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Spinal manipulative therapy and exercise for seniors with chronic neck pain

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Abstract

BACKGROUND CONTEXT: Neck pain, common among the elderly population, has considerable implications on health and quality of life. Evidence supports the use of spinal manipulative therapy (SMT) and exercise to treat neck pain; however, no studies to date have evaluated the effectiveness of these therapies specifically in seniors.

PURPOSE: To assess the relative effectiveness of SMT and supervised rehabilitative exercise, both in combination with and compared to home exercise (HE) alone for neck pain in individuals ages 65 years or older.

STUDY DESIGN/SETTING: Randomized clinical trial.

PATIENT SAMPLE: Individuals 65 years of age or older with a primary complaint of mechanical neck pain, rated ≥3 (0–10) for 12 weeks or longer in duration.

OUTCOME MEASURES: Patient self-report outcomes were collected at baseline and 4, 12, 26, and 52 weeks after randomization. The primary outcome was pain, measured by an 11-box numerical rating scale. Secondary outcomes included disability (Neck Disability Index), general health status (Medical Outcomes Study Short Form-36), satisfaction (7-point scale), improvement (9-point scale), and medication use (days per week).

METHODS: This study was funded by the US Department of Health and Human Services, Health Resources and Services Administration. Linear mixed model analyses were used for comparisons at

FDA device/drug status: Not applicable.

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individual time points and for short- and long-term analyses. Blinded evaluations of objective outcomes were performed at baseline and 12 weeks. Adverse event data were collected at each treatment visit.

RESULTS: A total of 241 participants were randomized, with 95% reporting primary outcome data at all time points. After 12 weeks of treatment, the SMT with home exercise group demonstrated a 10% greater decrease in pain compared with the HE-alone group, and 5% change over supervised plus home exercise. A decrease in pain favoring supervised plus HE over HE alone did not reach statistical significance. Compared with the HE group, both combination groups reported greater improvement at week 12 and more satisfaction at all time points. Multivariate longitudinal analysis incorporating primary and secondary patient-rated outcomes showed that the SMT with HE group was superior to the HE-alone group in both the short- and long-term. No serious adverse events were observed as a result of the study treatments.

CONCLUSIONS: SMT with HE resulted in greater pain reduction after 12 weeks of treatment compared with both supervised plus HE and HE alone. Supervised exercise sessions added little benefit to the HE-alone program.

Keywords: Neck pain; Elderly; Spinal manipulative therapy; Exercise; Improvement; Satisfaction

Introduction

Neck pain (NP) is a considerable health care problem for individuals of all ages [1,2]. Approximately 20% of individuals 70 years of age and older experience NP at least once a month [3]; among this population, NP is associated with other health complaints and poorer self-rated health [2]. Considering the rapid growth of the elderly population, the socioeconomic and public health consequences of NP are serious [4]. It has been recommended that commonly used pain medications should be tempered in elderly patients because of the risk of drug interaction and associated comorbidities [5]. This increases the need to investigate safe and cost-effective approaches to managing NP conditions without medications, while aiming to improve the general health and quality of life among the elderly.

Recent reviews of conservative therapies for mechanical neck disorders support the use of manual treatment, including manipulation or mobilization, and exercise [6–8]. However, this research has primarily focused on nonelderly individuals; there have been no studies to date that evaluate the effectiveness of these therapies for NP in seniors. Furthermore, nonintensive interventions like home exercise have performed similarly to supervised exercise and manual therapy in past studies [9,10] but have not been tested in an elderly population.

The purpose of this randomized clinical trial was to determine the relative short- and long-term effectiveness of spinal manipulative therapy with home exercise (SMT with home exercise), supervised rehabilitative exercise and home exercise (supervised plus home exercise), and home exercise alone for patients 65 years and older with NP by the use of change in average pain during the past week as the primary outcome.

Methods

This randomized clinical trial was conducted from 2004 to 2007 at the Wolfe-Harris Center for Clinical Studies at Northwestern Health Sciences University in Minneapolis, Minnesota. Approval was granted by the institutional review boards of all participating institutions and informed consent was obtained from all participants. Detailed explanations of study methods are reported elsewhere [11].

Inclusion criteria

Criteria for inclusion were 65 years of age or older, independent ambulation and community dwelling, a stable pain medication plan (no changes in the prior month), and a score of 20 points or greater on the Folstein Mini-Mental State Examination [12]. Individuals had to have a primary complaint of weekly, mechanical NP, including stiffness or tenderness originating from the spinal joints, discs, vertebrae, or soft tissue, with or without radiation or neurologic signs, with an average rating of ≥3 (0–10) over the previous 2 weeks [13,14].

Randomization and blinding

A restricted randomization sequence was computer generated with a 1:1:1 allocation ratio using randomly permuted block sizes, which were stored in a locked cabinet concealed from the study team. As individuals became eligible, sequentially numbered opaque envelopes with treatment assignments were drawn in consecutive order and opened by study staff in the presence of the study participant.

The nature of the interventions precluded blinding of patients and providers. Patient-rated outcomes were measured by self-report questionnaires independent of staff influence. Biomechanical assessment was conducted by study staff blinded to treatment assignment. Patient expectations of improvement for each intervention was collected before randomization by the use of a 5-point scale (1=much better, 2=better, 3=no change, 4=worse, 5=much worse) [15].

Interventions

All participants in the study received 12 weeks of care, which is described in detail elsewhere [11]. Standardized forms were used to document treatment. Adverse events were inquired about at each visit; documentation included categorization for seriousness and relatedness to treatment (http://ohsr.od.nih.gov/index.html). Providers, trained in study protocols, were monitored for compliance through chart audits, observations, and team meetings.

Home exercise

Home exercise consisted of four, 45- to 60-minute sessions provided by nine practitioners certified by study investigators to instruct the study intervention (exercise therapists or chiropractors) [11]. Participants were given basic information regarding pain management, including postural instructions and practical demonstrations of body mechanics for lifting, pushing, pulling, and rising from a lying position. To supplement consistent messaging to stay active, simple exercises were prescribed to do daily at home, to improve flexibility, balance, and coordination, as well as enhance trunk strength and endurance [16]. These included head retraction, cervical flexion and extension (either isometric or using resistance tubing), push-ups, chest press and seated upright rows with resistance tubing, and full spine flexion/extension motion cycles. Exercises were individualized based on patient ability and included graded progressions once 20 repetitions of an exercise could be done with proper form.

SMT with home exercise

Participants allocated to this group received SMT in addition to home exercise (described previously in this article) [11]. Care was delivered by 11 chiropractors with a minimum 5 years of clinical practice. Pain provocation [17] and static/motion palpation [18] findings were used to determine areas of treatment in the cervical spine. The focus of treatment was manual SMT, aimed at inducing joint motion using a diversified, thrust technique, and mobilization, a low-velocity type of joint oscillation [19]. The type of SMT and the force applied were modified to accommodate the age and physical condition of the study participants. Adjunct therapies common to clinical practice included limited use of light soft-tissue massage, assisted stretching, and hot and cold packs applied to the cervical and upper thoracic area. The number and frequency of treatments was determined by the individual chiropractor, with a maximum of 20 visits allotted to each patient.

Supervised rehabilitative exercise plus home exercise

Participants assigned to this group participated in supervised rehabilitative exercise in addition to home exercise (described previously in this article) [11]. A series of 20, 1-hour exercise sessions were supervised by one of nine exercise therapists certified to deliver the intervention by study investigators. Prescribed exercises were individualized in terms of intensity (ie, load and repetitions) according to patients' abilities. Similar to the home exercise program, emphasis was placed on performing high repetitions of low load exercises with the aim of increasing flexibility, endurance, strength, and balance. Supervised session expanded on the home program with supplementary exercises and progressions to challenge neck and upper torso strength and endurance, as well as balance, to participant tolerance. Exercise therapists supervised each session to monitor form, modify exercises, and provide encouragement to complete repetitions.

Outcome measures

Patient self-report outcomes were collected at baseline and 4, 12, 26, and 52 weeks after randomization [11]. The primary outcome measure was the average level of NP over the previous week, as measured using an 11-box numerical rating scale (0=no pain, 10=the worst pain possible) [20]. Self-report secondary outcomes included neck disability, general health status, satisfaction, global improvement, duration of medication use. Neck disability was measured on the Neck Disability Index, containing 10 items relevant to NP on a scale of 0 (no disability) to 5 (maximal disability); the total score of 50 is converted to percentage points [21]. General health status was measured by the Medical Outcomes Study Short Form-36 [22] and separated into mean physical and mental component scores. Satisfaction with care was measured on a 7-point scale from 1 (completely satisfied, couldn't be better) to 4 (neither satisfied nor dissatisfied) to 7 (completely dissatisfied, couldn't be worse) [23]. Global improvement in NP was measured on a 9-point scale from 1 (100% improvement) to 5 (0% improvement) to 9 (100% worse) [24]. Duration of medication use was the number of days during the previous week (0–7) that participants reported taking medication for their NP [25,26]. Biomechanical outcomes, including cervical motion, strength and endurance, as well as hand grip strength and ''Timed Up-and-Go'' tests [27,28], were collected at baseline and week 12 [11].

Cervical spine dynamic motion was measured using the Zebris CMS-HS Spine Motion Analyzer (Zebris Inc., Isny im Allgau, Germany) [29]. Isometric flexion and extension strength was measured by a computerized load-cell transducer dynamometer (Promotron 3000, Promatek Medical Systems, Joilet, IL, USA). Static endurance was measured with participants holding their head in flexion while supine, and in extension while prone, while holding 50% maximum voluntary contraction resistance until their muscles failed [25]. Hand grip strength was measured with the use of a hydraulic dynamometer (Jamar Hand dynamometer, Sammons Preston U.S.A., Bolingbrook, IL, USA).

Power calculations

Based on change scores in average pain intensity from previous studies dealing with the effectiveness of SMT and

exercise in chronic NP patients, we anticipated a difference between the groups of 8 percentage points in pain, the primary outcome. This translates to a near medium effect size of f=0.24 in both the short- and long-term [25]. With an alpha level of 0.05, 70 participants per group provided power of 0.88 to detect this difference. To allow for a drop-out rate of 15%, 240 participants (80 participants per group) were required.

Statistical analysis

The primary analysis evaluated changes in pain, the main outcome measure, between the three groups at week 12. In secondary analyses, differences in pain were also calculated at weeks 4, 26, and 52. Longitudinal analyses were performed for the short-term (weeks 4 and 12 data), and the long-term (weeks 4, 12, 26, and 52 data). All analyses used linear mixed model analysis, with the Tukey-Kramer adjustment for multiple comparisons (MIXED procedure in SAS 9.1) [30]. Baseline variables considered to be clinically different between groups were used as covariates in analysis if they were found to be correlated with change in pain (r=0.5 [31] or greater).

Additional analyses were conducted to assess group differences in secondary outcomes at individual time points and through the short and long term, using the methods described above. Intention-to-treat analysis included all participants with baseline data regardless of loss to follow-up.

We conducted multivariate analyses to assess consistency in the direction of short- and long-term differences between groups in terms of patient oriented outcomes while controlling for the problem of spurious significant findings due to multiple tests [32]. Outcomes included in these analyses were pain, disability, general health, satisfaction, and improvement. To take into account increasing time intervals between assessments and to represent the cumulative burden of NP over time, ‘‘areas under the curve’’ were calculated for each participant for all patient-oriented outcomes and tested for group differences with analysis of variance [33]. Change scores for biomechanical outcomes were analyzed for group differences from baseline using linear mixed model analysis.

To facilitate the interpretation of the magnitude of group differences, responder analyses were conducted using 30%, 50%, and 75% reductions in pain from baseline [34–36] and compared by group with 95% confidence intervals.

Sensitivity analyses were performed to reflect two different ways of handling missing data. The first method eliminated any participant with incomplete data and restricted analyses to those that remained; the second method used the SAS 9.1 procedure MI (SAS Institute, Cary, NC, USA) to impute values for both patterned and randomly missing data. Analyses were conducted to test assumptions of data normality and homogeneity for analysis of variance and covariance; any data not meeting these assumptions were rank transformed. Data were prepared for analysis by a data manager blinded to group status.

Results

Recruitment, retention, and baseline data

Of 593 individuals evaluated, 241 were enrolled in the study. A summary of patient recruitment, participation, and attrition is shown in Fig. 1. Baseline demographic and clinical characteristics were comparable across groups with two exceptions: grip strength and expectations (Table 1). Neither was found to be correlated with the primary outcome, and thus were not included as covariates in the analyses. Patient-rated outcomes for each time point and between-group comparisons are shown in Tables 2 and 3, respectively.

Primary outcome

There were statistically significant between-group differences in self-reported pain at 12 weeks in favor of the SMT with home exercise group compared with both the supervised plus home exercise, and home exercise–alone groups. The greatest difference was between the SMT with home exercise and home exercise–alone groups (approximately 10 percentage points). A decrease in pain favoring the supervised plus home exercise group compared with the home exercise–alone group was similar in magnitude to the contrast between the SMT with home exercise and supervised plus home exercise groups but was not statistically significant. The short-term longitudinal analysis showed more pain reduction in the SMT with the HE group compared with both the supervised plus home exercise, and home exercise–alone groups. The majority of this is based on between-group differences at the week 12 time point.

There were no significant between-group differences in pain during posttreatment follow-up at weeks 26 and 52. Although the long-term longitudinal analysis resulted in a statistically significant between-group difference in pain in favor of the SMT with home exercise group over the home exercise–alone group, the magnitude of difference at week 52 was one-third of what it was at 12 weeks. Similar to the short-term analysis, the long-term difference can be attributed mainly to between-group differences at the week 12 time point. Area under the curve analyses showed no statistically significant between-group differences in terms of pain through either the short- or long-term.

Secondary outcomes

There were statistically significant group differences in terms of improvement favoring the SMT with home

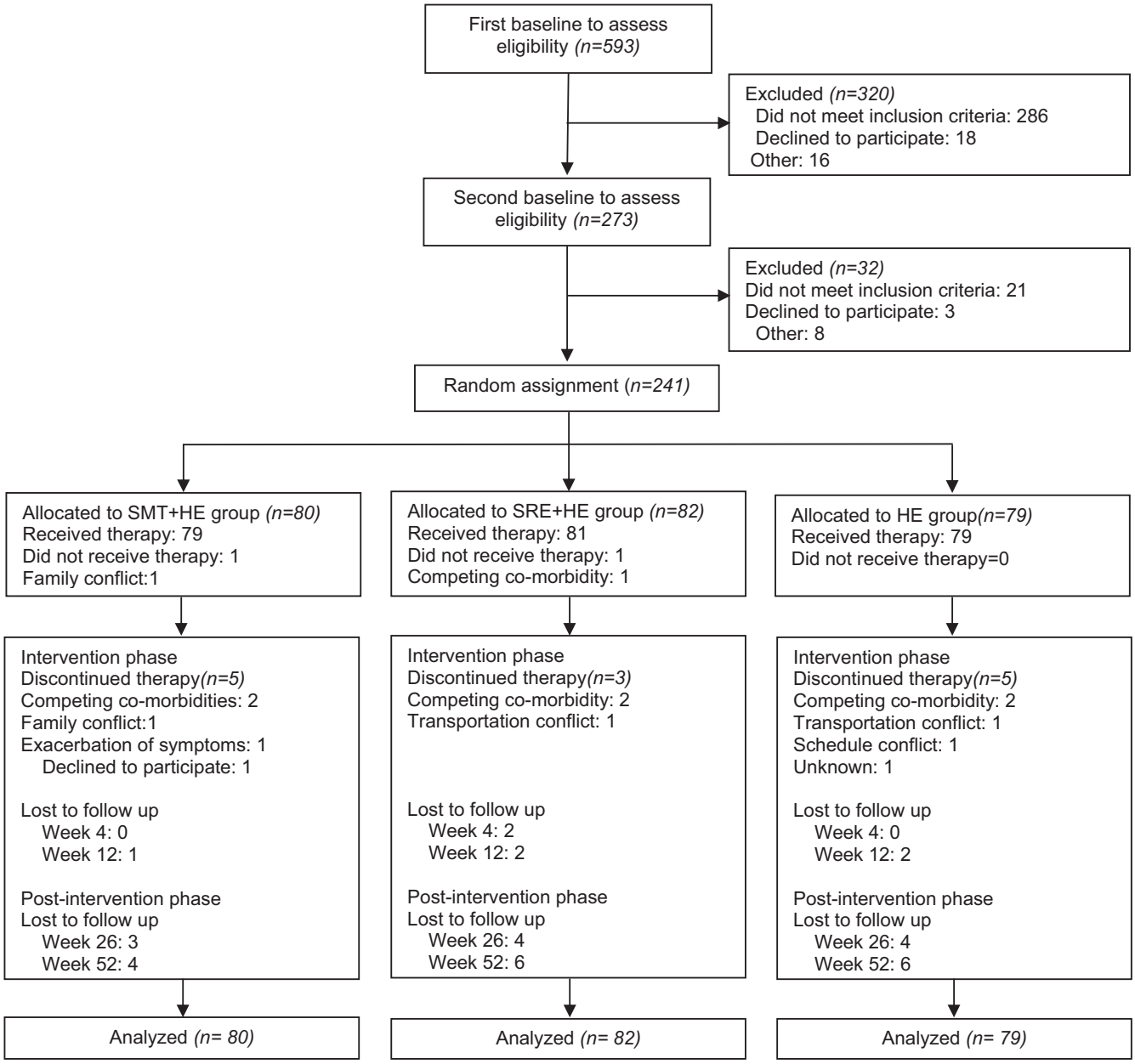

Fig. 1. Participant flow through the study. SMT+HE, spinal manipulative therapy with home exercise; SRE+HE, supervised rehabilitative exercise plus home exercise; HE, home exercise alone.

exercise group over the home exercise–alone group at week 12 and week 26, and favoring the supervised plus home exercise group over the home exercise–alone group at week 12. Both combination groups were more satisfied than the home exercise–alone group at all time points. The SMT with home exercise group reported a statistically significant decrease in duration of medication use compared with both groups at week 52. Area under the curve analysis showed an advantage of the SMT with home exercise group over the supervised plus home exercise group in terms of medication use in the long-term. There were small improvements across all groups in terms of disability and general health status, but nearly all between-group differences failed to reach statistical significance. There were no significant between-group differences in biomechanical outcomes (Table 4).

The multivariate analysis showed a statistically significant advantage of the SMT with home exercise group over the home exercise–alone group in both the short- and long-term, consistent with the pattern of results of the linear mixed model analysis.

Fig. 2 shows the proportions of participants by group who achieved or exceeded 30, 50, or 75% reduction in pain at the

Table 1
Baseline demographic and clinical characteristics

Characteristic	SMT+HE group	SRE+HE group	HE group
Participants, n	80	82	79
Mean age, y (SD)	71.7 (5.2)	72.6 (5.6)	72.7 (5.3)
Women, %	45.0	51.2	44.3
Height, cm (SD)	168.5 (9.8)	166.8 (8.9)	168.4 (9.7)
Weight, kg (SD)	78.9 (14.7)	77.5 (16.1)	82.2 (18.5)
Median duration of neck pain, y (interquartile range)	6.5 (2.0–19.0)	7.5 (1.8–20.0)	5.0 (2.0–15.0)
Pain radiating to upper extremity, %	16.3	13.6	21.5
Awake at night because of neck pain, %	37.5	35.4	40.5
Neck pain associated with automobile accident, %	10.0	17.1	7.6
Neck pain associated with work or leisure time trauma, %	13.8	15.9	10.1
Expectation, 1–5 (SD)	1.5±0.6	1.7±0.5	2.0±0.4
Handgrip strength, kg (SD)*	35.3 (9.5)	30.5 (9.6)	32.0 (11.3)
Timed Up and Go test, s (SD)	10.8 (2.1)	11.3 (2.4)	11.3 (2.4)

HE, home exercise alone; SMT+HE, spinal manipulative therapy with home exercise; SRE+HE, supervised rehabilitative exercise plus home exercise.
* Grip strength measurement was added late in the trial as exploratory and was collected on the last 166/241 participants.

week 12 and 52 follow-up time points. Group differences clearly favored SMT with home exercise over home exercise alone at week 12. These group differences were no longer present at week 52.

Missing data analysis

Of the 241 participants randomized, 228 (95%) provided data on the primary outcome, pain, at all time points; 239 provided data through week 12. Two participants died

Table 2
Patient-rated outcomes at individual time points

Variable	Group	Baseline	Week 4	Week 12	Week 26	Week 52
Pain						
Mean score (SD)	SMT+HE	5.3 (1.5)	3.9 (1.6)	2.3 (1.6)	2.9 (1.8)	3.1 (1.9)
	SRE+HE	4.9 (1.3)	4.0 (1.7)	2.7 (2.0)	3.2 (2.1)	3.0 (1.9)
	HE	4.9 (1.3)	3.8 (1.8)	3.2 (2.0)	3.3 (2.1)	3.2 (2.1)
Neck Disability Index						
Mean score (SD)	SMT+HE	22.8 (9.4)	18.6 (9.9)	14.4 (9.0)	14.8 (11.3)	15.8 (11.2)
	SRE+HE	22.9 (9.2)	20.2 (10.7)	14.7 (9.2)	17.1 (11.4)	16.6 (11.5)
	HE	24.2 (9.9)	20.1 (11.4)	16.9 (11.8)	17.7 (11.9)	18.3 (12.6)
Duration of medication use						
Mean (SD)	SMT+HE	2.6 (2.5)	2.2 (2.5)	1.8 (2.6)	1.6 (2.3)	1.5 (2.3)
	SRE+HE	2.9 (2.8)	2.9 (2.9)	2.3 (2.9)	2.1 (2.8)	2.5 (2.9)
	HE	2.7 (2.5)	2.2 (2.6)	2.2 (2.7)	2.3 (2.8)	2.2 (2.8)
Satisfaction with care						
Mean score (SD)	SMT+HE	NA	1.8 (0.7)	1.7 (0.8)	1.9 (0.9)	2.1 (1.1)
	SRE+HE	NA	1.9 (0.8)	1.7 (0.8)	1.9 (1.1)	1.8 (0.9)
	HE	NA	2.4 (1.1)	2.4 (1.2)	2.4 (1.0)	2.5 (1.3)
Global improvement						
Mean score (SD)	SMT+HE	NA	3.6 (1.1)	2.7 (1.1)	2.8 (1.3)	3.1 (1.6)
	SRE+HE	NA	3.8 (1.2)	2.9 (1.2)	3.1 (1.6)	3.1 (1.4)
	HE	NA	3.9 (1.1)	3.4 (1.3)	3.3 (1.5)	3.4 (1.7)
SF-36 score						
Physical component mean score (SD)	SMT+HE	44.5 (6.7)	45.6 (7.1)	47.1 (7.4)	46.4 (7.7)	46.0 (9.1)
	SRE+HE	43.6 (7.2)	44.8 (8.3)	46.7 (7.9)	45.7 (8.5)	45.2 (8.7)
	HE	41.9 (7.6)	43.6 (8.4)	45.4 (8.4)	44.7 (9.0)	44.9 (9.2)
Mental component mean score (SD)	SMT+HE	53.9 (7.9)	54.6 (8.6)	54.5 (8.4)	55.3 (8.5)	54.5 (8.6)
	SRE+HE	54.2 (8.8)	55.1 (8.1)	55.3 (8.1)	54.4 (8.2)	54.9 (8.5)
	HE	54.2 (7.1)	54.7 (8.7)	54.8 (7.6)	54.5 (8.4)	54.2 (8.0)
Number of participants at each time point*	SMT+HE	80	80	79	78	78
	SRE+HE	82	80	80	81	78
	HE	79	79	77	77	73

HE, home exercise alone; NA, not applicable; SMT+HE, spinal manipulative therapy with home exercise; SRE+HE, supervised rehabilitative exercise plus home exercise.
* Numbers shown are patients who provided data for the main outcome, self-reported pain. Number of patients who reported data for other outcomes were the same at baseline and at weeks 4 and 12. At week 26, 5 participants gave information about pain but did not give information about any other outcomes (HE group=2; SRE+HE group=2; SMT+HE group=1). At 52 weeks, 3 patients who gave information about pain did not give information about any other outcomes (SRE+HE group=1; SMT+HE group=2).

Table 3
Between-group differences for changes from baseline in primary and secondary outcomes

Group comparison by variable	Week 4	Week 12	Short term*	Week 26	Week 52	Long term*
	Difference (95% CI)	Difference (95% CI)	Difference (95% CI)	Difference (95% CI)	Difference (95% CI)	Difference (95% CI)
Neck pain						
SMT+HE vs. SRE+HE	−0.42 (−0.90 to 0.05)	−0.55 (−1.10 to −0.00)†	−0.48 (−0.93 to −0.04)†	−0.46 (−1.04 to 0.13)	−0.15 (−0.75 to 0.45)	−0.41 (−0.83 to 0.01)
SMT+HE vs. HE	−0.17 (−0.65 to 0.30)	−1.04 (−1.59 to −0.49)‡	−0.61 (−1.05 to −0.17)‡	−0.53 (−1.12 to 0.06)	−0.35 (−0.96 to 0.26)	−0.55 (−0.97 to −0.12)‡
SRE+HE vs. HE	0.25 (−0.22 to 0.72)	−0.49 (−1.04 to 0.06)	−0.13 (−0.57 to 0.31)	−0.07 (−0.66 to 0.51)	−0.20 (−0.81 to 0.40)	−0.13 (−0.55 to 0.29)
Neck Disability Index						
SMT+HE vs. SRE+HE	−1.69 (−3.58 to 0.20)	−0.27 (−2.55 to 2.02)	−0.98 (−2.71 to 0.75)	−2.68 (−5.69 to 0.33)	−1.32 (−4.32 to 1.67)	−1.63 (−3.60 to 0.34)
SMT+HE vs. HE	−0.21 (−2.10 to 1.69)	−1.59 (−3.90 to 0.73)	−0.92 (−2.66 to 0.82)	−1.92 (−4.97 to 1.13)	−1.82 (−4.85 to 1.22)	−1.48 (−3.47 to 0.51)
SRE+HE vs. HE	1.49 (−0.41 to 3.38)	−1.32 (−3.63 to 0.99)	0.06 (−1.68 to 1.80)	0.76 (−2.28 to 3.80)	−0.50 (−3.53 to 2.54)	0.15 (−1.83 to 2.14)
Duration of medication use						
SMT+HE vs. SRE+HE	−0.53 (−1.07 to 0.01)	−0.31 (−0.94 to 0.31)	−0.42 (−0.87 to 0.04)	−0.38 (−1.06 to 0.31)	−0.86 (−1.55 to −0.18)‡	−0.51 (−0.94 to −0.08)†
SMT+HE vs. HE	0.11 (−0.44 to 0.65)	−0.33 (−0.96 to 0.30)	−0.11 (−0.57 to 0.35)	−0.56 (−1.26 to 0.13)	−0.74 (−1.43 to −0.05)†	−0.37 (−0.81 to 0.06)
SRE+HE vs. HE	0.63 (0.09 to 1.17)†	−0.02 (−0.65 to 0.61)	0.31 (−0.15 to 0.76)	−0.19 (−0.88 to 0.50)	0.12 (−0.57 to 0.81)	0.13 (−0.30 to 0.57)
Satisfaction with care						
SMT+HE vs. SRE+HE	−0.05 (−0.33 to 0.22)	0.03 (−0.26 to 0.32)	−0.01 (−0.26 to 0.24)	0.01 (−0.30 to 0.33)	0.25 (−0.10 to 0.60)	0.06 (−0.20 to 0.32)
SMT+HE vs. HE	−0.54 (−0.82 to −0.27)‡	−0.62 (−0.91 to −0.33)‡	−0.59 (−0.84 to −0.34)‡	−0.43 (−0.75 to −0.11)‡	−0.46 (−0.81 to −0.10)†	−0.50 (−0.77 to −0.24)‡
SRE+HE vs. HE	−0.49 (−0.77 to −0.22)‡	−0.66 (−0.95 to −0.36)‡	−0.58 (−0.83 to −0.33)‡	−0.44 (−0.76 to −0.12)‡	−0.70 (−1.06 to −0.35)‡	−0.57 (−0.83 to −0.30)‡
Global improvement						
SMT+HE vs. SRE+HE	−0.16 (−0.51 to 0.18)	−0.18 (−0.56 to 0.20)	−0.17 (−0.48 to 0.15)	−0.31 (−0.77 to 0.15)	−0.01 (−0.50 to 0.48)	−0.18 (−0.53 to 0.17)
SMT+HE vs. HE	−0.25 (−0.60 to 0.10)	−0.71 (−1.09 to −0.33)‡	−0.47 (−0.79 to −0.15)‡	−0.49 (−0.95 to −0.03)†	−0.28 (−0.77 to 0.22)	−0.43 (−0.78 to −0.08)†
SRE+HE vs. HE	−0.09 (−0.43 to 0.26)	−0.53 (−0.91 to −0.15)‡	−0.30 (−0.62 to 0.01)	−0.18 (−0.64 to 0.28)	−0.27 (−0.76 to 0.23)	−0.25 (−0.60 to 0.10)
SF-36 physical component						
SMT+HE vs. SRE+HE	0.11 (−1.25 to 1.47)	−0.14 (−1.75 to 1.46)	−0.01 (−1.30 to 1.27)	0.16 (−1.67 to 1.99)	0.52 (−1.45 to 2.49)	0.26 (−1.04 to 1.55)
SMT+HE vs. HE	−0.47 (−1.85 to 0.91)	−0.27 (−1.91 to 1.36)	−0.34 (−1.65 to 0.96)	−0.60 (−2.47 to 1.28)	−0.91 (−2.92 to 1.10)	−0.54 (−1.86 to 0.78)
SRE+HE vs. HE	−0.58 (−1.95 to 0.79)	−0.13 (−1.75 to 1.49)	−0.33 (−1.63 to 0.96)	−0.76 (−2.61 to 1.10)	−1.44 (−3.44 to 0.56)	−0.80 (−2.11 to 0.51)
SF-36 mental component						
SMT+HE vs. SRE+HE	−0.16 (−1.74 to 1.42)	−0.45 (−2.04 to 1.13)	−0.30 (−1.57 to 0.96)	1.27 (−0.75 to 3.29)†	0.00 (−2.00 to 2.01)	0.15 (−1.09 to 1.39)
SMT+HE vs. HE	0.19 (−1.39 to 1.78)	0.23 (−1.37 to 1.83)	0.20 (−1.08 to 1.48)	1.00 (−1.04 to 3.04)	0.58 (−1.45 to 2.61)	0.46 (−0.79 to 1.71)
SRE+HE vs. HE	0.35 (−1.24 to 1.93)	0.68 (−0.91 to 2.27)	0.51 (−0.77 to 1.78)	−0.27 (−2.31 to 1.76)	0.58 (−1.45 to 2.61)	0.31 (−0.93 to 1.55)

HE, home exercise alone; SMT+HE, spinal manipulative therapy with home exercise; SRE+HE, supervised rehabilitative exercise plus home exercise.

A negative difference favors the first group listed in the comparison. Follow-up outcomes other than Satisfaction with care and Global improvement are adjusted for levels at baseline. pValues for Satisfaction with care and SF-36 mental component scores are based on rank-transformed values.

Neck pain was measured on an 11-point scale from 0 (no neck pain) to 10 (worst neck pain possible). Neck disability was measured on the Neck Disability Index, a questionnaire containing 10 items relevant to neck pain that are rated on a scale of 0 (no disability) to 5 (Maximal disability); the total score of 50 is converted to percentage points (0–100). Duration of medication use was the number of days during the previous week (0–7) that participants reported taking nonprescription or over-the-counter medication for neck pain. Satisfaction with care was measured on a 7-point scale from 1 (completely satisfied, couldn't be better) to 4 (neither satisfied nor dissatisfied to 7 (completely dissatisfied, couldn't be worse.) Global improvement in neck pain was measured on a 9-point scale from 1 (100% improvement) to 5 (0% improvement) to 9 (100% worse). SF-36 physical and mental component scores are norm-based, using a linear T-score transformation with a mean of 50 (SD, 10).

* Short- and long-term results are based on linear mixed model analysis using data through week 12 for short term and week 52 for long term.

† $p \leq .05$.

‡ $p \leq .01$.

Table 4
Change* in biomechanical outcomes

	SMT+HE group		SRE+HE group		HE group	
Neck performance measure	n	Mean (95% CI)	n	Mean (95% CI)	n	Mean (95% CI)
Isometric strength, lbs						
Extension	74	−0.4 (−2.1 to 1.3)	76	1.0 (−0.4 to 2.3)	71	−0.4 (−2.1 to 1.3)
Flexion	73	0.9 (−0.2 to 1.9)	76	0.7 (−0.3 to 1.7)	71	0.6 (−0.2 to 1.5)
Static endurance, lbs×s						
Extension	72	175.9 (63.7 to 288.1)	75	166.9 (64.7 to 269.1)	69	71.5 (−64.9 to 207.9)
Flexion	71	167.8 (73.2 to 262.5)	73	195.3 (78.6 to 312.0)	69	96.3 (−7.4 to 200.0)
Handgrip strength test, kg	48	−0.5 (−1.6 to 0.6)	55	0.7 (−0.4 to 1.8)	47	−0.5 (−1.9 to 1.0)
Timed up and go test, s	77	−0.3 (−0.8 to 0.2)	78	−0.3 (−0.7 to 0.1)	72	−0.2 (−0.7 to 0.3)
Range of motion, degrees						
Flexion and extension	76	2.9 (1.1 to 4.6)	78	3.3 (1.5 to 5.0)	73	3.4 (1.6 to 5.2)
Rotation	76	8.4 (5.5 to 11.3)	78	6.8 (3.9 to 9.7)	73	8.3 (5.4 to 11.3)
Lateral flexion	76	2.1 (−0.1 to 4.4)	78	2.9 (0.6 to 5.1)	73	3.6 (1.3 to 5.9)

HE, home exercise alone; SMT+HE, spinal manipulative therapy with home exercise; SRE+HE, supervised rehabilitative exercise plus home exercise. There were no significant differences between groups.
* Change is week 12 minus the baseline average.

before completing the trial and six withdrew due to competing comorbidities (n=3) and personal reasons (n=3). Results of sensitivity analyses were nearly identical to those from the primary analyses.

Compliance

The average number of chiropractic visits was 15.1 (range, 5–19); six of the 80 participants randomized to this group were considered to be noncompliant with their treating chiropractors' recommendations or attendance at the four home exercise program sessions. The average number of supervised exercise sessions was 16.6 (range, 0–19), with four of the 82 participants considered noncompliant (attending fewer than 80%, or 16, sessions). In the group receiving home exercise alone, five of the 79 randomized participants did not attend the four instructional sessions required for compliance (Fig. 1). The frequency with which participants conducted exercises at home was not measured in any of the groups.

Adverse events

No serious adverse events were observed as a result of the study treatments. One severe, unexpected adverse event related to treatment was reported in the supervised plus home exercise group: a participant fell and fractured his radius while performing study-related exercises during a supervised visit. Nonserious, expected adverse events were frequently reported in all three treatment groups (56% in the SMT with home exercise group; 90% in the supervised plus home exercise group; 58% in the home exercise–alone group). Relatedness of these events to study treatment was not assigned, nor were nonserious events graded in terms of severity. They typically required little to no modification of activity or only symptomatic therapy. The most common adverse events in all three groups included an aggravation of neck symptoms, muscle soreness, lower and upper extremity joint pain, back pain, and stiffness.

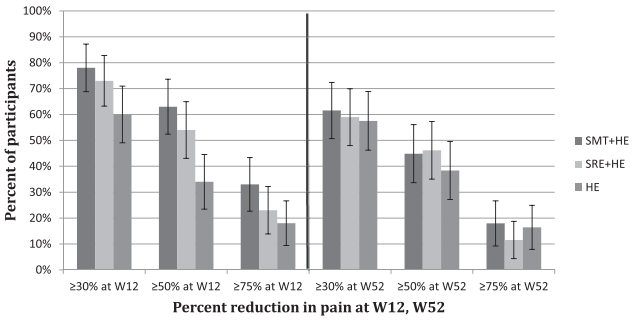

Fig. 2. Participants reporting reduction in pain. SMT+HE, spinal manipulative therapy with home exercise; SRE+HE, supervised rehabilitative exercise plus home exercise; HE, home exercise alone; WK12, week 12; WK52, week 52. Bars represent 95% confidence intervals.

Discussion

The SMT with home exercise group showed a greater decrease in pain by the end of the 12 week treatment period compared with both the supervised plus home exercise, and home exercise–alone groups. There were small, nonsignificant differences between the supervised plus home exercise and home exercise–alone groups at all time points. The SMT with home exercise group rated their improvement higher than the home exercise–alone group both at the end of treatment and during follow-up. The combined treatment groups reported greater satisfaction than those in the home exercise–alone group at all time points. Reported adverse events were common and primarily musculoskeletal in nature, similar to what is reported in the literature [37,38].

The advantage the SMT with home exercise group demonstrated over the other two groups must be considered from both individual and group perspectives [39]. Among NP sufferers, a change in pain of 2.5 on a 0–10 scale is considered a minimal clinically important difference [34]. Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials consensus recommendations for chronic

pain reporting suggest changes of approximately two points, or 30% to 36% from baseline, indicate ''meaningful'' decreases in pain and a decrease of over four points, or 50% from baseline, is considered ''substantial.'' [36] From an individual perspective, nearly two-thirds of those who received SMT with home exercise reached what is considered a substantial decrease in pain after 12 weeks, with three quarters of the group achieving meaningful change [36]. The proportion of individuals reaching 50% reduction in pain after 12 weeks of treatment is greater in the SMT with home exercise group than in the home exercise–alone group. This should be interpreted with caution, as no absolute standards for meaningful differences between groups of responders currently exist [39]. From a group perspective, the magnitude of pain reduction in the SMT with home exercise group in this study is larger than that previously measured by our team among 20–65 year olds receiving similar treatment [25], which is also larger than those reported in a review of manual therapies for NP in the general population [7]. In addition to the outcomes reported in this study, the lack of serious adverse events, tolerability, and high adherence to care suggest the combination of SMT with home exercise is an effective treatment in seniors with chronic NP [39].

The majority of research on chronic musculoskeletal conditions to date has focused on short courses of care, as opposed to long-term management. This may be shortsighted, as NP is often chronic or recurrent in nature and part of a constellation of comorbidities [2]. In complicated cases such as these, a more appropriate therapeutic approach is probably to focus on management of exacerbations and functional limitations, as opposed to resolving the condition. This theory may explain, in part, why there is no clear gold standard for treatment for any age group [40,41]. The clinical and cost-effectiveness of a management strategy has yet to be explored in an elderly population with spine-related complaints. A study to test this question is currently underway (ClinicalTrials.gov Identifier NCT01057706).

Neither of the combined treatment groups showed an advantage over home exercise alone in terms of biomechanical outcome measures. This is of particular interest for the supervised rehabilitative exercise group, which was designed specifically to improve motion and endurance using high repetitions of low resistance exercise. Despite a lack of difference between the supervised plus home exercise and home exercise–alone groups in biomechanical outcomes, supervised exercise may have other benefits in an aging population, including reduced kinesiophobia, or fear avoidance. These outcomes were not a focus in this study and should be considered in future trials.

Although some authors suggest that rehabilitative exercise may be effective for NP in nonelderly patients [6], it did not result in significantly better outcomes compared with home exercises alone in the senior patients in this study. This may be due to our focus on low resistance exercise versus greater-resistance approaches used in other studies. Research on SMT for NP in the nonelderly adult population suggests it is most effective when combined with exercise [6–8]. The results of this study do not allow us to deduce whether home exercise provided any additional benefit compared with SMT alone; however, advice and recommendations for home exercises are commonly employed by practitioners who use SMT [42]; the combination of these therapies in this trial reflect typical clinical practice.

Strengths and limitations

This study met standards set by Consolidated Standards of Reporting Trials [43,44]. Compliance with treatment and follow-up rates for data collection were high, and there was no difference in adherence between groups. Active interventions preclude the ability to blind participants and providers. Further, variation between groups in provider attention and the impact of nonspecific effects were not controlled for in this trial. Although these may contribute to some of the treatment effect, the pragmatic design of this study more accurately reflects actual treatment encounters associated with these therapies.

Conclusions

SMT with home exercise resulted in greater decreases in pain after 12 weeks of treatment compared with both the supervised plus home exercise and the home exercise–alone groups. Supervised exercise sessions appear to add little to home exercise alone. There were no long-term differences in pain between groups.

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