity and the University of Minnesota, and informed consent was obtained from all study participants.

Recruitment. Patients were recruited through newspaper advertisements in the Minneapolis/St. Paul, Minnesota, area. Initial screening was done by telephone, and eligible persons attended two baseline evaluation appointments to fully inform individuals about the study, establish eligibility, and collect baseline measures. Qualified and willing individuals were randomly assigned to one of three treatment groups at the end of the second baseline evaluation appointment. Randomization was performed by a member of the study staff using sequentially numbered, opaque envelopes, which were prepared using a computer-generated list before the start of the study. The allocation of the patients to the three study treatments was 1:1:1, and study staff, investigators, clinicians, and patients were masked to upcoming treatment assignments.

Eligibility Criteria. To be eligible for the study, patients had to be between 20 and 65 years of age and have a primary complaint of mechanical neck pain that had lasted for 12 weeks or more. Mechanical neck pain was defined as having no specific, identifiable etiology (*i.e.*, infection, inflammatory disease), but could be reproduced by neck movement or provocation tests.[1] Specifically, the pain had to be localized to the dorsal part of the neck in an area limited by a horizontal line through the most inferior portion of the occipital region and a horizontal line through the spinous process of the first thoracic vertebra.

Exclusion criteria were: neck pain referred from peripheral joints or viscera, severe osteopenia, progressive neurologic deficits, vascular disease of the neck or upper extremity, significant infectious disease or other severe disabling health conditions, previous cervical spine surgery, current or pending litigation, inability to work because of neck pain, spinal manipulative therapy or exercise therapy three months before study entry, or concurrent treatment for neck pain by other health care providers.

Interventions. To ensure equal time and attention among the three treatment groups, all patients attended 20 1-hour appointments over 11 weeks.

Spinal Manipulation Combined With Rehabilitative Exercise. Spinal manipulation was delivered by experienced chiropractic clinicians trained in the study protocol. Treatment included manual spinal manipulation with light soft-tissue massage as indicated to facilitate the spinal manipulative therapy.[3] Rehabilitative exercise for the SMT/Exercise group was guided by trained exercise therapists. Each session began with a warm-up on a stationary bike with arm levers and light stretching, followed by upper-body strengthening exercises including push-ups and dumbbell shoulder exercises.[10] Dynamic neck extension, flexion, and rotation exercises were performed with the patient lying on a therapy table wearing headgear with variable weight attachments (1.25 to 10 lbs) guided by a simple pulley system attached to a physical therapy table. Beginning weights were determined by baseline strength performance and were increased gradually during the treatment phase.

MedX Rehabilitative Exercise. Each appointment began with a warm-up of stretching and aerobic exercise using a dual-action stationary bike, followed by strengthening exercises of the shoulders and upper back using variable resistance equipment. Neck strengthening exercises were performed on the MedX variable resistance, cervical extension, and rotation machines (MedX Corporation, Ocala, FL).[23] Patients were stabilized with torso restraints to isolate and specifically exercise the cervical musculature. They were encouraged to perform repetitions to volitional muscle fatigue (maximum 20 reps) even if pain was exacerbated, and resistance was increased periodically.[29]

Spinal Manipulation. Patients randomized to the SMT group received spinal manipulation as described for the SMT/Exercise group. To minimize differences in potential attention bias, patients receiving SMT alone were also given 45 minutes of detuned (sham) microcurrent therapy after the 15 minutes of evaluation and treatment provided by the chiropractor.

Outcome Measures. Participants attended evaluation appointments twice at baseline and 5 and 11 weeks after starting treatment. Self-report questionnaires were completed, and a blinded, objective outcomes assessment (including measurement of neck motion, strength, and endurance) was performed. At 3, 6, 12, and 24 months after treatment, all participants were mailed self-report questionnaires to be returned in self-addressed, postage-paid envelopes. All outcome measures were collected independent of provider and investigator influence.

The primary outcome measure was patient-rated pain. Patients were asked to rate their typical neck pain over the past week on an ordinal, 11-box scale (0 = no neck pain, 10 = the worst neck pain possible)—a simple, frequently used assessment of variation in pain intensity and a reliable measure of treatment efficacy.[16,18]

Neck-related disability was measured by the Neck Disability Index (NDI),[32] and general health status was measured by the Medical Outcomes Study Short Form 36-item Health Survey (SF-36 D).[7,28,33]

Patient-rated improvement or global change was measured using a nine-point ordinal scale, with response choices ranging from "no symptoms" to "twice as bad."[9,12,21] Patients were also asked how frequently they used over-the-counter (OTC), pain-relieving medication for their neck pain over the past week using a five-point scale varying from "none" to "everyday."[4] Satisfaction with care was evaluated on a seven-point scale which varied from "completely satisfied (couldn't be better)" to "completely dissatisfied (couldn't be worse)."[4] Patient expectations were measured before randomization by asking patients how they expected to respond to each of the three possible treatments (worse = 1, no change = 2, better = 3, or much better = 4). Additional health care use during the follow-up period was measured by asking patients if they had seen any nonstudy health care providers for their neck pain since they filled out their previous self-report questionnaire.

Statistical Analyses

Main Analyses. To assess the long-term effects of treatment, the primary outcome measure, *i.e.*, patient-rated pain, was analyzed using repeated measures analysis of covariance (ANCOVA) with data collected at weeks 5 and 11, and months 3, 6, 12, and 24. Baseline values were used as covariates. Possible treatment-time interactions were accounted for and intention-to-treat analyses were used.[15] Based on variance data from the ANCOVA table, the preplanned, three-pair–wise comparisons between groups were performed using the Student-

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Table 1. Demographic and Baseline Clinical Characteristics of Randomized Patients

Characteristic	SMT/Exercise	MedX	SMT	All Patients
No. 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 min–max)	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 due to neck pain (%)	73.4	73.0	70.3	72.3
Frequency				
Pain all or most of the time (% of patients)	68.0	63.5	53.9	61.8

Values are means and standard deviations (SD) unless otherwise noted.
SMT/Exercise = spinal manipulation combined with low-tech rehabilitative exercise; MedX = MedX rehabilitative exercise; SMT = spinal manipulation alone.

Newman-Keuls multiple range test.[11] Patient-rated disability, general health status, improvement, OTC medication use, and satisfaction were analyzed in the same way. Data that were not normally distributed were rank transformed and analyzed using the same parametric analyses.[6] The sample size and statistical power calculations are described in a previous publication.[3]

Supplementary Analyses. A missing data analysis was performed to assess to what extent missing data may have affected the study outcomes using an SPSS Missing Value Analysis™ 7.5 module.

To assess whether patient expectations and health care use in the two-year follow-up period had any influence on patient-rated pain, the repeated measures ANCOVA was repeated with each variable used as a covariate. These analyses were then compared to the original analyses.

A repeated measures multivariate analysis of covariance (MANCOVA) was performed as a confirmatory analysis to assist with the interpretation of study results. In this analysis, all patient-rated outcome measures (pain, disability, satisfaction, improvement, general health status, and OTC medication use) at all time points were used to test for overall differences between groups.[11]

To take into account increasing time intervals between assessments, areas under the curve were calculated for each patient for all patient-oriented outcomes as recommended by Matthews *et al.*[27] Effect size differences were then calculated to standardize the units of measurement of the outcomes and to help evaluate the importance of the magnitude of group differences.[5,14]

■ Results

Results of Main Analyses

A total of 191 patients were randomized, 178 of which completed the 11-week treatment period, and 145

Table 2. Means and Standard Deviations for Patient-Rated Outcome Measures

Measure	Group (n)	Baseline	Week 5	Week 11	Month 3	Month 6	Month 12	Month 24
Pain	SMT/Exer (51)	5.6 (1.5)	3.2 (1.7)	2.4 (1.8)	2.9 (2.1)	3.0 (2.1)	3.0 (2.2)	3.4 (2.4)
	MedX (44)	5.6 (1.5)	3.3 (1.7)	2.3 (1.8)	2.4 (1.8)	2.9 (2.2)	2.9 (2.0)	3.4 (2.4)
	SMT (50)	5.6 (1.4)	3.8 (1.7)	2.9 (2.1)	3.7 (2.3)	3.5 (2.5)	3.5 (2.3)	3.9 (2.3)
Disability	SMT/Exer (51)	26.3 (8.4)	18.0 (8.4)	13.8 (8.6)	13.6 (10.2)	14.3 (10.2)	15.5 (10.5)	15.6 (11.8)
	MedX (44)	26.4 (10.2)	17.0 (10.2)	11.8 (9.6)	12.8 (10.2)	14.2 (11.1)	15.0 (11.6)	16.6 (12.4)
	SMT (50)	27.9 (10.2)	20.3 (11.1)	15.4 (11.7)	18.7 (13.0)	17.5 (12.6)	19.5 (12.9)	20.5 (13.5)
Health status	SMT/Exer (51)	71.9 (11.3)	76.8 (13.2)	81.7 (12.0)	78.4 (14.2)	79.8 (12.4)	77.2 (13.2)	76.2 (15.3)
	MedX (45)	69.7 (12.7)	76.5 (9.8)	81.5 (11.3)	81.1 (9.9)	80.5 (11.2)	78.8 (12.2)	76.3 (14.1)
	SMT (50)	68.8 (16.4)	73.5 (16.6)	78.8 (16.1)	74.9 (17.8)	74.6 (18.1)	75.0 (17.0)	70.8 (20.4)
Improvement	SMT/Exer (51)		80.3 (47.1)	76.6 (43.3)	77.5 (41.9)	75.7 (43.5)	78.2 (46.8)	65.7 (40.6)
	MedX (45)		95.7 (46.7)	85.4 (48.7)	75.9 (48.3)	80.3 (48.7)	77.8 (48.3)	75.0 (43.2)
	SMT (50)		89.1 (53.0)	95.6 (46.8)	91.3 (44.6)	90.9 (45.7)	88.8 (44.3)	83.1 (41.7)
Satisfaction	SMT/Exer (51)		74.4 (40.3)	76.9 (41.8)	70.8 (41.0)	67.7 (39.6)	64.7 (41.0)	54.4 (34.6)
	MedX (45)		85.0 (41.5)	87.0 (42.2)	83.1 (42.3)	88.0 (40.4)	85.1 (44.7)	82.5 (41.7)
	SMT (50)		103.3 (48.8)	95.2 (48.6)	91.7 (44.9)	91.9 (48.5)	96.8 (45.7)	88.3 (37.4)
OTC medication	SMT/Exer (51)	101.0 (57.4)	88.1 (46.9)	81.8 (42.2)	79.9 (42.8)	83.3 (43.1)	80.4 (45.0)	78.7 (40.6)
	MedX (45)	90.3 (50.1)	83.0 (45.2)	87.8 (46.1)	74.7 (40.4)	78.0 (44.4)	76.3 (43.2)	70.2 (38.1)
	SMT (50)	92.4 (52.4)	93.5 (50.1)	86.1 (46.0)	92.4 (46.4)	83.2 (45.5)	90.7 (47.9)	76.2 (42.9)

Includes only patients who provided data for all time points.
Pain: (0 = no pain, 10 = worst pain); Disability: (0 = no disability, 100 = maximal disability); Health status: (0 = poorest possible health status, 100 = best possible health status). OTC medication use, Improvement, and Satisfaction data are rank transformed. OTC medication use: (lower score = less medication use); Improvement: (lower score = more improvement); and Satisfaction: (lower score = more satisfaction).
OTC = over the counter; SMT/Exer = spinal manipulation combined with low-tech rehabilitative exercise; MedX = MedX rehabilitative exercise; SMT = spinal manipulation alone.

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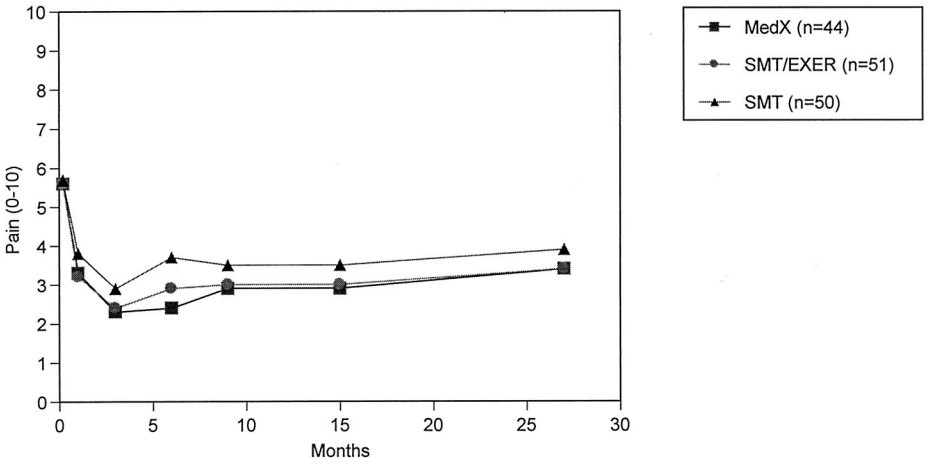

Figure 1. Patient-rated pain. Group means, baseline to 24 months post-treatment. Pain scale: 0 = no pain, 10 = worst pain. $P = 0.04$ in favor of the two exercise groups: SMT/Exercise *vs.* SMT ($P = 0.05$) and MedX *versus* SMT ($P = 0.02$).

provided self-report data for all time points over the 2-year follow-up period. A summary of patient flow and a detailed account of disqualifiers is reported in a previous publication.[3] Randomization resulted in three groups comparable on measured clinical and demographic characteristics[3] and are reported in Tables 1 and 2.

The means and standard deviations for all outcomes at all time points are reported in Table 2. Using repeated measures ANCOVA, a difference in patient-rated pain [$F_{(2,141)} = 3.2$; $P = 0.04$] with no group-time interaction was observed in favor of the two exercise groups [SMT/Exercise *vs.* SMT ($P = 0.05$); MedX *versus* SMT ($P = 0.02$)] (Figure 1).

Data for improvement, OTC medication use, and satisfaction were rank transformed. Repeated measures ANOVA showed a group difference in satisfaction with care [$F_{(2,143)} = 7.7$; $P = 0.001$], with SMT/Exercise superior to MedX ($P = 0.02$) and SMT ($P < 0.001$). No significant group differences were found for neck disability [$F_{(2,141)} = 2.6$; $P = 0.08$], general health status [$F_{(2,142)} = 2.5$; $P = 0.08$], improvement [$F_{(2,143)} = 1.9$; $P = 0.15$], and OTC medication use [$F_{(2,142)} = 1.3$; $P = 0.27$], although the trend over time was in favor of the two exercise groups.

Twenty-three patients reported increased neck or headache pain as a result of treatment, with approximately the same frequency of reporting among the three groups.[3]

Results of Supplementary Analyses

Controlling for early drop-outs, the pattern of missing data for all outcomes were determined to be missing either completely at random (MCAR) or at random (MAR) within each group, and therefore not related to measurement history.[24] The results of the analysis with imputed data (using both the expectation-maximization and regression methods) did not change the results of the original statistical analysis (data not shown).

The overall MANOVA showed a statistically significant group difference with no group-time interaction (Wilk's Lambda = 0.85)[$F_{(12,272)} = 1.9$; $P = 0.03$)],

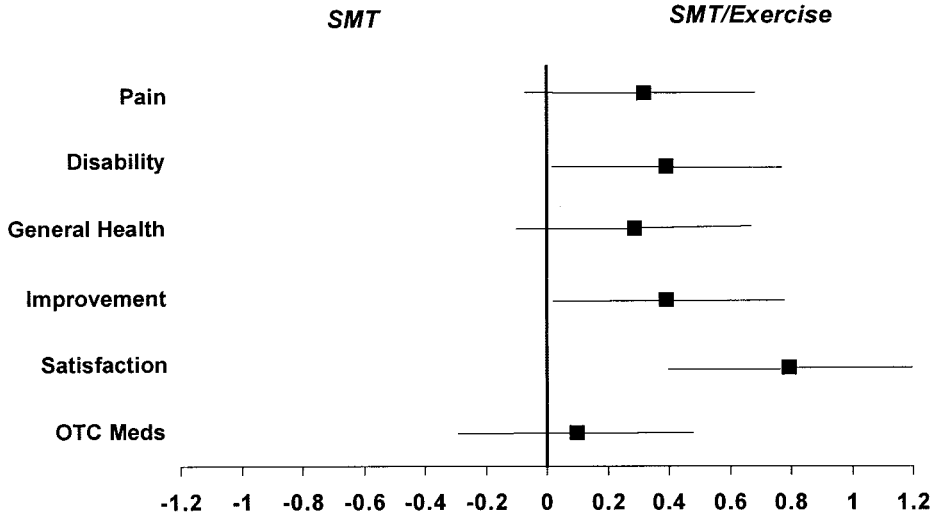

Figure 2. Effect size differences and 95% confidence intervals for SMT/Exercise *vs.* SMT (based on area under the curve calculations incorporating all time points).

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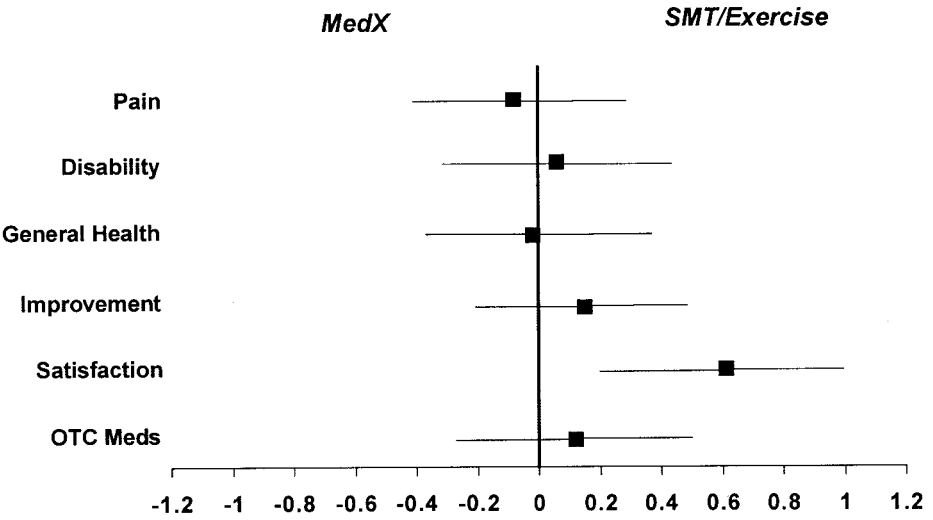

Figure 3. Effect size differences and 95% confidence intervals for SMT/Exercise *vs.* MedX (based on area under the curve calculations incorporating all time points).

with SMT being inferior to both the SMT/Exercise and MedX exercise groups.

Effect sizes and 95% confidence intervals were calculated for the area under the curve group differences (Figures 2–4). Near-medium effect size differences (0.3–0.4) were observed in favor of the two exercise groups in patient-rated pain, disability, health status, and improvement. Large effect size differences (0.6–0.8) in favor of SMT/Exercise were demonstrated for patient-rated satisfaction.

Sixty-nine patients sought additional health care use after the end of the study treatment phase; 23 in the SMT/Exercise group, 17 in MedX, and 29 in SMT (χ^2_2 = 3.6; P = 0.165). When the main analysis (repeated measures ANCOVA for patient-rated pain) was repeated with additional health care use as a covariate, the results did not change appreciably [$F_{(2,141)}$ = 3.0; P = 0.06]. The main analysis was also repeated including patient expectation as a covariate; the results of the sensitivity analysis were essentially the same as the original analysis [$F_{(2,141)}$=3.0; P = 0.05].

■ Discussion

Our study compared the relative long-term effects of spinal manipulation in combination with low-tech exercise, high-tech exercise, and spinal manipulation alone for chronic neck pain. The advantage of SMT/Exercise and MedX over SMT alone, observed after one year and reported previously,[3] persisted over the two-year follow-up period. Overall effect size differences varied from 0.3 to 0.4 in favor of the two exercise groups for patient-rated pain, disability, health status, and improvement. Admittedly, it is questionable whether these differences are clinically important.[17] Based on previous research, we determined *a priori* that a medium-effect size difference (0.5) would be considered clinically relevant. Thus, for these outcomes, the results fall just short of this cut-off point. The fact that there are consistent group differences in most outcome measures across time indicates the robustness of the results and suggests that although the differences may be small, they are likely real.

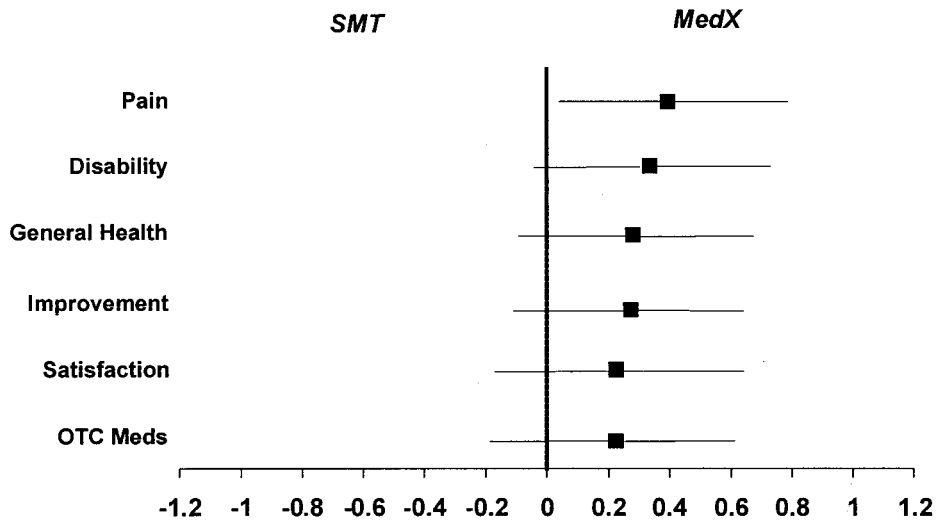

Figure 4. Effect size differences and 95% confidence intervals for MedX *vs.* SMT (based on area under the curve calculations incorporating all time points).

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Greater effect size differences of 0.6 to 0.8 were observed for patient satisfaction, favoring SMT/Exercise over MedX and SMT. Future studies using qualitative research methods may be helpful in assessing what "satisfaction with care" really means to patients and in assisting with the interpretation of studies similar to ours.

The long-term results of our study suggest an advantage for the two supervised exercise groups and are consistent with the findings of a recent randomized clinical trial by Taimela *et al* (n = 76).[31] They demonstrated that patients receiving 24 sessions of supervised exercise faired better than those who exercised at home, experiencing significantly fewer neck symptoms, greater general health, and improved working ability at 3 and 12 months.

Two other previous studies evaluating supervised, intensive exercise have had less promising results.[19,30] The studies by Randlov *et al*[30] and Jordan et al[19] had exercise programs of less frequency and intensity than what was provided in our study. This may explain the more encouraging results observed in our trial's exercise groups and suggests that dose (how much treatment and at what intensity) is an important factor in studies assessing supervised exercise for neck and back pain conditions.[19,26]

Additional health care use during follow-up periods can affect outcomes, especially those that are long-term. After two years, there was no statistically significant difference between groups in terms of additional health care use in this study. However, patients in the SMT group sought the most additional care (29 patients), and those in the MedX group sought the least (17 patients). Thus, the effect of additional care in this trial may have resulted in an overestimate of the treatment effect in the SMT group, and an underestimate of treatment group differences, particularly between the SMT and MedX group. When additional health care use was factored into the main repeated measures analysis, the significant differences in patient-rated pain between groups remained.

Patients in this study were recruited through newspaper advertising, possibly limiting the extent to which the results can be generalized to clinical settings. However, there is evidence to suggest that recruitment through advertising and clinical settings results in patients with similar demographic and clinical characteristics.[9,22] Importantly, patient demographics in this study were similar to those in the Jordan *et al* study,[19] in which patients were recruited mostly through family physician referrals.

■ Conclusion

In this study, an advantage of SMT/Exercise and MedX over SMT alone was maintained over the two-year follow-up period. The SMT/Exercise group was most satisfied with the care they received. These findings suggest that treatments including supervised rehabilitative exercise should be considered for chronic neck pain patients. Further studies are needed to explore the cost effectiveness of these treatments and assess how spinal manipulation compares to no treatment or a minimal intervention, such as a booklet or advice for self-care.

■ Key Points

- There have been few randomized clinical trials of treatments for neck pain that have included a two-year follow-up.
- This randomized clinical trial compared spinal manipulation combined with exercise, MedX exercise, and spinal manipulation for chronic neck pain over a two-year period.
- The two exercise groups had less pain than the spinal manipulation group, and patients who received spinal manipulation combined with exercise were most satisfied with care.
- Rehabilitative exercise appears to have positive effects for chronic neck pain sufferers two years after treatment.

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