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Cost-effectiveness of spinal manipulative therapy, supervised exercise, and home exercise for older adults with chronic neck pain

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Abstract

Background Context—Chronic neck pain is a prevalent and disabling condition among older adults. Despite the large burden of neck pain, little is known regarding the cost-effectiveness of commonly used treatments.

Purpose—To estimate the cost-effectiveness of home exercise and advice (HEA), spinal manipulative therapy (SMT) plus HEA, and supervised rehabilitative exercise (SRE) plus HEA.

Study Design/Setting—Cost-effectiveness analysis conducted alongside a randomized clinical trial (RCT).

Patient Sample—241 older adults (> 65 years) with chronic mechanical neck pain.

Outcome Measures—Direct and indirect costs, neck pain, neck disability, SF-6D-derived quality-adjusted life years (QALYs), and incremental cost-effectiveness ratios over a one-year time horizon.

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Methods—This work was supported by grants from the National Center for Complementary and Integrative Health (#F32AT007507), National Institute of Arthritis and Musculoskeletal and Skin Diseases (#P60AR062799), and Health Resources and Services Administration (#R18HP01425). The RCT is registered at ClinicalTrials.gov (#NCT00269308). The primary analysis adopted a societal perspective, a healthcare perspective was adopted as a sensitivity analysis. Cost-effectiveness was a secondary aim of the RCT which was not powered for differences in costs or QALYs. Differences in costs and clinical outcomes were estimated using generalized estimating equations and linear mixed models, respectively. Cost-effectiveness acceptability curves were calculated to assess the uncertainty surrounding cost-effectiveness estimates.

Results—Total costs for SMT+HEA were 5% lower than HEA (mean difference: -\$111; 95% CI -\$1,354 to \$899) and 47% lower than SRE+HEA (mean difference: -\$1,932; 95% CI -\$2,796 to -\$1,097). SMT+HEA also resulted in a greater reduction of neck pain over the year relative to HEA (0.57; 95% CI 0.23 to 0.92) and SRE+HEA (0.41; 95% CI 0.05 to 0.76). Differences in disability and QALYs favored SMT+HEA. The probability that adding SMT to HEA is cost-effective at willingness to pay thresholds of \$50,000 to \$200,000 per QALY gained ranges from 0.75 to 0.81. If adopting a healthcare perspective, costs for SMT+HEA were 66% higher than HEA (mean difference: \$515; 95% CI \$225 to \$1,094), resulting in an ICER of \$55,975 per QALY gained.

Conclusions—On average, SMT+HEA resulted in better clinical outcomes and lower total societal costs relative to SRE+HEA and HEA alone, with a 0.75 to 0.81 probability of cost-effectiveness for willingness to pay thresholds of \$50,000 to \$200,000 per QALY.

Keywords

Chronic neck pain; Spinal manipulative therapy; Exercise; Home exercise; Cost-effectiveness; Older adults

Introduction

Chronic pain affects more U.S. adults than heart disease, diabetes, and cancer combined.[1] Although often considered benign and self-limiting, chronic neck pain is a substantial burden to society. Neck pain is the third most common chronic pain condition in the U.S.[2] and the fourth leading cause of disability worldwide.[3] Disability from neck pain has increased by 29% in the U.S. over the past two decades, largely due to population growth and aging.[4] Up to 22% of older adults experience neck pain, which is associated with diminished physical function and overall health.[5, 6]

The economic burden of spine pain in the U.S. is substantial, accounting for 9% of total healthcare expenditures[7] and nearly \$20 billion in reduced productivity.[8] Annual healthcare expenditures for spine pain increased by 95% from 1999 to 2008, largely due to rising costs for specialty care.[9] Although older adults represent 18.5% of the adult population receiving care for spine pain, they account for an estimated 34% of healthcare expenditures.[10] Given the individual and economic burden of neck pain in our aging society, the identification of safe and cost-effective interventions has become paramount.

Spinal manipulative therapy and exercise are commonly used for the management of neck pain.[11, 12] While emerging evidence supports the use of these treatments,[13–17] there is

a paucity of research addressing their effectiveness within older populations. A recent randomized clinical trial (RCT) by our group found spinal manipulative therapy with home exercise was well-tolerated among older adults and resulted in less neck pain compared to home exercise alone.[18, 19]

The number of RCT-based cost-effectiveness analyses (CEAs) of conservative treatments, including spinal manipulative therapy and exercise, for neck pain is limited.[20] To date, no trial-based CEAs of spinal manipulative therapy and exercise have been performed in the U.S., where healthcare costs dramatically differ from other industrialized countries.[21] Further, none of the existing analyses have focused on older adults, who account for a substantial share of healthcare costs.[10]

The purpose of this study was to estimate the cost-effectiveness of home exercise and advice (HEA), spinal manipulative therapy (SMT) plus HEA, and supervised rehabilitative exercise (SRE) plus HEA for older adults with chronic neck pain using cost data collected alongside a RCT.

Methods

The RCT methodology has been detailed previously. [18, 22]

Target Population

Older adults (≥ 65 years old) with chronic mechanical neck pain (≥ 3 months duration), a stable prescription pain medication plan, and independent ambulation were included. Neck pain needed to be accompanied by cervical spine stiffness or tenderness, with or without radiating arm pain and non-progressive neurologic deficits (Grades I and II from the Neck Pain Task Force classification[23]) for inclusion. Exclusion criteria included pain ratings less than 3 (0–10 scale), contraindications to study treatments (e.g. spinal infection, bleeding disorders), severe disabling health problems, substance abuse, neck pain litigation, or ongoing non-pharmacological healthcare for neck pain.

Setting and Location

The clinical trial was conducted within a University-based outpatient research clinic in the Minneapolis, Minnesota metropolitan area from 2004 to 2008. Participants were recruited from the general public using newspaper advertisements, direct mailings, and community posters.

Perspective

We adopted a societal perspective for the primary analysis which included costs for healthcare, patient time, transportation, and lost productivity. A healthcare perspective was adopted as a sensitivity analysis.

Interventions

Participants were randomly assigned to 12 weeks of treatment with the following interventions. Participant and provider blinding was not possible. Study interventions were

provided by exercise therapists (with a minimum requirement of a bachelor's degree in exercise science) and licensed chiropractors (with at least 5 years of clinical experience). All providers were trained on treatment delivery protocols and protocol compliance was monitored through chart audits, observations, and team meetings.

Home Exercise and Advice (HEA): Participants in the HEA group received four, one hour sessions with an exercise therapist or chiropractor. Patients were instructed to do daily neck and shoulder exercises at home. In addition to the home exercise instruction, information regarding neck pain and advice on self-management (e.g. ice, heat, ergonomics) was provided. The intervention was considered low dose due to the limited number of visits.

Spinal Manipulative Therapy (SMT) + HEA: Participants in the SMT+HEA group received four, one hour sessions of HEA in addition to a maximum of 20 sessions of SMT by a chiropractor. The number and frequency of treatments was determined by the provider. SMT consisted of high velocity, low amplitude manipulation or low velocity, variable amplitude mobilization to the cervical and thoracic spine.

Supervised Rehabilitative Exercise (SRE) + HEA: Participants in the SRE+HEA group received four, one hour sessions of HEA in addition to 20 one-on-one supervised one hour sessions of SRE by exercise therapists. The exercises consisted of neck and upper body strengthening using rubber tubing in addition to stretching, balance, and coordination exercises. Emphasis was placed on high repetitions and progressively increased resistance. Exercises were preceded by a light aerobic warm-up.

Time horizon & Discount Rate

Costs and clinical outcomes were collected for one year. No discount rate was applied.

Clinical Outcomes

Clinical outcomes were collected twice at baseline (one week apart) and at 4, 12, 26 and 52 weeks post-randomization.

Self-reported pain using the numerical rating scale (0 = no pain; 10 = worst possible pain) was the primary outcome for the clinical trial and the cost effectiveness analysis. The scale has been shown to be reliable and valid for older adults with persistent pain. [24]

Disability was measured using the Neck Disability Index (NDI), an instrument previously shown to be reliable and valid for adults with neck pain.[25, 26] A total NDI score was obtained by summing the responses from individual items and dividing by the maximum possible score resulting in a 0–100 scale, where 0 equals no disability.[27]

Health related quality of life was measured using the Medical Outcomes Study Short Form 36-item Health Survey (SF-36).[28] Quality-adjusted life years (QALYs) were estimated using the SF-6D, a multidimensional utility measure derived from the SF-36.[29] Preferences for SF-6D health states were obtained from a U.S. population using discrete choice experiments.[30] QALYs were additionally estimated using the Euroqol EQ-5D-3L as a sensitivity analysis. Preferences for EQ-5D-3L health states were calculated using

published values from a representative sample of the US population elicited by time trade-off methods.[31]

Direct Healthcare Costs

Healthcare utilization was collected using a combination of standardized study provider forms, telephone interviews, and patient self-report questionnaires. Study treatments were recorded at each visit by the provider. Non-study related healthcare use for neck pain was collected by self-report questionnaires and telephone interviews. Participants also reported the number of days and types of medication taken in the past week using self-report questionnaires.

We estimated costs of healthcare resources using 2006 Medicare national allowable payments or relative value units with constant 2006 U.S. dollars (see table 1). Medication costs were estimated using the average cost per prescription day reported within Medicare's 2008 prescription drug profiles public use file.[32] Cost estimates from years other than 2006 were adjusted for inflation using the annual chained consumer price index.

Indirect Costs

Participant time costs for healthcare utilization and transportation were included using an opportunity cost approach. Standardized time estimates for healthcare resources were multiplied by the U.S. median wage rate for adults 65 and older.[33] Costs for healthcare-related transportation were valued using the average travel distance and time for medical care in the U.S.[34] The U.S. Internal Revenue Service's 2006 standard mileage deduction rate for operating an automobile (\$0.445/mile) was used to value travel distance.

Lost productivity costs for paid and unpaid labor were estimated using an adapted question from the U.S. National Health Interview Survey. [35] Participants reported the number of days in the past month they were unable to carry out their daily work (in or away from home) due to neck pain. Productivity costs were valued using the U.S. national median wage rate for adults 65 and older.[33]

Analysis

Intention-to-treat analyses, including all trial participants according to their allocated treatment assignment were used. The cost-effectiveness evaluation was a secondary objective of the clinical trial, which was primarily designed to determine differences in pain between treatment groups after 12 weeks. Accordingly, an estimation approach was used for the cost-effectiveness analysis rather than hypothesis testing.[36] Treatment effectiveness was estimated using linear mixed effect models. Baseline measures of the respective outcomes were included as covariates.[37, 38] Pain, disability and QALYs over the one year study duration were calculated using time weighted averages via linear interpolation.[39]

Generalized estimating equations specifying a poisson distribution and identity link were used to estimate mean costs over the year.[40, 41] Separate models were performed to estimate cost rates for medication use (one week) and lost productivity (one month). Mean costs for medication use and lost productivity over the one-year time horizon were estimated

by multiplying the cost rate at each measurement period by the appropriate time interval using linear interpolation. To estimate the incremental cost-effectiveness ratio (ICER), treatment strategies were ranked by mean costs. We estimated the mean difference in cost divided by the mean difference in effects (i.e. neck pain, neck disability, QALYs) for treatment strategies that were both more costly and more effective. ICERs were not calculated for “dominated” treatments (i.e. greater mean costs and worse mean effects).[39, 42]

We assessed the uncertainty of cost-effectiveness estimates using the following methods. Bias-corrected bootstrap confidence intervals were calculated using 5000 samples taken with replacement with the subject as the unit of observation.[43] Bootstrapped cost-effect pairs were displayed graphically on the cost effectiveness plane.[36] Cost-effectiveness acceptability curves were created to illustrate the probability of cost-effectiveness at different willingness to pay (WTP) thresholds for a QALY.[44]

Missing Data Analysis

Linear mixed model analyses provide unbiased estimates provided data is missing at random.[45, 46] To explore the potential for data missing not at random we compared mean clinical outcomes for participants with missing and complete primary outcome data at week 52. Sensitivity analyses for data missing not at random were performed using pattern mixture methods.[47, 48] Missing clinical outcome and cost data were imputed separately for each treatment group using multiple imputation (Procedure MI in STATA). Five imputed data sets were created using a multivariate normal model for clinical outcomes and predictive mean matching for costs. The imputation models included clinical outcomes in addition to baseline covariates associated with missing data. The sensitivity analyses for data missing not at random assumed the imputed clinical outcomes and costs were worse by 1) 10% and 2) 50%.

Sensitivity analyses

We assessed the impact of deriving QALYs with the commonly used EQ-5D, the adoption of a healthcare perspective, and the potential for data missing not at random on cost-effectiveness results.

Results

A Consort flow diagram[49] is provided in Figure 1. The number of participants and reasons for discontinuing treatment were similar between groups. Over the one-year time horizon, a total of 17 participants were lost to follow up across the three groups. Baseline clinical and demographic characteristics were similar across groups (Table 2). Approximately one-quarter of participants received care for their neck pain in the three months prior to enrollment.

Outcomes

Group differences in clinical outcomes are provided in Table 3. Overall, SMT+HEA resulted in the greatest reduction of neck pain and disability, and the most gains in QALYs. In terms

of neck pain, the primary outcome of the clinical trial, group differences favored SMT+HEA over HEA (0.57 95%CI 0.23 to 0.92) and SRE+HEA (0.41 95%CI 0.05 to 0.76). Results also favored SMT+HEA for reductions of neck disability and QALY gains over HEA (disability = 1.67 95%CI -0.15 to 3.41; QALYs = 0.009 95%CI -0.011 to 0.029) and SRE +HEA (disability = 1.85 95%CI 0.06 to 3.57; QALYs = 0.009 95%CI -0.009 to 0.027). Group differences favored SRE+HEA over HEA for neck pain (0.17 95%CI -0.20 to 0.52), but not neck disability (-0.18 95%CI -1.92 to 1.63) nor QALYs (-0.0001; 95%CI -0.018 to 0.018). 95% confidence intervals for the SMT+HEA vs SRE+HEA neck pain and disability estimates and the SMT+HEA vs HEA neck pain estimate did not cross 0. Other treatment effectiveness estimates had greater uncertainty with 95% confidence intervals that crossed 0.

Costs

Healthcare, lost productivity, total indirect, and total costs are detailed in Table 3. From the societal perspective, SMT+HEA resulted in the lowest mean costs (\$2,198) followed by HEA (\$2,305) and SRE+HEA (\$4,129). Total costs for SMT+HEA were 47% lower compared to SRE+HEA (mean difference: -\$1,932 95%CI -\$2,796 to -\$1,097), and 5% lower than HEA alone (mean difference: -\$111 95%CI -\$1,354 to \$899). The HEA group reported the lowest mean healthcare costs (\$779) followed by SMT+HEA (\$1,297) and SRE +HEA (\$2,556). Mean lost productivity costs were smallest for SMT+HEA (\$548) followed by SRE+HEA (\$1,042) and HEA (\$1,390). The majority of indirect costs were due to lost productivity. Further details on resource use and costs by treatment group are provided in table 4. Study related treatments accounted for the majority of healthcare costs (HEA: 58%, SMT+HEA: 71%, SRE+HEA: 91%). Over one-quarter of participants were unable to carry out their daily work (in or away from home) for at least one day. Less than 20% of the older adults participating in the trial were employed, and unpaid labor accounted for approximately 75% of lost productivity costs.

Cost-effectiveness

Cost-effectiveness results are provided in Table 5. From the societal perspective, SMT+HEA resulted in lower costs, and greater improvements in pain, disability, and QALYs relative to SRE+HEA and HEA, leading to treatment dominance. Figure 2 displays the 5000 bootstrap replicates of the SMT+HEA treatment contrasts on the cost-effectiveness planes for QALYs and pain. All bootstrap replicates found SMT+HEA was less expensive than SRE+HEA, and 84% and 99% of the replicates favored SMT+HEA for QALYs and pain, respectively. When adding SMT to HEA, bootstrap replicates crossed all four quadrants of the cost-effectiveness plane for QALYs. 47% of replicates found SMT+HEA to be dominant, 10% revealed HEA to be dominant, and the remaining 45% found adding SMT to HEA was either more expensive and more effective or less expensive and less effective. For pain, 55% of the bootstrap replicates found adding SMT to HEA was less expensive and more effective.

Results of sensitivity analyses are provided in Table 5. Group differences for QALYs derived with the commonly used EQ-5D were very similar to the base case analysis, and did not impact the cost-effectiveness results. If adopting a healthcare perspective, adding SMT to HEA resulted in 66% higher costs (mean difference: \$515 95%CI \$225 to \$1,094) and ICERs of \$895 for pain, \$308 for disability, and \$55,975 for QALYs.

Figure 3 shows cost-effectiveness acceptability curves (CEAC) for adding SMT to HEA using sensitivity analyses. The most favorable CEAC for adding SMT to HEA was the base case analysis with a 75% probability of cost-effectiveness at a WTP threshold of \$50k per QALY. Small increases in cost-effectiveness were observed at higher threshold values. Using the EQ-5D to value QALYs results in small decreases (<5%) in the probability of cost-effectiveness relative to the base case analysis. If a healthcare perspective is adopted, the probability of cost-effectiveness decreases to 47% at a WTP threshold of \$50k, 65% at a WTP threshold of \$100k, and 71% at a WTP threshold of \$150k.

Missing data analyses

Study participants with missing data at week 52 reported higher pain and disability, and lower QALYs at prior assessments compared to participants with complete data, which suggests data may be missing not at random. Sensitivity analyses for data missing not at random produced very similar results to the primary analysis with minimal impact on the magnitude of group differences for both clinical outcomes and costs.

Discussion

This is the first reported RCT based cost-effectiveness analysis addressing the management of chronic mechanical neck pain in older adults. We collected self-report data on healthcare utilization and lost productivity to estimate the relative cost-effectiveness of home exercise and advice (HEA), spinal manipulative therapy (SMT) plus HEA, and supervised rehabilitative exercise (SRE) plus HEA. Adding SMT to HEA resulted in a 5% decrease in total societal costs and better outcomes. Although there is uncertainty surrounding the dominance of SMT+HEA from the societal perspective, the cost-effectiveness acceptability curve for adding SMT to HEA is favorable with a 0.75 probability of cost-effectiveness for willingness to pay thresholds greater than \$50,000 per QALY. SMT+HEA also resulted in 47% lower costs and better outcomes relative to SRE+HEA. Overall, the additional exercise sessions (~16) attended by the SRE+HEA group conferred little advantage to 4 sessions of HEA alone. Mean annual healthcare costs for individuals within the HEA (\$779) and SMT +HEA groups (\$1297) were well below national estimates for spine pain (roughly \$2600 in 2006 U.S. dollars).[7, 50]

The perspective from which cost-effectiveness analyses are performed can have an important impact. In this study, when the societal perspective was adopted (incorporating lost productivity), the addition of SMT to HEA was less costly. When the healthcare perspective was considered (excluding lost productivity), adding SMT to HEA was more costly. Whether the additional healthcare costs for SMT are worthwhile depends on how much insurers and patients are willing to pay for health outcomes. Currently, there is no consensus on threshold values for QALYs or other health outcomes within the U.S. [51, 52] The ICER of \$55,975 for a QALY when adding SMT to HEA is below thresholds recommended by the World Health Organization (3 times the 2006 per-capita gross domestic product = \$118,635) [53, 54] and Brathwaite and colleagues (\$109,000 to \$297,000; using 2003 U.S. dollars). [55] Inflating to 2014 U.S. dollars would result in an ICER of \$65,731 per QALY gained which is still below the World Health Organizations' recommended threshold (3 times the

2014 per-capita gross domestic product = \$163,889).[54] The interpretation of ICERs for outcomes specific to neck pain can be aided by framing the additional costs needed for clinically important differences. Clinically important differences for individual improvement are estimated at 1 to 2.5 for neck pain (0–10 scale)[56, 57] and 7 to 19 for neck disability (0–100 scale)[57, 58]. Achieving similar mean group differences when adding SMT to HEA requires an additional \$895 to \$2,238 for neck pain and \$2,156 to \$5,852 for neck disability. Inflating costs to 2014 U.S. dollars results in an additional \$1,060 to \$2,649 for neck pain and \$2,534 to \$6,878 for neck disability. Individual patient estimates of clinically important differences are a conservative measure for interpreting ICERs, as the magnitude of clinically important group differences are likely smaller.[59]

The inclusion of lost productivity costs increases the value of SMT for older adults with chronic neck pain. The most appropriate method for including lost productivity within cost-effectiveness analyses has been contentiously debated.[60, 61] While recent evidence has shown that approximately half of the public includes lost productivity when valuing health states, their inclusion has little to no impact on QALYs.[62, 63] Accordingly, there have been recommendations to include lost productivity as a “cost” to ensure it is properly accounted for.[63] This is especially important for chronic pain conditions, where a substantial amount of societal burden is attributed to lost productivity.[8, 64]

Previously published RCT-based cost-effectiveness analyses for neck pain have included a limited number of older adults and none have been performed in the U.S. A 2012 systematic review of economic evaluations of conservative treatments for neck pain identified five cost-effectiveness analyses all performed within Europe.[20] Three studies share similar characteristics to our trial and are suitable for comparison.[65–67] All three studies found manual therapy to result in less total costs, and more QALYs relative to exercise. One study by Kortals de Bos also found similar advantages in terms of pain and disability;[65] however, the studies by Bosmans[67] and Lewis[66] did not. This discrepancy might be explained by differences in treatment content and dose, and the age of the population. We searched for additional studies published before March 2015 using the same search strategy reported in the 2012 systematic review which queried Medline, EMBASE, EconLit, EURONHEED, and NHS EED. Our updated literature search identified an additional trial by Manca et al.[68, 69] which found usual physiotherapy (which included exercise in 21% and manual therapy in 25% of visits) produced higher healthcare expenditures and total costs, but also more QALYs and less disability relative to a brief physiotherapy intervention.

The majority of cost-effectiveness analyses do not address lost productivity costs for work done outside the labor market (e.g. household or volunteer work), which is especially relevant for older adults.[61, 70] A strength of this study is that it included lost productivity costs related to both paid and unpaid work, reflecting meaningful impacts of chronic pain to older individuals and society. Other strengths of this study include the randomized design to limit selection bias when determining differences in healthcare resource use, lost productivity, and clinical outcomes, the limited amount of missing data, and the adoption of both societal and healthcare perspectives.

This study also has several limitations. Similar to other cost-effectiveness analyses conducted alongside RCTs [71], the economic analysis was a secondary aim of the primary clinical trial which was not powered for differences in costs or QALYs. Although cost-effectiveness analyses conducted alongside RCTs are often underpowered, they are the strongest study design for limiting bias when estimating differences in costs and outcomes, the primary goal of economic evaluations.[36, 71] Another limitation is the use of self-report for healthcare and medication utilization. Obtaining healthcare claims for trial participants would provide a more valid measure of healthcare use and cost; however, some level of self-reported utilization is necessary when including costs for non-covered services (e.g. massage, acupuncture) and over the counter medications. Finally, concerns may be raised about the generalizability of results from a single-center RCT. However, participants in this study were similar to other populations of older adults in the U.S. with neck or back pain. [72, 73]

Conclusions

On average, SMT+HEA resulted in better clinical outcomes and lower total societal costs relative to SRE+HEA and HEA alone, with a 0.75 to 0.81 probability of cost-effectiveness for willingness to pay thresholds of \$50,000 to \$200,000 per QALY.

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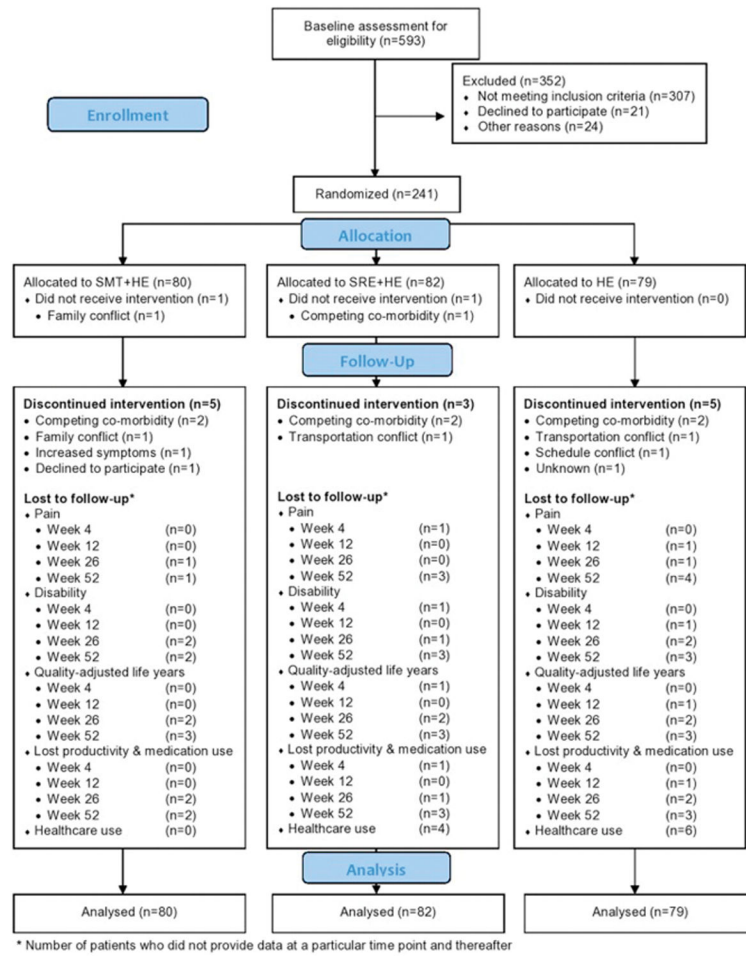


Figure 1. CONSORT Flow diagram for clinical outcomes, lost productivity, and healthcare use

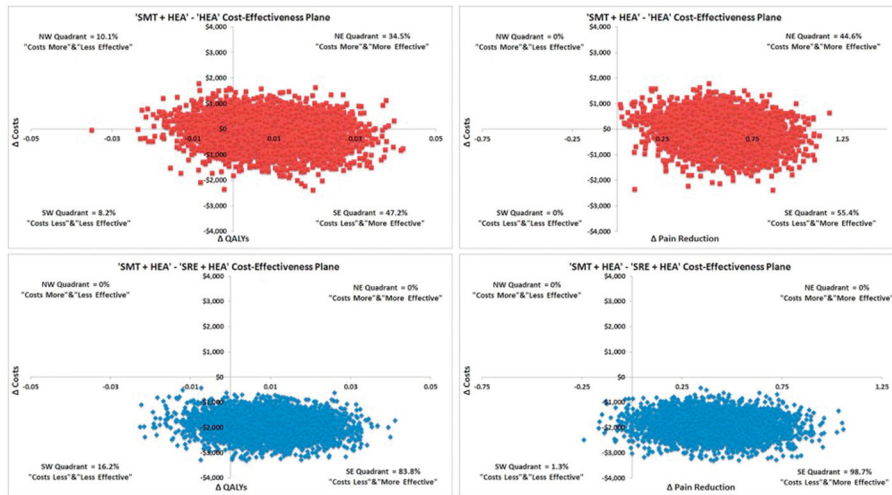


Figure 2. Cost-QALY and cost-pain reduction pairs for spinal manipulation therapy (SMT) when added to home exercise and advice (HEA), and SMT+HEA compared to supervise rehabilitative exercise (SRE) plus HEA plotted on the cost-effectiveness plane from the societal perspective

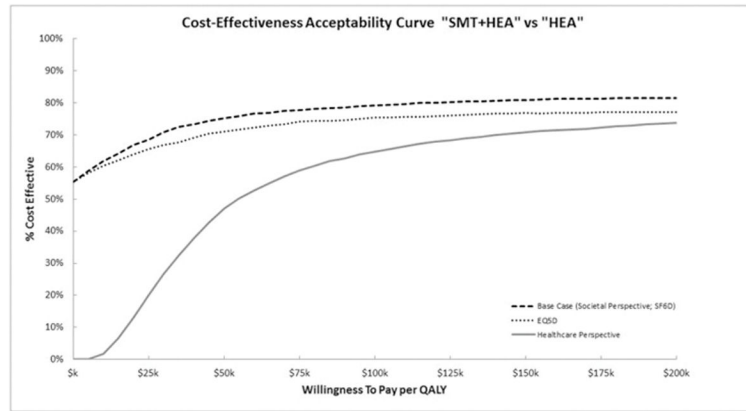


Figure 3. Cost-effectiveness acceptability curve for base case and sensitivity analyses when adding spinal manipulation therapy (SMT) to home exercise and advice (HEA) for QALYs

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Table 1

Unit cost of healthcare resources

Healthcare resource	Source (2006 Medicare Allowed Charges)	
Study Treatments		
Spinal manipulative therapy visit	\$30.74	Average resource use from random sample of 20 participants (301 visits)
Supervised rehabilitative exercise visit (60 minutes)	\$112.80	HCPCS 97110 (4 units)
Home exercise and advice visit (60 minutes)	\$115.09	HCPCS 97110 (3 units) & 97535 (1 unit)
Non-study Treatments		
Chiropractic evaluation	\$37.07	HCPCS 99212
Spinal manipulative therapy	\$25.37	HCPCS 98940
Heat	\$13.40	HCPCS 97010 (1 unit)
Ultrasound	\$12.30	HCPCS 97035 (1 unit)
Acupuncture (60 minutes)	\$119.00	HCPCS 97810 (1 unit) & 97811 (3 units)
Manual therapy	\$26.52	HCPCS 97140 (1 unit)
Physician evaluation	\$51.26	HCPCS 99213
Physical therapy evaluation	\$75.57	HCPCS 97001
Exercise therapy (30 minutes)	\$56.39	HCPCS 97110 (2 units)
Traction	\$14.55	HCPCS 97012 (1 unit)
Massage (30 minutes)	\$45.79	HCPCS 97124 (2 units)
Cervical spine radiographs	\$33.93	HCPCS 72040 Global
Epidural injection	\$431.51	2006 Average for HCPCS 62310
CT	\$251.22	HCPCS 70490 Global
MRI	\$500.84	HCPCS 72141 Global
Fusion	\$15,181.14	(Facility + Anesthesiologist + Surgeon Costs)
Facility Costs	\$12,157.44	Average reimbursement for DRG's 471–3
Anesthesiologist Costs	\$218.68	2006 Average for HCPCS 00630
Surgeon Costs	\$3,023.70	(Arthrodesis + Discectomy + Autograft + Instrumentation)
- Arthrodesis	\$734.35	HCPCS 22554
- Discectomy	\$1,048.68	HCPCS 63075
- Autograft	\$203.62	HCPCS 20938
- Anterior Instrumentation	\$818.37	HCPCS 22845

HCPCS = Healthcare common procedure coding system; DRG = Diagnosis-related group

Table 2

Baseline clinical and demographic characteristics

	HEA	SMT + HEA	SRE + HEA
Participants, n	79	80	82
Mean age (SD), years	72.7 (5.3)	71.7 (5.2)	72.6 (5.6)
Women, n (%)	35 (44.3)	36 (45.0)	42 (51.2)
Median duration neck pain (IQR), years	5.0 (2.0–15.0)	6.5 (2.0–19.0)	7.5 (1.8–20.0)
Pain radiating to upper extremity, n (%)	17 (21.5)	13 (16.3)	11 (13.4)
Timed up & go test (SD), seconds	11.3 (2.4)	10.8 (2.1)	11.3 (2.4)
Neck pain (SD), [0–10]	4.95 (1.26)	5.33 (1.49)	4.89 (1.34)
Neck disability (SD), [0–100]	24.23 (9.88)	22.78 (9.37)	22.85 (9.20)
SF6D-derived quality adjusted life years (SD), [0.1–1]	0.76 (0.12)	0.77 (0.12)	0.77 (0.13)
EQ5D-derived quality adjusted life years (SD), [–0.1–1]	0.80 (0.07)	0.79 (0.06)	0.80 (0.09)
Employment status			
- Employed, n (%)	12 (12.5)	16 (16.8)	17 (17.7)
- Retired, n (%)	65 (67.7)	57 (60.0)	59 (61.5)
- Homemaker, n (%)	8 (8.3)	7 (7.4)	8 (8.3)
- Other (e.g. unemployed, disabled), n (%)	11 (11.5)	15 (15.8)	12 (12.5)
Education level, n (%)			
- Less than high school	1 (1.3)	2 (2.5)	1 (1.2)
- High school degree	23 (29.1)	24 (30.0)	23 (28.1)
- Some college	20 (25.3)	14 (17.5)	21 (25.6)
- Associate or technical degree	11 (13.9)	6 (7.5)	8 (8.5)
- College degree	12 (15.2)	18 (22.5)	17 (20.7)
- Post-graduate degree	12 (15.2)	16 (20.0)	13 (15.9)
Previous Treatment (prior 3 months), n (%)			
- Medical Doctor	6 (7.6)	8 (10.0)	9 (11.0)
- Specialist	1 (1.3)	3 (3.8)	5 (6.1)
- Chiropractor	10 (12.7)	14 (17.5)	12 (14.6)
- Physical Therapy	1 (1.3)	6 (7.5)	1 (1.2)
- Massage	5 (6.3)	9 (11.3)	3 (3.7)

Table 3

One year time-weighted clinical outcomes and cumulative costs

	HEA	SMT+HEA	SRE+HEA	SMT+HEA HEA	SMT+HEA - SRE+HEA	SRE+HEA HEA
	Mean (SD) [*]	Mean (SD) [*]	Mean (SD) [*]	Mean (95% CI) [†]	Mean (95% CI) [†]	Mean (95% CI) [†]
Clinical Outcomes						
Pain Reduction [0–10]	1.6 (1.9)	2.4 (2.1)	1.8 (1.9)	0.57 (0.23 to 0.92)	0.41 (0.05 to 0.76)	0.17 (–0.20 to 0.52)
Disability Reduction [0–100]	6.1 (8.8)	7.4 (9.9)	5.6 (8.5)	1.67 (–0.15 to 3.41)	1.85 (0.06 to 3.57)	–0.18 (–1.92 to 1.63)
QALY Gain (SF6D) [0.1–1]	0.031 (0.101)	0.039 (0.106)	0.030 (0.084)	0.009 (–0.011 to 0.029)	0.009 (–0.009 to 0.027)	–0.0001 (–0.018 to 0.018)
QALY Gain (EQ5D) [–0.1–1]	0.020 (0.090)	0.027 (0.110)	0.011 (0.090)	0.007 (–0.012 to 0.025)	0.015 (–0.004 to 0.033)	–0.009 (–0.025 to 0.009)
Costs (2006 US \$)						
Healthcare	779 (281)	1,297 (1,792)	2,556 (505)	515 (225 to 1,094)	–1,260 (–1,562 to –682)	1,775 (1,590 to 1,948)
Lost productivity	1,390 (1,596)	548 (844)	1,042 (1,299)	–842 (–2,194 to –33)	–495 (–1,362 to 104)	–348 (–1,646 to 643)
Total indirect	1,526 (1,597)	901 (848)	1,573 (1,302)	–625 (–1,837 to 245)	–672 (–1,481 to –22)	47 (–1,170 to 1,111)
Total	2,305 (1,634)	2,198 (2,040)	4,129 (1,438)	–111 (–1,354 to 899)	–1,932 (–2,796 to –1,097)	1,821 (592 to 2,912)

^{*} Unadjusted mean (SD);

[†] Model-based results with baseline outcome included as a covariate for clinical outcomes, 95% bias-corrected bootstrap confidence intervals, positive values favor the first treatment contrast;

HEA = Home exercise and advice; SMT = Spinal manipulation therapy; SRE = Supervised rehabilitative exercise; Pain reduction = numerical rating scale, higher scores indicate more improvement; Disability reduction = neck disability index, higher scores indicate more improvement; QALY = Quality-adjusted life year, higher scores indicate more quality adjusted life years; Total indirect costs = lost productivity + time + transportation costs.

Table 4

Resource use and associated cost over one year

	HEA			SMT+HEA			SRE+HEA		
	% use	Mean use (SD)	Mean \$ (SD)	% use	Mean use (SD)	Mean \$ (SD)	% use	Mean use (SD)	Mean \$ (SD)
Study Treatments									
HEA	100	3.9 (0.4)	449 (44)	99	3.9 (0.5)	455 (51)	100	3.9 (0.5)	446 (61)
SMT	--	--	--	99	15.1 (3.5)	463 (107)	--	--	--
SRE	--	--	--	--	--	--	99	16.6 (3.4)	1,868 (379)
Non-study Treatments									
SMT	13	1.0 (4.1)	25 (103)	15	1.3 (4.3)	32 (110)	14	0.5 (1.6)	14 (41)
Exercise Therapy	7	0.4 (2.2)	23 (125)	--	--	--	9	0.7 (2.8)	41 (159)
Physician Evaluation	7	0.1 (0.5)	5 (26)	9	0.1 (0.3)	5 (17)	9	0.1 (0.3)	5 (18)
Heat	--	--	--	1	0.01 (0.1)	0.2 (2)	3	0.1 (1.1)	2 (15)
Ultrasound	3	0.3 (2.1)	4 (26)	3	0.1 (1.1)	2 (14)	3	0.1 (0.8)	2 (10)
Massage	4	0.4 (2.3)	12 (73)	3	0.4 (2.9)	19 (131)	1	0.04 (0.3)	2 (15)
Acupuncture	4	0.2 (1.3)	26 (160)	1	0.01 (0.1)	1 (13)	1	0.06 (0.6)	8 (67)
X-rays	1	0.01 (0.1)	0.4 (4)	1	0.01 (0.1)	0.4 (4)	--	--	--
CT	1	0.01 (0.1)	3 (29)	--	--	--	--	--	--
MRI	1	0.01 (0.1)	7 (57)	1	0.01 (0.1)	6 (56)	--	--	--
Injection	3	0.03 (0.2)	11 (69)	--	--	--	3	0.03 (0.2)	11 (68)
Fusion	--	--	--	1	0.01 (0.1)	190 (1697)	--	--	--
Medication			85 (32)			110 (57)			133 (63)
Indirect Costs									
Lost productivity	%	Mean days (SD)	Mean \$ (SD)	%	Mean days (SD)	Mean \$ (SD)	%	Mean days (SD)	Mean \$ (SD)
Paid labor	6	3.5 (8.1)	407 (945)	6	2.0 (6.5)	235 (752)	2	0.4 (0.9)	42 (102)
Unpaid labor	19	8.4 (11.2)	976 (1,308)	19	2.7 (3.4)	312 (395)	32	8.5 (11.1)	995 (1,293)
Total	25	11.9 (13.7)	1,390 (1,596)	25	4.7 (7.2)	548 (844)	34	8.9 (11.1)	1,042 (1,299)
Patient time			74 (34)			147 (63)			311 (62)
Transportation			63 (45)			206 (53)			220 (51)

HEA = Home exercise and advice; SMT = Spinal manipulation therapy; SRE = Supervised rehabilitative exercise

Table 5

Cost-effectiveness results

	Mean Costs (SD) *	Costs (95% CI) †	Mean Outcome (SD) *	Outcomes (95% CI) †	ICER (95% CI) †
Societal Perspective					
Pain Reduction					
SMT + HEA	\$2,198 (\$2,040)	-	2.4 (2.1)	-	Reference
HEA	\$2,305 (\$1,634)	-	1.6 (1.9)	-	Dominated‡
SRE + HEA	\$4,129 (\$1,438)	-	1.8 (1.9)	-	Dominated‡
Disability Reduction					
SMT + HEA	\$2,198 (\$2,040)	-	7.4 (9.9)	-	Reference
HEA	\$2,305 (\$1,634)	-	6.1 (8.8)	-	Dominated‡
SRE + HEA	\$4,129 (\$1,438)	-	5.6 (8.5)	-	Dominated‡
QALYs Gained (SF-6D)					
SMT + HEA	\$2,198 (\$2,040)	-	0.039 (0.106)	-	Reference
HEA	\$2,305 (\$1,634)	-	0.031 (0.101)	-	Dominated‡
SRE + HEA	\$4,129 (\$1,438)	-	0.030 (0.084)	-	Dominated‡
Sensitivity Analyses					
QALYs Gained (EQ-5D)					
SMT + HEA	\$2,198 (\$2,040)	-	0.027 (0.110)	-	Reference
HEA	\$2,305 (\$1,634)	-	0.020 (0.090)	-	Dominated‡
SRE + HEA	\$4,129 (\$1,438)	-	0.011 (0.090)	-	Dominated‡
Healthcare Perspective					
Pain Reduction					
HEA	\$779 (\$281)	-	1.6 (1.9)	-	Reference
SMT + HEA	\$1,297 (\$1,792)	\$515 (\$225 to \$1,094)	2.4 (2.1)	0.57 (0.23 to 0.92)	\$895 (\$317 to \$3,178) ¥

	Mean Costs (SD) [*]	Costs (95% CI) [†]	Mean Outcome (SD) [*]	Outcomes (95% CI) [†]	ICER (95% CI) [‡]
SRE + HEA	\$2,556 (\$505)	-	1.8 (1.9)	-	Dominated [‡]
Disability Reduction					
HEA	\$779 (\$281)	-	6.1 (8.8)	-	Reference
SMT + HEA	\$1,297 (\$1,792)	\$515 (\$225 to \$1,094)	7.4 (9.9)	1.67 (-0.15 to 3.41)	\$308 (\$97 to Dominated [‡]) [‡]
SRE + HEA	\$2,556 (\$505)	-	5.6 (8.5)	-	Dominated [‡]
QALYs Gained (SF6D)					
HEA	\$779 (\$281)	-	0.031 (0.101)	-	Reference
SMT + HEA	\$1,297 (\$1,792)	\$515 (\$225 to \$1,094)	0.039 (0.106)	0.009 (-0.011 to 0.029)	\$55,975 (\$18,733 to Dominated [‡]) [‡]
SRE + HEA	\$2,556 (\$505)	-	0.030 (0.084)	-	Dominated [‡]

^{*} Unadjusted mean (SD);

[†] Adjusted mean (95% bias-corrected bootstrap confidence intervals) from longitudinal model for treatments with higher costs and better outcomes;

[‡] Dominated = worse mean outcome and higher mean cost;

[‡] ICERs are calculated based on 7 digit accuracy of in costs and outcomes, reported in costs and outcomes were rounded for presentation;

HEA = Home exercise and advice; ICER = Incremental cost-effectiveness ratio; SMT = Spinal manipulation therapy; SRE = Supervised rehabilitative exercise; QALY = Quality-adjusted life year