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RANDOMIZED TRIAL

Supervised Exercise With and Without Spinal Manipulation Performs Similarly and Better Than Home Exercise for Chronic Neck Pain

A Randomized Controlled Trial

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Study Design. Randomized controlled trial using mixed methods.
Objective. To evaluate the relative effectiveness of high-dose supervised exercise with and without spinal manipulation and low-dose home exercise for chronic neck pain.
Summary of Background Data. Neck pain is a common global health care complaint with considerable social and economic impact. Systematic reviews have found exercise therapy (ET) to be effective for neck pain, either alone or in combination with spinal manipulation. However, it is unclear to what extent spinal manipulation adds to supervised exercise or how supervised high-dose exercise compares with low-dose home exercise.
Methods. Two hundred and seventy patients with chronic neck pain were studied at an outpatient clinic. Patients were randomly assigned one of the following interventions: (1) high-dose supervised strengthening exercise with spinal manipulation (exercise therapy combined with spinal manipulation therapy [ET + SMT]), (2) high-dose supervised strengthening exercise (ET) alone, or (3) low-dose home exercise and advice (HEA). The primary outcome was patient-rated pain at baseline and at 4, 12, 26, and 52 weeks. Secondary measures were disability, health status, global perceived effect, medication use, and satisfaction.
Results. At 12 weeks, there was a significant difference in patient-rated pain between ET + SMT and HEA (1.3 points, $P < 0.001$) and ET and HEA (1.1 points, $P = 0.001$). Although there were smaller group differences in patient-rated pain at 52 weeks (ET + SMT *vs*. HEA, 0.2 points, $P > 0.05$; ET *vs*. HEA, 0.3 points, $P > 0.05$), linear mixed model analyses incorporating all time points yielded a significant advantage for the 2 supervised exercise groups (ET + SMT *vs*. HEA, $P = 0.03$; ET *vs*. HEA, $P = 0.02$). Similar results were observed for global perceived effect and satisfaction.
Conclusion. Supervised strengthening exercise with and without spinal manipulation performed similarly, yielding better outcomes than home exercise particularly in the short term. Various stakeholders' perspectives should be considered carefully when making recommendations regarding these therapies, taking into account side effects, preferences, and costs.
Key words: neck pain, exercise, manipulation, chiropractic, orthopedic, randomized clinical trial. **Spine 2012;37:903–914**

Neck pain is a common, global health care complaint with considerable social and economic impact. Up to 3 quarters of individuals worldwide experience neck pain at some time in their lives.[1,2] Although not life threatening, neck pain can limit work and activities of daily living and put significant burden on workers and employers in terms of work absenteeism.[1,3–5] Although most individuals who experience neck pain do not seek care, it is still one of the most commonly reported symptoms in primary care settings.[6,7] This has resulted in millions of ambulatory health care visits annually for neck pain conditions[8–10] and increasing health care expenditures.[11]

Systematic reviews have consistently found exercise therapy (ET) to be effective for neck pain, either alone or in combination with spinal manipulation or mobilization.[12–15] In a previous randomized clinical trial, we found that spinal manipulation combined with low-tech supervised ET and high-tech supervised exercise on its own resulted in significantly greater pain reduction 1 and 2 years after treatment than spinal manipulation alone.[16,17]

It remains unclear, however, to what extent spinal manipulation adds to supervised exercise for chronic neck pain or how more intensive supervised high-dose exercise compares

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with low-dose home exercise programs.[16,17] Given the differences in effort and costs, resolution of these questions has consequence for patients, providers, and policy makers. Finally, although the methodological quality of neck pain studies continues to improve, there is a need for rigorous trials that take into account patient preferences and views.[18–20]

The purpose of this mixed-methods randomized trial was to address these issues by evaluating the relative effectiveness of 3 treatment approaches for chronic neck pain: (1) high-dose supervised strengthening ET combined with spinal manipulation therapy (ET + SMT); (2) high-dose supervised strengthening ET alone; and (3) low-dose home exercise and advice (HEA). To assist with the interpretation of trial results, we explored patients' perspectives, specifically the issues they considered when determining their satisfaction with care and the outcomes that were most important to them.

MATERIALS AND METHODS

Participants

This study took place at the Wolfe-Harris Center for Clinical Studies at Northwestern Health Sciences University in Bloomington, Minnesota. The study was approved by the Northwestern Health Sciences University and the University of Minnesota institutional review boards, and written informed consent was obtained from all participants.

Patients were recruited through newspaper advertisements, community posters, and mass mailings in the Minneapolis/St. Paul, Minnesota, area. Interested individuals were screened for eligibility at 2 baseline appointments, 7 to 10 days apart, by clinicians blinded to the randomization schedule. Inclusion criteria were 18 to 65 years of age, primary complaint of mechanical, nonspecific neck pain (equivalent to grades I and II classification according to the Neck Pain Task Force[21,22]), pain duration of 12 weeks or more, and neck pain score of 3 or greater (0–10 scale).

Exclusion criteria were previous cervical spine surgery, neck pain referred from peripheral joints or viscera, progressive neurological deficits, existing cardiac disease requiring medical treatment, blood clotting disorders, diffuse idiopathic hyperostosis, inflammatory or destructive tissue changes of the cervical spine, significant infectious disease or other severe disabling health problems, substance abuse, pregnant or nursing women, pending or current litigation, or ongoing treatment of neck pain by other health care providers.

Randomization and Blinding

Randomization took place at the end of the second baseline appointment. Consecutively numbered, opaque envelopes with treatment assignment cards were created off-site by the statisticians prior to the start of enrollment, using a 1:1:1 allocation ratio and randomly mixed permuted blocks of different sizes.[23] The randomization schedule and block sizes were concealed from the study team. As patients became eligible, the envelopes were opened in consecutive order by study staff in the presence of the patient.

Trial Procedures and Outcome Measures

We collected patient demographic and clinical characteristics at the initial appointment through self-report questionnaires, clinical history, and physical examination. Self-report outcomes were measured 4 times during the 12-week treatment period (at 2 baseline appointments and at 4 and 12 weeks postrandomization). In addition, self-report outcomes were collected twice during the post-treatment period (at 26 and 52 wk) *via* mailed questionnaire. All self-report questionnaires were independently completed by patients free of investigator, study staff, or treatment provider influence.

We chose patient-rated pain, *a priori*, as the primary outcome measure, using the 11-box numerical rating scale: 0 (no symptoms) to 10 (highest severity of pain).[24–27] Secondary measures included the Neck Disability Index,[28] Medical Outcomes Study 36-Item Short Form Health Survey (SF-36),[29] global perceived effect,[30–32] medication use,[33] and satisfaction with care.[16,33] Objective biomechanical assessments of cervical spine motion, isometric strength, and static and dynamic endurance were performed at baseline and at 12 weeks by blinded examiners.[16]

We measured expectations prior to randomization in the self-report questionnaire by asking patients how they thought their neck pain would change in response to each of the study treatments. Response choices were much better, better, no change, worse, and much worse. Patients' additional health care use with nonstudy providers was documented in the self-report questionnaires. Side effects were recorded in the treatment notes at each visit; these were then classified using the National Institutes of Health Office of Human Subjects Research definitions for adverse events (*e.g.*, mild, expected).[34] As part of a qualitative study conducted alongside the randomized trial, standardized, face-to-face interviews were conducted at the week 12 visit. Patients were queried regarding which outcomes they considered most important and the factors they considered when determining their satisfaction with care.

Description of Interventions

The treatment period was 12 weeks. Patients had to attend 80% of their scheduled treatment visits to be considered compliant with treatment; those who did not complete the regimen were considered to have discontinued treatment, but were followed up to the extent possible and remained in the intention-to-treat analysis. Side effects of treatment were documented by the treatment providers in progress notes. The exercise component of the 3 interventions was classified according to type, program design, delivery, and dose as described by Hayden *et al*.[35]

Exercise Therapy

ET was provided by exercise therapists under the supervision of study clinicians. The program was based on 1 tested in a previous trial.[16,17] The exercise type was predominantly neck and upper body strengthening and was partially individualized in terms of intensity (*i.e.*, load and repetitions)

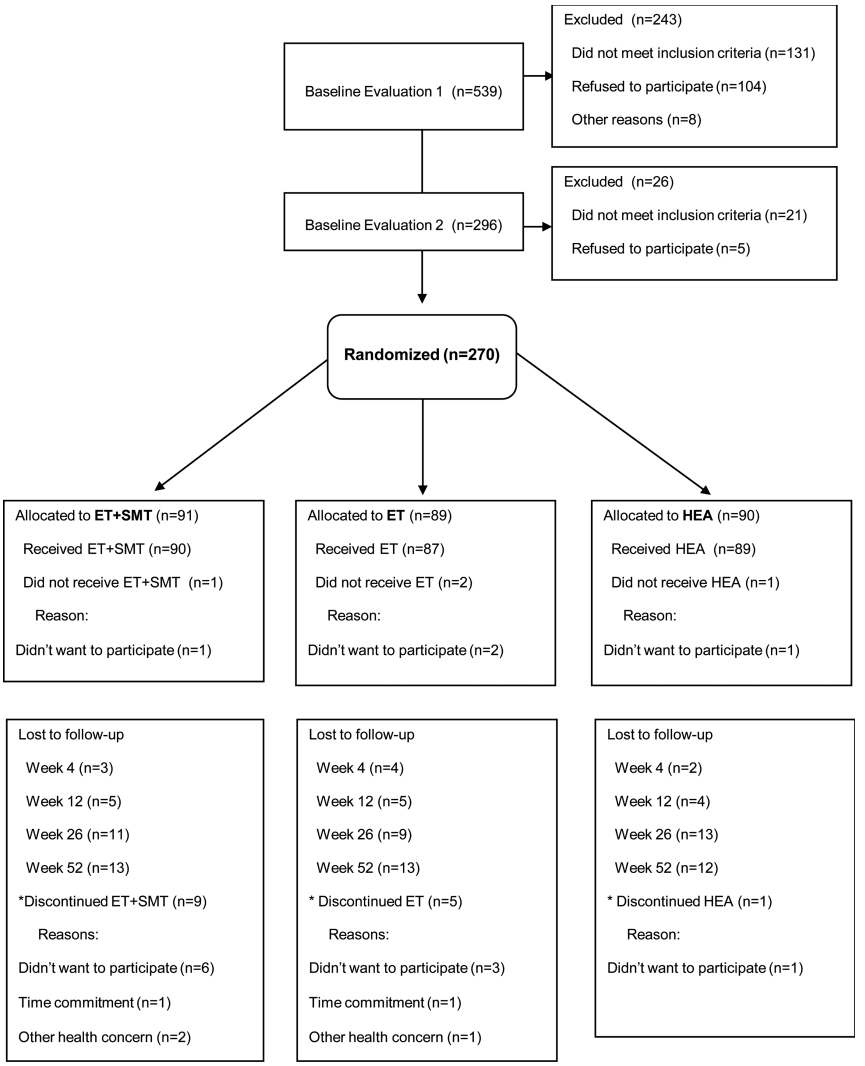

Figure 1. Flow of participants. ET + SMT indicates exercise therapy combined with spinal manipulation therapy; ET, exercise therapy; HEA, home exercise and advice.

according to patients' abilities. The delivery method was one-on-one supervision and high dose[35] entailing 20, 1-hour sessions, with an emphasis on high numbers of repetitions and progressively increased loads. The main focus was cervical strengthening exercises using low-tech methods performed with the patient lying on a therapy table, wearing headgear with variable weight attachments (1.25–10 lb) guided by a simple pulley system attached to the table. Three sets of 15 to 25 repetitions of dynamic neck extension, flexion, and rotation exercises were performed.[16,17] Upper body strengthening exercises included push-ups and dumbbell shoulder and chest exercises.[36] The strengthening program was supplemented by light aerobic warm-up (5 min) and stretching before and after strengthening.[16,17,36]

Exercise Therapy Combined With Spinal Manipulation Therapy (ET + SMT)

Patients in the ET combined with spinal manipulation therapy (ET + SMT) group received 20 sessions of ET (as described earlier) preceded by a 15- to 20-minute session with a licensed chiropractor who administered spinal manipulation therapy (SMT). The spinal levels treated were determined using static and/or motion palpation.[37] Sessions focused mainly on manual SMT to the cervical and thoracic spines using high velocity, low amplitude thrust procedures applied to the joints of interest.[38] Up to 5 minutes of light soft tissue massage was used as indicated to facilitate therapy.

Home Exercise and Advice

Patients in the HEA group attended two, 1-hour sessions with therapists under the supervision of study clinicians. The exercise type was simple self-mobilization (gentle controlled movements) of the neck and shoulder joints, including neck retraction, extension, flexion, rotation, and lateral bending motions, as well as scapular retraction, with no resistance. The program was individualized in terms of patients' abilities, tolerance, and activities of daily living. The delivery method was one-on-one with a therapist, with instructions for patients to perform the exercises on their own. Patients were instructed to do 5 to 10 repetitions of each exercise in the series, up to 6 to 8 times per day. A booklet[39] and laminated cards with photographs of the prescribed exercises were provided. Sessions were supplemented with information regarding the basic anatomy of the cervical spine, advice on posture, and practical demonstrations with instructions for lifting, pushing, pulling, and

TABLE 1. Demographic and Clinical Characteristics of Participants

	ET + SMT	ET	HEA	Total
Number of participants	91	89	90	270
Age (yr)	44.1 ± 11.6	48.7 ± 9.6	46.0 ± 10.4	46.3 ± 10.7
% female	71.4	73.0	72.2	72.2
% married/living with someone	62.6	73.0	65.6	67.0
% college graduate	36.3	34.8	51.1	40.7
% current smoker	15.4	7.9	13.3	12.2
BMI (kg/m^2)	27.5 ± 4.7	28.1 ± 5.2	27.6 ± 5.5	27.7 ± 5.1
Duration of neck pain (yr)	8.8 ± 9.1	10.4 ± 9.6	8.9 ± 8.8	9.4 ± 9.1
Frequency of neck pain (0–5)	3.7 ± 0.9	4.0 ± 0.8	3.8 ± 0.9	3.8 ± 0.9
% diagnosis pain + radiation	22.0	30.7	28.9	27.1
% neck pain trauma				
Auto accident	14.3	15.7	13.3	14.4
Work or leisure accident	14.3	14.6	8.9	12.6
Depression (CES-D) score (0–100)	16.2 ± 12.3	13.2 ± 9.9	17.0 ± 12.3	15.5 ± 11.6
Neck pain (0–10)	5.6 ± 1.4	5.7 ± 1.3	5.5 ± 1.4	5.6 ± 1.4
Neck disability score (0–100)	27.8 ± 9.0	26.1 ± 9.8	28.6 ± 8.8	27.5 ± 9.2
SF-36 Physical component score*	45.7 ± 6.4	46.6 ± 6.8	44.6 ± 6.9	45.6 ± 6.8
SF-36 Mental component score*	51.5 ± 9.9	53.7 ± 9.2	51.6 ± 10.6	52.3 ± 9.9
Days medication use in past week	2.4 ± 2.3	2.2 ± 2.1	2.7 ± 2.1	2.4 ± 2.2
Expectation of treatment (1–5)†				
Expectation of ET + SMT	1.4 ± 0.5	1.4 ± 0.5	1.5 ± 0.6	1.4 ± 0.5
Expectation of ET	1.7 ± 0.5	1.6 ± 0.5	1.8 ± 0.5	1.7 ± 0.5
Expectation of HEA	2.1 ± 0.7	2.0 ± 0.7	2.1 ± 0.6	2.1 ± 0.6

**Norm-based T-scores are presented for SF-36.*

†Expectation scale (1–5): much better = 1; much worse = 5.

ET + SMT indicates exercise therapy combined with spinal manipulation therapy; ET, exercise therapy; HEA, home exercise and advice; BMI, body mass index.

other daily actions. Basic ergonomic advice aimed at minimizing neck strain was offered, including seated postures, computer placement, and desk organization. Patients were followed up in-person 1 to 2 weeks later and then instructed to continue the exercises on their own for the remainder of the intervention phase. We considered the program to be of low dose due to the simplicity of the exercises, time required to perform them (2–3 min per series), the lack of resistance and load on the cervical musculature, and the low number of provider visits.

Sample Size

The sample size calculation was based on an expectation of observing an 8 percentage point difference between the highest and lowest of the group means in patient-rated neck pain (the main outcome).[16,17] With a power of 0.80 and a 3-group design tested at an alpha level of 0.05 (2-tailed test), 77 subjects per group were required (SPSS SamplePower 1.0 International Business Machines, Armonk, NY). We allowed for a loss to follow up rate of 15%. Therefore, we aimed to recruit 90 patients per group, for a total of 270 participants.

Data Analysis

Intention-to-treat analyses were used. We evaluated changes in patient-rated outcomes at the individual time points for weeks 4, 12, 26, and 52 using analysis of covariance, with mean baseline values as covariates. We also used linear mixed model analyses (SAS 9.1, MIXED procedure, SAS Institute, Cary, NC) to assess group differences using data from weeks 4 and 12 (short-term outcomes) and weeks 4, 12, 26, and 52 (long-term outcomes), with baseline values as covariates.[40–45] All available data were used for analyses, including data from

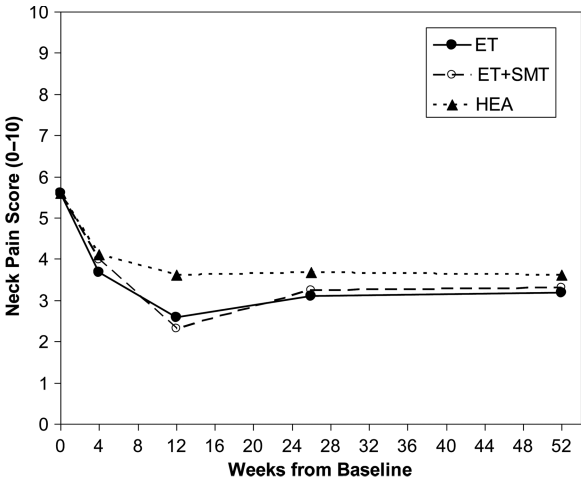

Figure 2. Mean values of patient-rated neck pain over time. ET + SMT indicates exercise therapy combined with spinal manipulation therapy; ET, exercise therapy; HEA, home exercise and advice.

participants who missed visits at random or because of attrition. Adjustments for multiple comparisons were performed using the Tukey correction.

We evaluated changes in objective biomechanical motion and strength measures using analysis of covariance. Two of the investigators performed the content analysis of interviews as part of the qualitative study.[46] Frequencies of thematic categories were then calculated and described.

Missing data analyses were performed by repeating the original analyses using imputation of data missing at random (MI procedure SAS 9.1) and data missing because of attrition.[47,48] The proportions of patients who reported additional health care use and side effects were tested with χ^2 analysis. Finally, to interpret the clinical importance of results, the relative risk and absolute risk reduction (with 95% confidence intervals) were calculated on the basis of the proportion of patients reporting a 2.5-point reduction in pain on the numerical rating scale.[49–51]

RESULTS

Study Population

A total of 539 individuals were evaluated for the study, of which 270 were randomized (ET + SMT = 91; ET = 89; HEA = 90). Overall, 92% of study participants attended at least 80% of their treatment visits (ET + SMT = 89%; ET = 92%; HEA = 98%). A summary of patient recruitment, participation, and attrition across the length of the study is shown in Figure 1.

Demographic and clinical characteristics of randomized participants are summarized in Table 1. Randomization resulted in 3 groups comparable on most baseline variables. Differences between groups were noted for age, duration, and frequency of symptoms. These variables were factored in as covariates in the statistical analyses. Nearly 3 quarters (72%) of participants were women. The mean duration of neck pain was 9.4 years and was moderate in severity (5.6). All 3 groups reported similar prerandomization expectations for study interventions, with the lowest expectations given for the HEA group.

Outcomes

All 3 groups demonstrated improved outcomes during the 12-week treatment period. Consistent trends were observed for all outcomes, with the ET + SMT and ET groups performing similarly and better than the HEA group. Figure 2 illustrates the mean values of the primary outcome, patient-rated pain over time. Table 2 displays mean values for all patient-rated outcome measures at each time point.

At 12 weeks, significant between-group differences were noted in favor of the ET + SMT and ET groups compared with HEA for pain, global perceived effect, and satisfaction ($P \leq 0.001$). The ET + SMT group also demonstrated a significantly greater reduction in disability than the HEA group ($P = 0.001$). Table 3 illustrates the mean group differences. With the exception of disability, these findings were confirmed by the linear mixed model analyses, taking into account weeks 4 and 12 measures. No significant differences between groups were observed for the other self-report measures in the short term.

At 52 weeks, the advantage of the ET + SMT and ET groups compared with HEA diminished, with no significant between-group differences observed except for satisfaction (ET + SMT *vs.* HEA, $P = 0.001$; ET *vs.* HEA, $P = 0.028$). However, the linear mixed model analyses, which included all time points through 52 weeks, yielded significant differences in favor of the ET + SMT and ET groups *versus* HEA for pain, global perceived effect, and satisfaction (Table 3). No other significant differences between groups were observed in the long term.

Results of the neck muscle strength, endurance, and motion tests at 12 weeks are shown in Table 4. Significant group differences were observed for static flexion, dynamic flexion, dynamic extension, and left and right rotation isometric strength. All differences were in favor of the 2 supervised exercise groups, except for static flexion, in which ET + SMT was significantly better than both ET and HEA.

From the week 12 qualitative interviews, we determined that the most important outcome to patients was pain severity (55% of participants). Also, the most prevalent issue when determining overall satisfaction with care was interaction with study personnel (62% of participants), which was cited more frequently in the 2 supervised exercise groups (ET + SMT = 56/72, ET = 48/69, HEA = 25/68; $\chi^2 = 27.6$, $P < 0.001$). Detailed results of the qualitative analysis will be reported elsewhere.

Results of the missing data analyses were consistent with results of the primary and secondary analyses. By week 52, a total of 64 individuals sought additional health care after the end of the study treatment phase, with no significant differences noted between groups (ET + SMT = 23, ET = 23, and HEA = 18; $P = 0.545$).

All except 1 documented side effect were classified as mild and expected (transient in nature, requiring little or no

TABLE 2. Mean Values for Patient-Rated Outcomes at Each Time Point

Outcome	Group	Baseline	Week 4	Week 12	Week 26	Week 52
Pain	ET + SMT	5.6 ± 1.4	4.0 ± 1.9	2.3 ± 1.8	3.3 ± 2.2	3.4 ± 2.3
	ET	5.7 ± 1.3	3.7 ± 2.0	2.6 ± 1.9	3.1 ± 2.3	3.1 ± 2.2
	HEA	5.5 ± 1.4	4.1 ± 1.8	3.6 ± 2.1	3.7 ± 2.3	3.6 ± 2.3
Disability	ET + SMT	27.8 ± 9.0	21.4 ± 9.8	14.5 ± 9.5	17.3 ± 11.3	18.0 ± 11.3
	ET	26.1 ± 9.8	20.4 ± 10.8	16.0 ± 11.3	16.8 ± 13.4	17.5 ± 13.3
	HEA	28.6 ± 8.8	21.9 ± 10.0	19.6 ± 10.5	19.4 ± 10.7	19.3 ± 10.9
SF-36 Physical*	ET + SMT	45.7 ± 6.6	47.5 ± 7.4	50.7 ± 6.7	50.1 ± 7.1	50.0 ± 6.4
	ET	46.6 ± 6.8	48.4 ± 6.6	50.1 ± 6.6	50.4 ± 7.5	49.8 ± 7.2
	HEA	44.6 ± 6.9	48.0 ± 6.5	48.7 ± 6.6	49.1 ± 7.1	49.4 ± 6.2
SF-36 Mental*	ET + SMT	51.5 ± 9.9	52.9 ± 9.3	53.9 ± 9.8	53.5 ± 8.8	53.0 ± 8.9
	ET	53.7 ± 9.2	54.8 ± 8.0	54.6 ± 9.7	54.8 ± 9.1	54.8 ± 8.5
	HEA	51.6 ± 10.6	52.6 ± 9.0	52.7 ± 9.4	51.8 ± 9.2	52.5 ± 8.7
Medication use†	ET + SMT	2.4 ± 2.3	2.1 ± 2.1	1.4 ± 1.9	1.6 ± 2.1	1.9 ± 2.3
	ET	2.2 ± 2.1	1.9 ± 2.2	1.5 ± 2.1	1.5 ± 2.0	2.0 ± 2.3
	HEA	2.7 ± 2.1	2.0 ± 2.1	1.8 ± 2.2	2.1 ± 2.4	2.1 ± 2.3
Global perceived effect‡	ET + SMT	NA	3.4 ± 1.2	2.6 ± 1.0	3.0 ± 1.4	3.2 ± 1.5
	ET	NA	3.5 ± 1.2	2.7 ± 1.2	3.0 ± 1.6	3.3 ± 1.7
	HEA	NA	3.9 ± 1.3	3.5 ± 1.5	3.3 ± 1.3	3.5 ± 1.5
Satisfaction§	ET + SMT	NA	1.9 ± 0.8	1.6 ± 0.7	1.8 ± 0.9	2.1 ± 1.1
	ET	NA	2.1 ± 0.9	1.8 ± 0.9	2.1 ± 1.1	2.4 ± 1.3
	HEA	NA	3.0 ± 1.1	2.9 ± 1.1	2.7 ± 1.1	2.9 ± 1.3
Number of participants‖	ET + SMT	91	88	86	80	78
	ET	89	85	84	79	76
	HEA	90	88	86	77	78

Values are means and standard deviations. Low scores are more desirable (e.g., less severity or more improvement) than high scores, except for SF-36 measures, in which high scores are more desirable than low scores.

**SF-36 scores are t-transformed.*

†Medication use was measured by asking how many days in the past week participants had taken pain-relieving medication for their neck pain.

‡Global perceived effect was assessed by querying how much participants' neck pain changed since starting treatment in the study; response choices were 1 = 100% improvement to 9 = 100% worse.

§Satisfaction was measured by asking how satisfied participants were with the care they had received for their neck pain; responses ranged from 1 = completely satisfied to 7 = completely dissatisfied.

‖Numbers shown are for patients who provided data for the main outcome, self-reported pain.

ET + SMT indicates exercise therapy combined with spinal manipulation therapy; ET, exercise therapy; HEA, home exercise and advice.

change to activity levels, and no therapy or only symptomatic therapy). Side effects were more frequently reported in the 2 supervised exercise groups (ET + SMT = 90/91, ET = 86/89, HEA = 30/90; $\chi^2 = 137.9$, $P < 0.001$) and included muscle soreness, upper extremity symptoms, headache, back pain, jaw pain, nausea, and dizziness. Specifically, 4 of these patients (ET + SMT = 1, ET = 3) required a short course of prescription medication during the 12-week intervention period due to increased pain. One additional patient in the ET group experienced a moderate, unexpected event as a result of a 1-lb weight slipping during exercise setup. She required 1 suture to the upper lip and repair to a dental bridge.

Table 5 shows the proportion of patients, relative risk, and absolute risk reduction for clinically meaningful improvements in the primary outcome, patient-rated pain. Greater number of patients in the 2 supervised exercise groups

TABLE 3. Short- and Long-Term Between-Group Differences for Patient-Rated Outcomes

Outcome	Group Comparisons	Week 12			Week 52		
		Mean Difference (95% CI)*	*P*	Short term, *P*†	Mean Difference (95% CI)*	*P*	Long term, *P*‡
Pain	ET + SMT *vs*. ET	–0.19 (–0.89 to 0.51)	1.000	0.859	0.07 (–0.77 to 0.91)	1.000	0.820
	ET + SMT *vs*. HEA	–1.27 (–1.96 to –0.58)	<0.001	0.003	–0.22 (–1.05 to 0.61)	1.000	0.030
	ET *vs*. HEA	–1.07 (–1.77 to –0.38)	0.001	0.002	–0.29 (–1.13 to 0.55)	1.000	0.020
Disability	ET + SMT *vs*. ET	–2.26 (–5.43 to 0.92)	0.265	0.202	–0.97 (–4.70 to 2.77)	1.000	0.217
	ET + SMT *vs*. HEA	–4.66 (–7.80 to –1.52)	0.001	0.028	–0.08 (–3.76 to 3.60)	1.000	0.086
	ET *vs*. HEA	–2.40 (–5.56 to 0.76)	0.205	0.367	0.89 (–2.83 to 4.60)	1.000	0.638
SF-36 Physical	ET + SMT *vs*. ET	0.89 (–1.19 to 2.97)	0.192	0.665	0.79 (–1.52 to 3.10)	1.000	0.338
	ET + SMT *vs*. HEA	1.64 (–0.42 to 3.67)	0.167	0.866	–0.11 (–2.38 to 2.16)	1.000	0.670
	ET *vs*. HEA	0.75 (–1.32 to 2.82)	1.000	0.792	–0.90 (–3.20 to 1.40)	1.000	0.598
SF-36							
Mental	ET + SMT *vs*. ET	0.29 (–2.59 to 3.17)	1.000	0.869	–0.91 (–3.55 to 1.74)	1.000	0.778
	ET + SMT *vs*. HEA	0.88 (–1.98 to 3.73)	1.000	0.486	–0.09 (–2.71 to 2.53)	1.000	0.358
	ET *vs*. HEA	0.58 (–2.29 to 3.45)	1.000	0.394	0.81 (–1.81 to 3.44)	1.000	0.235
Medication use	ET + SMT *vs*. ET	–0.09 (–0.77 to 0.59)	1.000	0.854	–0.15 (–0.10 to 0.70)	1.000	0.610
	ET + SMT *vs*. HEA	–0.24 (–0.91 to 0.43)	1.000	0.905	0.08 (–0.76 to 0.92)	1.000	0.700
	ET *vs*. HEA	–0.15 (–0.83 to 0.52)	1.000	0.947	0.22 (–0.62 to 1.07)	1.000	0.890
Global perceived effect	ET + SMT *vs*. ET	–0.12 (–0.60 to 0.36)	1.000	0.376	–0.03 (–0.66 to 0.61)	1.000	0.345
	ET + SMT *vs*. HEA	–0.82 (–1.29 to –0.35)	<0.001	<0.001	–0.18 (–0.81 to 0.45)	1.000	0.001
	ET *vs*. HEA	–0.70 (–1.17 to –0.23)	0.001	0.001	–0.15 (–0.78 to 0.48)	0.967	0.013
Satisfaction	ET + SMT *vs*. ET	–0.27 (–0.61 to 0.08)	0.173	0.099	–0.29 (–0.80 to 0.22)	0.723	0.077
	ET + SMT *vs*. HEA	–1.33 (–1.67 to –1.00)	<0.001	<0.001	–0.75 (–1.26 to –0.25)	0.001	<0.001
	ET *vs*. HEA	–1.07 (–1.41 to 0.73)	<0.001	<0.001	–0.47 (–0.97 to 0.04)	0.028	<0.001

**Individual time point differences (means) with 95% confidence intervals and P values are based on analysis of covariance, with baseline values as covariates.*

†P value for group differences based on linear mixed model analyses using weeks 4 and 12 data.

‡P value for group differences based on linear mixed model analyses using weeks 4, 12, 26, and 52 data.

CI indicates confidence interval; ET + SMT, exercise therapy combined with spinal manipulation therapy; ET, exercise therapy; HEA, home exercise and advice.

(65%–74% at 12 wk and 51%–57% at 52 wk) experienced the prespecified 2.5-point reduction in pain, compared with home exercise (42% at 12 wk and 41% at 52 wk).

DISCUSSION

Statement of Principal Findings

This study suggests that high-dose supervised strengthening exercise with or without manipulation results in greater pain reduction, global perceived effect, and satisfaction than low-dose home mobilization exercise and advice for chronic neck pain, particularly in the short term. The 2 supervised exercise groups were not significantly different from one another in terms of any of the patient-rated outcomes, suggesting that spinal manipulation confers little additional benefit when added to supervised exercise for chronic neck pain.

Strengths and Weaknesses of the Study

Strengths of this study include a high level of adherence to the study interventions and no observed group differences in cointerventions, which enhances our confidence in the study results. Also, to aid future systematic review efforts and clinical interpretation, we have described the exercise interventions, using a standardized classification format (*i.e.*, type, program design, delivery, and dose).[35]

A limitation of this study is that it was not designed to differentiate between the specific effects of the exercise and spinal manipulation treatments and the contextual, or

TABLE 4. Between-Group Differences in Changes in Strength, Endurance, and Motion Outcomes

Outcome	Group Comparisons	Week 12 Difference (95% CI)	*P*
Isometric extension strength (lb)	ET + SMT *vs.* ET	–0.87 (–3.97 to 2.22)	1.000
	ET + SMT *vs.* HEA	2.04 (–1.03 to 5.12)	0.149
	ET *vs.* HEA	2.92 (–0.15 to 5.98)	0.079
Isometric flexion strength (lb)	ET + SMT *vs.* ET	0.13 (–2.07 to 2.33)	1.000
	ET + SMT *vs.* HEA	1.21 (–0.99 to 3.40)	0.053
	ET *vs.* HEA	1.08 (–1.11 to 3.26)	0.314
Isometric right rotational strength (lb)	ET + SMT *vs.* ET	0.52 (–0.92 to 1.96)	0.530
	ET + SMT *vs.* HEA	2.21 (0.78 to 3.64)	<0.001
	ET *vs.* HEA	1.70 (0.26 to 3.13)	0.008
Isometric left rotational strength (lb)	ET + SMT *vs.* ET	0.56 (–0.92 to 2.03)	0.742
	ET + SMT *vs.* HEA	2.27 (0.81 to 3.73)	<0.001
	ET *vs.* HEA	1.71 (0.25 to 3.18)	0.009
Static extension endurance (weight × s)	ET + SMT *vs.* ET	93.33 (–179.88 to 366.54)	0.647
	ET + SMT *vs.* HEA	173.82 (–98.72 to 446.37)	0.171
	ET *vs.* HEA	80.49 (–191.02 to 352.00)	1.000
Static flexion endurance (weight × s)	ET + SMT vs. ET	62.71 (–32.64 to 158.05)	0.040
	ET + SMT *vs.* HEA	72.75 (–22.64 to 168.14)	0.033
	ET *vs.* HEA	10.05 (–85.02 to 105.11)	1.000
Dynamic extension endurance (weight [lb] × maximum number of repetitions)	ET + SMT *vs.* ET	–8.22 (–69.86 to 53.42)	1.000
	ET + SMT *vs.* HEA	84.67 (23.18 to 146.16)	0.005
	ET *vs.* HEA	92.89 (31.63 to 154.15)	0.003
Dynamic flexion endurance (weight [lb] × maximum number of repetitions)	ET + SMT *vs.* ET	27.28 (–8.80 to 63.35)	1.000
	ET + SMT *vs.* HEA	64.07 (28.08 to 100.06)	<0.001
	ET *vs.* HEA	36.80 (0.95 to 72.65)	<0.001
Flexion/extension range of motion (°)	ET + SMT *vs.* ET	0.40 (–3.48 to 4.28)	1.000
	ET + SMT *vs.* HEA	–0.19 (–4.03 to 3.66)	1.000
	ET *vs.* HEA	–0.59 (–4.43 to 3.25)	1.000
Rotational range of motion (°)	ET + SMT *vs.* ET	–0.42 (–4.92 to 4.08)	1.000
	ET + SMT *vs.* HEA	0.58 (–3.87 to 5.04)	1.000
	ET *vs.* HEA	1.01 (–3.45 to 5.46)	1.000
Lateral bending range of motion (°)	ET + SMT *vs.* ET	0.12 (–3.54 to 3.78)	1.000
	ET + SMT *vs.* HEA	–0.48 (–4.11 to 3.16)	1.000
	ET *vs.* HEA	–0.60 (–4.23 to 3.03)	1.000

CI indicates confidence interval; ET + SMT, exercise therapy combined with spinal manipulation therapy; ET, exercise therapy; HEA, home exercise and advice.

nonspecific, effects, including patient-provider interactions and expectations. Rather, this study was intended to be pragmatic in nature, answering clinical questions regarding treatments offered in health care practice for which patients have varying degrees of experience and expectations. Also, the home exercise group was intentionally minimal in its approach in terms of time and resources and, as such, served as a control. Indeed, patients in all 3 groups had greater

TABLE 5. Clinically Meaningful Improvements in Pain for the 2 Supervised Exercise Groups *Versus* Home Exercise and Advice

	Number With 2.5-Point Change in NRS*	Proportion (95% CI)	Relative Risk (95% CI)	Absolute Risk Reduction (95% CI)
Week 12				
ET + SMT	64/86	0.74 (0.64–0.82)	1.78 (1.35–2.35)	0.33 (0.18–0.45)
ET	55/84	0.65 (0.55–0.75)	1.56 (1.17–2.10)	0.24 (0.09–0.37)
HEA†	36/86	0.42 (0.32–0.52)	…	…
Week 52				
ET + SMT	40/78	0.51 (0.40–0.62)	1.25 (0.89–1.78)	0.10 (–0.05–0.25)
ET	43/76	0.57 (0.45–0.67)	1.38 (0.99–1.92)	0.16 (0.00–0.30)
HEA†	32/78	0.41	…	…

**Numeric rating scale.*

†Comparison/control group.

CI indicates confidence interval; ET + SMT, exercise therapy combined with spinal manipulation therapy; ET, exercise therapy; HEA, home exercise and advice.

expectations of improvement for supervised exercise than for home exercise; this was likely due to obvious differences in dose and supervision. The observed between-group differences in some of the blinded strength measures in favor of the 2 supervised exercise groups (consistent with patient self-report measures) suggest that at least some of the demonstrated effects may be attributable to the high-dose strengthening exercise program (*i.e.*, number of sessions, repetitions, and load on the cervical musculature). We did not measure patients' long-term adherence with exercise and thus do not know whether that affected outcomes. However, an earlier study conducted by our group found no difference in outcomes at 1-year follow-up between those who complied with exercise and those who did not.[16]

Side effects were more frequently reported in the 2 supervised exercise groups; this was expected because of the dose and intensity of the exercise treatment; however, it is possible that side effects in the home exercise group were underreported because of our data collection methods (*i.e.*, side effects were queried at treatment visits, of which there were fewer for home exercise).

Another limitation of our study is that, like all research on exercise, we were unable to blind study participants to treatment group. This limitation was minimized by measuring expectations at baseline and factoring them into the statistical analyses.[19]

Strengths and Weaknesses of the Study in Relation to Other Studies

The clinical and baseline characteristics of our study population are similar to those observed in other studies (including primary care settings), which enhances the generalizability of our findings[18,51–53]; however, the growing variety of exercise types, program designs, delivery methods, and dosages (*e.g.*, repetitions, load, number of sessions) evaluated for chronic neck pain makes it difficult to compare our results with other studies.[15,35] The most comparable study is an earlier trial performed by our group, in which supervised high-dose, low-tech exercise with spinal manipulation was compared with supervised high-dose, high-tech exercise alone and spinal manipulation alone.[16,17] That study found an advantage for the 2 high-dose supervised exercise groups, with the magnitude of effects similar to what was observed in this study. Similar results were also reported by Walker *et al*,[52] who demonstrated a combination of manual therapy and exercise to be superior to minimal intervention (advice and home exercise), both in the short and the long term.

Furthermore, our study demonstrated that spinal manipulation conferred little additional benefit to supervised exercise. This seems consistent with the findings of Dziedzic *et al*,[54] who found that manual therapy in addition to a home exercise program and advice did not result in improved outcomes when compared with HEA alone. Our findings differ from the conclusions of the Task Force on Neck Pain and Its Associated Disorders[12] and systematic reviews,[14,15] which found an advantage for exercise combined with manual therapy for chronic neck pain. Contrary to the trials that were the basis for these reviews, our study design allowed us to evaluate the added benefit of spinal manipulation to high-dose supervised exercise. Importantly, our study was not designed to assess the effect of spinal manipulation alone. A recent Cochrane systematic review has found limited evidence to support spinal manipulation alone for the short-term relief of chronic neck pain.[19]

Meaning of the Study: Possible Explanations and Implications for Clinicians and Policymakers

There remains no standard method for interpreting the clinical importance of study results for patient-rated outcomes in neck and back pain studies.[55] One approach is to calculate standardized between-group effect sizes (between-group mean difference divided by the baseline standard

deviation).[56] In our study, the between-group differences for pain between the 2 supervised exercise groups and home exercise were 11 to 13 percentage points at week 12, which translated into large effect size differences (0.8–0.9); however, these group differences diminished to 3 to 6 percentage points by week 26 and 2 to 3 percentage points at week 52, which translate to small effect sizes (0.2–0.4). Although some have argued that even small between-group effect size differences are meaningful at the population level, others remain skeptical.[57] A complementary method to aid with study interpretation is the calculation of proportions of patients in each group who experience a prespecified clinical improvement.[51] We used a 2.5-point reduction for the primary outcome, patient-rated pain, to calculate relative risk and absolute risk reduction (Table 5).[49–51] Overall, similar proportions of patients in the 2 supervised exercise groups reported clinically meaningful improvements (ET + SMT = 74% and ET = 65% at 12 wk; ET + SMT = 51% and ET = 57% at 52 wk). Noteworthy, however, is the sizeable proportion of the home exercise group (41%–42%) who experienced meaningful improvements in pain in both the short term and the long term (Table 5). From a societal or payer's perspective, the benefits of frequent, supervised exercise, with or without manipulation, may not outweigh the associated time, effort, side effects, and costs when compared with a home exercise program.[58] Consequently, a low-dose home exercise program may be a prudent first line of therapy for people with chronic neck pain, which, if unsuccessful, could be followed by more aggressive, high-dose supervised exercise.

Careful consideration should be given to choosing the most appropriate exercise program for individual patients.[59] The time commitment, physical effort, and side effects associated with high-dose supervised exercise *versus* low-dose home exercise may be important factors in terms of patient willingness and compliance. Furthermore, the amount of supervision necessary to motivate patients is likely to vary among individuals. Future studies are needed to investigate individual preferences related to supervised and home exercise programs and their relationship to outcomes and program adherence for people with chronic neck pain.

CONCLUSION

Our study found that groups receiving high-dose supervised ET with and without spinal manipulation performed similarly, reporting less pain, greater global perceived effect, and more satisfaction than the low-dose home exercise group, particularly in the short term. The supervised exercise groups also demonstrated greater gains in blinded assessment of neck endurance and strength, supporting the patient-self report measures. The results of qualitative interviews suggest that personal attention played an important role in the supervised exercise groups. Various stakeholders' perspectives should be considered carefully when making recommendations regarding these therapies for chronic neck pain patients, taking into account side effects, preferences, and costs.

➢ Key Points

- ❑ ET, with or without spinal manipulation, has previously been shown to be more effective than other noninvasive treatments for nonspecific chronic neck pain. Little is known to what extent spinal manipulation contributes to clinical benefits.
- ❑ There has been little research comparing high-dose supervised exercise with low-dose home exercise programs.
- ❑ High-dose supervised exercise (with or without spinal manipulation) resulted in greater short-term pain reduction, global perceived effect, and satisfaction than low-dose home exercise for people with nonspecific chronic neck pain.
- ❑ No significant differences were found between supervised exercise with or without spinal manipulation, suggesting that spinal manipulation confers little additional benefit.
- ❑ A sizeable proportion of the home exercise group experienced clinically meaningful improvements in pain in both the short term and the long term. This suggests that home exercise may be a prudent first line of therapy for people with chronic neck pain, which, if unsuccessful, could be followed by more aggressive, high-dose supervised exercise programs.

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