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Cost analysis related to dose-response of spinal manipulative therapy for chronic low back pain: outcomes from a randomized controlled trial

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Abstract

Objective—The purpose of this analysis is to report the incremental costs and benefits of different doses of spinal manipulative therapy (SMT) in patients with chronic low back pain (LBP).

Methods—We randomized 400 patients with chronic LBP to receive a dose of 0, 6, 12, or 18 sessions of SMT. Participants were scheduled for 18 visits over 6 weeks and received SMT or light massage control from a doctor of chiropractic. Societal costs in the year following study enrollment were estimated using patient reports of healthcare utilization and lost productivity. The main health outcomes were the number of pain-free days and disability-free days. Multiple regression was performed on outcomes and log-transformed cost data.

Results—Lost productivity accounts for a majority of societal costs of chronic LBP. Cost of treatment and lost productivity ranged from $3398 for 12 SMT sessions to $3815 for 0 SMT sessions with no statistically significant differences between groups. Baseline patient characteristics related to increase in costs were greater age (P=0.03), greater disability (P=0.01), lower QALY scores (P=0.01), and higher costs in the period preceding enrollment (P<0.01). Pain-free and disability-free days were greater for all SMT doses compared to control, but only SMT 12 yielded a statistically significant benefit of 22.9 pain-free days (P=0.03) and 19.8 disability-free days (P=0.04). No statistically significant group differences in QALYs were noted.

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Conclusions—A dose of 12 SMT sessions yielded a modest benefit in pain-free and disability-free days. Care of chronic LBP with SMT did not increase the costs of treatment plus lost productivity.

Keywords

Chiropractic; Manipulation; Spinal; Low Back Pain; Costs and Cost Analysis; Health Care Costs

INTRODUCTION

The estimated incidence of moderate back pain is 10–15% of the adult population, with a point prevalence of 15–30%.[1–3] Low back pain is the 5th most common reason for physician office visits in the US.[4, 5] Amongst people with LBP, who see a complementary and alternative medicine (CAM) practitioner for any reason, approximately 49% see a doctor of chiropractic for LBP.[6, 7] The use of CAM, including chiropractic care, has increased significantly over the past 50 years,[2, 8] and may be associated with lower treatment costs.[9–11]

Back pain is the 4th costliest health and productivity burden for US employers among physical and mental health conditions.[7, 12] Biennial expenditures were estimated as high as $35.7 billion for ambulatory services for chronic back pain in 2006 to 2007.[13] Including indirect costs, annual US costs of LBP could range from $84.1 to $624.8 billion.[5, 7] A recent study in the UK found that patients with chronic LBP had annual treatment costs that were twice those of matched controls.[14] Furthermore, episodes of LBP have been associated with increased spending on other health conditions.[15]

The utilization of any kind of patient-initiated treatment is intermittent and ongoing LBP often persists beyond reception of care.[16] The costs paid by the insurer for a course of care provided by a doctor of chiropractic may be as much as 40% less than care provided by an MD.[17] While patients do not seem to seek coordinated care across provider types within LPB episodes, perhaps this integration will improve over time.[18] Few studies have been done evaluating the dose effect of spinal manipulative therapy (SMT).[19–21] The scientific evidence on SMT for the relief of chronic LBP has been well discussed in systematic reviews.[22, 23]

Previously reported data for our trial showed a sustainable within dose-group treatment effect across multiple dose groups to 52 weeks and, while 12 SMT visits were favored, this was not well distinguished from 6 and 18 visits.[24] The purpose of this analysis is to report the incremental cost of treatment and lost productivity as well as the benefit in terms of pain-free and disability-free days.

METHODS

Design

This secondary analysis utilized data from a prospective open-label, randomized controlled trial registered on ClinicalTrials.gov (NCT00376350). This trial is discussed in detail by Haas et al.[24] The study was conducted in Portland, Oregon between March 2007 and July

2011. A total of 400 participants were randomized to receive a dose of 0, 6, 12, or 18 SMT sessions out of 18 treatment visits with a doctor of chiropractic. All participants were assigned 3 treatments per week for 6 weeks. Treating physicians provided care at each visit: SMT or a minimal light massage control to isolate the effect of SMT from the effect of touching the patient therapeutically.

Participants

Volunteers with a current episode of chronic LBP[25,26] of mechanical origin lasting 3 months or longer were eligible if they were at least 18 years old, ambulatory, and English literate.[27] Participants were required to have some LBP on at least 30 days of the prior 6 weeks and a minimum score of 25 on the 100-point pain intensity scale described below. They were excluded for contraindications to SMT such as active cancer, spine pathology, inflammatory arthropathies, autoimmune disorders, and anti-coagulant conditions. Also excluded were potentially confounding conditions including neurodegenerative diseases, pain radiating below the knee, organic referred pain, and disability compensation.[24] This study was approved by the University of Western States Institutional Review Board.

Intervention

The SMT treatments consisted of high-velocity, low-amplitude spinal manipulation of the lumbar spine and transition thoracic regions.[28] The light massage used as the control intervention was gentler and of shorter duration than recommended for therapeutic massage practice.[29, 30]

Outcome Measures

The main outcome measures for this analysis were pain-free days (PFDs) and disability-free days (DFDs), defined as the estimated number of days in the year following randomization that the participant was free of LBP and disability. PFDs and DFDs were computed using methods similar to those employed by Lave et al[31] to calculate depression-free days and by Dickinson et al[32] to calculate pain-related disability-free days. Patients with Modified Von Korff scores of over 80 were assumed to be impacted on all intervening days by pain/disability, and those with scores no greater than 20 were assumed free of pain/disability on those days. For those with intermediate pain or disability scores, the number of days of discomfort was assumed to increase linearly with the score. The mean of 2 consecutive scores was used to estimate the number of days with pain/disability in the intervening time interval.

Modified Von Korff LBP pain intensity and pain-related functional disability range from 0 to 100, with higher scores denoting greater severity.[33] The pain score is an average of 3 scales, 0 to 10 each, multiplied by 10: back pain today, worst back pain in the last 4 weeks, and average back pain in the last 4 weeks. Similarly, the disability score is the rescaled average of 3 questions, also 0 to 10 each, covering interference with daily activities, social and recreational activities, and the ability to work outside or around the house. Pain and disability are recognized as key indicators of severity in pain conditions, and indices measuring pain and disability from a composite of several patient responses have desirable psychometric properties for assessments of health.[34, 35]

Quality-adjusted life years (QALY) were computed from EuroQol-5D measures collected at baseline, 12, 24, 39, and 52 weeks.[36, 37] Other patient measures, including reports of health care utilization, were collected at baseline, 6, 12, 18, 24, 39, and 52 weeks summarizing experiences over the prior four-weeks.

Costs

Our objective was to estimate costs from a societal perspective consisting of costs of study-provided care, patient reports of outside care, and lost productivity. While treatment and lost productivity likely account for a majority of costs related to LBP, some costs were not included in our data. These include the cost transportation and travel time to obtain care, as well as the cost of any equipment purchases, or modifications to accommodate LBP. Consequently, we may underestimate the full societal cost of LBP.

Treatment costs—To estimate costs of treatment not included as part of the study protocol, we used patient reports of outside care utilization in the previous 4 weeks. Patient reports of care are widely employed to estimate utilization and are regarded as reliable over short time periods.[38] Medicare's 2009 national non-facility (i.e., non-hospital) payments were used to estimate costs of patient-reported visits to health care providers.[39] The resource-based relative value scale underlying these payments is designed to reflect the resources used to provide services.[40] Assigned costs of treatment are listed in Table 1. Physician fees for emergency department visits were estimated using Medicare's 2009 national facility payment to account for hospital facility fees under the hospital outpatient prospective payment system.[41] We assumed that the light massage control was minimally therapeutic, being similar to a massage that might be delivered for a few minutes by a friend, and assigned it no cost.[24]

Patients reported no hospitalizations, and a single patient from the SMT 6 group reported 2 surgeries. It is unknown whether or not these were performed inside or outside the hospital. The costs for these 2 surgeries were excluded from the analysis. The minimum cost of back surgery is estimated at $15,000, and including these costs would create an extreme outlier. Costs of patient-reported use of over-the-counter and prescription medicines were estimated using per use rates of $0.20 and $1.00 respectively.

Lost Productivity Costs—Lost productivity was computed from patient reports of days with inability to perform usual activities including employment, household work, and self-care. Work status (and the related concept of productivity) is determined by a complex array of psychological, social, and economic factors.[42] Measurements of lost productivity due to impaired health including pain have mostly relied on direct patient reports of missed work or impaired ability.[43, 44] There is wide variation in the literature regarding methods employed in the computation of lost productivity due to impaired health.[7, 44, 45] Taking this into account, the cost of productivity lost due to LBP was computed from the number of days the patients were kept from their usual activities by LBP. Taking a societal (as opposed to purely employment-based) perspective on productivity, we assumed that on each day that a patient was kept from usual activities, s/he lost 6 hours of productive time (half of an approximate workday involving 8 hours of paid labor and 2 hours of self-care/household work). Each lost hour was assigned a cost of $15.95, the US median wage in 2009.[46] Annual costs reflect imputed costs incurred in the entire one-year study period from baseline to 52 weeks.

Statistical Analysis

Regression models of the natural logarithm of costs were used to compute the adjusted effect of treatment dose on treatment costs alone, as well as including the cost of lost productivity. Semi-log models such as these are commonly used to address skewness in cost data.[47] They yield an adjusted ratio of treatment group to control group costs.

Duan's smearing estimator (assuming homoscedasticity) was appropriate for use in all retransformations as we found no evidence of heteroscedasticity in the cost regressions.[48] Costs of study-provided treatment were excluded because they are additive and non-stochastic. Including these in the multiplicative log models would have created a functional misspecification resulting in biased results.[49]

Baseline explanatory variables (covariates) included in all regression models were age, sex, white non-Hispanic, married, college-educated, low-income (<$20,000), smoker, prior treatment experience with SMT and massage treatment, differential confidence in treatment success between SMT and massage, as well as baseline pain, disability, and QALY scores. Log of treatment costs in the 4 weeks before baseline was included in treatment cost regressions while log of treatment plus lost productivity in the 4 weeks before baseline was included in treatment plus lost productivity cost regressions.

To further demonstrate the variation in costs of treatment and lost productivity, we created 3 illustrative patient profiles by selecting 3 sets of patient characteristics and fitting our regression models post hoc. The patient in Profile M has baseline characteristics close to the mean for those enrolled in this study. Profiles L and H depict patients with baseline characteristics that are predictive of lower and higher costs respectively. The values of the baseline continuous variables in Profiles L and H were approximately 1 standard deviation from the values for Profile M. The costs of study-provided treatment are included, and the incremental effects of dose as well as some other key predictors of costs in the regression models were computed.[32, 50]

Linear regression models were used to compute the adjusted effect of treatment dose on the number of PFDs and DFDs experienced by patients. The same covariates used in the cost analysis were included with the exception of baseline cost variables.

Statistical testing for all variables was set at a 2-sided alpha of .05. A full intention-to-treat analysis was conducted with each participant included in the original allocation groups; missing data were imputed when possible. Two subjects declined to give annual income information and so were removed from modeling. Multiple-testing adjustments were not made because this was a secondary analysis. Analyses were conducted with Stata 11.0 (StataCorp, College Station, TX) and SAS 9.2 (SAS Institute, Inc. Cary, NC).

RESULTS

Figure 1 shows compliance with follow-up. Details are published elsewhere.[24] Compliance was excellent ranging from 81% to 99% per group per time point. There were 9 subjects who were entirely lost to follow-up after enrollment and were not included in the analysis. For the cost comparisons, the surgery patient was removed. Two participants refused to report income and were removed from adjusted analyses.

Baseline Patient Characteristics and Costs

Mean age for all groups was 41 years, 15% were minorities, and the groups were divided nearly evenly between men and women (Table 2). Over half of all patients reported having college degrees, 36% were married, and 11% were smokers. Participants had moderate low back pain with a mean pain of 51.5 on a 100-point Modified Von Korff scale and mean disability of 45.3 with an average QALY of 0.71. Mean treatment costs in the 4 weeks preceding the baseline were a modest $10.1, on average, and mean costs including the cost of lost productivity in the 4 weeks preceding baseline were substantially larger, $558, on average. No meaningful differences between groups at baseline were noted.

Treatment and Lost Productivity Costs During the Study Period

Table 3 shows that unadjusted one-year costs for treatment outside the study protocol for the groups ranged from $287 to $623. Mean costs for the one-year study period were much larger when the costs of lost productivity were added to the costs of outside care yielding $2,838 to $3,815. No statistically significant differences were observed.

The adjusted group effects in semi-log cost regressions are multiplicative, which are interpreted as ratios of costs compared to control. Annual treatment costs comparisons revealed ratios of 1.15, 1.18, and 0.78 respectively. Costs with lost productivity added resulted in ratios of 0.91, 1.02, and 0.90 respectively. These results were not statistically significant, and no trends across study groups can be inferred given the variability in the costs.

In Table 4, the full regression model for the natural log of annual costs shows that greater age ($P=0.02$) and disability ($P=0.01$) were predictors of higher annual treatment costs, while higher baseline QALY scores ($P<0.01$) predicted lower treatment costs. In the model that also includes costs of lost productivity, college education ($P=0.02$) and previous experience with massage ($P=0.04$) were predictive of higher costs, while higher baseline QALY scores ($P<0.01$) were predictive of lower costs. Costs in the 4 weeks preceding the baseline were strong predictors of higher costs in both these models ($P<0.01$).

Pain-Free and LBP-Related Disability-Free Days

Table 4 also shows the regression models for LBP-related PFDs and DFDs that patients experienced during the one-year study period. Compared to the SMT 0 reference group, patients benefitted from 16.8 to 22.9 more PFDs and 12.3 to 19.4 more DFDs. The greatest benefits in PFDs and DFDs were for the SMT 12 group and were the only statistically significant results ($P=0.03$ and 0.04, respectively). In addition, baseline health as measured by pain, disability, and the QALY score was strongly predictive of the number of PFDs and DFDs that patients experienced. A one-point increase in baseline pain on a 100-point scale predicted a 2.7-point decrease in PFDs (P<0.01), and a one-point increase in baseline disability predicted a 1.4-point decrease in DFDs (P < 0.01). QALY scores are measured on a much narrower, approximately 1 point scale. Each 0.01 point increase in the baseline QALY score predicted 1.07 and 1.05 additional PFDs and DFDs during the study period (P=0.01 and P<0.01, respectively).

QALYs

EuroQol-5D based QALY scores increased 4% to 6% during the one-year study period to 0.81 for SMT 0, 0.80 for SMT 6, 0.83 for SMT 12 and 0.81 for SMT 18. A regression analysis similar to the ones for PFDs/DFDs above found that relative to SMT 0, each dose of SMT yielded an additional 0.00 to 0.01 QALYs. None of the differences either between study groups or across time within study groups were statistically significant.

Incremental Effects of SMT Dose and Patient Characteristics on Adjusted Costs

The costs related to the 3 patient profiles are reported in Table 5. They include the cost of study-provided care, the cost of outside care and, where indicated, the cost of lost productivity. The effects of treatment groups and changes in selected baseline characteristics are presented for each profile.

For Profile M, doses of SMT 6, 12, and 18 predicted increases of $317, $123, and $345 in annual treatment costs, respectively, when compared to no SMT. When lost productivity was included, the doses predicted increases of $734, $94, and $476. Compared to the SMT 0 group, the treatment cost of an additional PFD was $19, $5, and $19 and the treatment cost of an additional DFD was $25, $6, and $28 for SMT 6, 12, and 18 respectively. When treatment and lost productivity were considered, the cost of an additional PFD was $44, $4, and $26 and the cost of an additional DFD was $57, $5, $39 for the 3 dose groups, respectively.

Treatment and lost productivity costs were less responsive to SMT dose for the lower cost patient in Profile L. Baseline patient characteristics such as smoking, age, and disability also had smaller effects on costs for such patients when compared to effects on Profile M.

For Profile H, doses of SMT 6, 12, and 18 predicted increases of $1,217, -$271, and $39 in annual treatment costs, respectively when compared to SMT 0. When the cost of lost productivity was included, the increases were predicted to be $2,777, −$277, and $710. Compared to the SMT 0 group, the treatment cost of an additional PFD was $72, −$12, and $2 and the treatment cost of an additional DFD was $95, −$14, and $3 for SMT 6, 12, and 18 respectively. When treatment and lost productivity were considered, the cost of an additional PFD was $165, −$12, and $39 and the cost of an additional DFD was $217, −$14, and $58 for the 3 dose groups, respectively.

Sensitivity Analysis

Sensitivity analyses that excluded weeks not covered by patient reports yielded results that were very similar to those obtained from analysis of annualized cost data for treatment costs but somewhat more favorable to the highest dose of SMT for costs of treatment plus lost productivity (Table 3).

Post-hoc power analysis of costs of lost productivity and treatments outside the study protocol showed that our trial had 80% power to detect cost increases of 145% for SMT 6, 101% for SMT 12, and 107% for SMT 18 relative to the reference SMT 0 group. Our trial had 80% power to detect relative cost decreases compared to SMT 0 of 44%, 53%, and 50% for the 3 groups, respectively.

DISCUSSION

This study shows that manipulation can have a modicum of benefit in LBP-related pain and disability without significantly increasing treatment or societal costs. In the main results paper reporting pain and disability on 100-point scales, Haas et al[24] found an 8.6-point advantage in pain (p=.002) and 7.5-point advantage in disability (p=.011) for SMT 12 compared to the control at 12 weeks. In this study, we found that this benefit may occur without significant increases in costs of treatment or lost productivity. We also found a modest incremental benefit of 23 PFDs and 19 DFDs from 12 spinal manipulation treatments relative to a no manipulation control. The incremental benefits from the other doses examined showed an increase in PFDs and DFDs, but not with statistical significance. SMT dose did not have a statistically significant effect on either QALYs, treatment costs, or on the combined cost of treatment and lost productivity.

Finding no statistically significant QALY differences either between study groups or across time within study groups is consistent with several prior studies suggesting that QALY scores are insensitive to small or moderate changes in health.[32, 51, 52] It is not uncommon for studies of chronic conditions, especially chronic pain to employ other measures of patient benefit in addition to QALYs. For example, Niemisto et al[53] used measures including VAS pain, self-rated disability, health-related quality of life, and patient satisfaction.

A number of studies have previously examined the benefits and cost of SMT in patients with low back pain.[50, 53–58] The estimated benefits and costs have varied between studies, and part of the difference in results may arise because the studies examined different or unspecified doses of SMT. Our results indicate that incremental benefits vary with SMT dose with SMT 12 yielding the greatest benefit. Our analysis of the effect of the SMT dose on costs should be interpreted with caution because of the large variability in costs (low power). Substantially larger sample sizes appear to be required in trials of SMT in patients with chronic LBP in order to detect differences in costs of treatment and, especially, lost productivity between patients receiving different doses of SMT.

The modest size of the incremental benefit from SMT 12 is not unusual for studies of interventions in patients with chronic pain. In their analysis of the cost of manipulation, stabilizing exercises, and physician consultation in comparison to physician consultation alone, Niemisto et al[53] found mean intervention group improvements relative to control of 6.3 points in pain and an improvement of 2.3 points in disability after 12 months when both pain and disability were measured on scales of 0 to 100. In a study of a collaborative intervention to treat chronic pain among veterans, the intervention yielded 16 additional pain disability free days relative to control.[32]

Our results confirm previous findings that the cost of lost productivity due to LBP is often much higher than the cost of treatment. A systematic review of LBP cost of illness studies lists 8 studies that examined both direct (mostly treatment) and indirect (mostly lost productivity) costs.[7] In 6 of these studies, direct costs comprised less that 20% of combined direct and indirect costs. In our study, cost of productivity lost due to LBP is between approximately 2.5 to 10 fold higher than the cost of treatment.

Kominski et al[58] found LBP patients' baseline characteristics including age, education, and baseline health to be important predictors of treatment costs. Our cost analyses reemphasize the importance of similar baseline patient characteristics, especially baseline pain and disability, as important predictors of treatment costs and lost productivity. In a result consistent with a previous analysis of treatment costs among patients with chronic pain, our results show that costs in the period preceding enrollment in the trial can also be predictive of the costs of treatment and lost productivity.[32]

A recent study on patients with back and neck problems found that CAM users had lower costs than non-CAM users.[9] Our results suggest a potentially more complex relationship for LBP treated by doctors of chiropractic. For patients with characteristics predictive of high costs (Profile H, Table 5), costs of treatment obtained outside the study were much larger than the costs of study-provided treatment, and costs of lost productivity were even larger. Furthermore, costs may increase with SMT for patients whose baseline characteristics predict low costs (Profile L) in contrast to the decrease with some SMT doses for patients whose baseline characteristics predict high costs (Profile H). This highlights the disproportionate share of the economic burden of LBP that patients similar to our Profile H bear in terms of treatment and lost productivity. Larger trials are necessary to clarify the actual causal relationships.

While there are no published standardized measures of the individual financial consequences of pain,[59] there are measures of meaningful clinical improvement to pain and disability. Retrospective reports of interference with daily activities show internal consistency and convergent validity[59, 60] and 11-point numerical rating scales provide sufficient levels of discrimination with similar sensitivity to 101-point scales.[59, 61] Using first-return-to-work as an indicator of recovery is challenging because it is frequently followed by recurrences of work absence.[62] It is difficult to measure work disability outside the usual measures of absence from/presence at work and the number of days of work absence. New measures, such as the clinical return-to-work-rule and testing at-work disability, may be of interest in future research.[59, 63, 64]

Limitations

The selected participants for this study were not on disability nor were they seeking disability claims. In addition, potential participants with confounding conditions were excluded. Our sample size was too small to sufficiently capture subjects who would eventually elect to get surgery, and the one patient who did so, was removed as an outlier. Therefore, this study population best generalizes to a subset of the population missing work. In addition, as over 70% of the participants had previous experience with SMT and over 40% had experience with massage, the expectations of the patients were balanced at baseline. An analysis of the doctor patient encounter showed that expectations were balanced across groups and had no notable effect on follow-up LBP.[65] Still, caution in interpretation of the results is advised.

In this study, patients' mean baseline QALY score was 0.75 which is higher than that observed in most other LBP trials, and may limit direct comparisons of results and may present ceiling effects. In their review of studies of interventions for LBP, Dagenais et al[66] compiled a list of baseline QALY scores in the reviewed studies (their Table 5) that ranged from 0.35 to 0.71; improvements in QALY scores reported by the studies tended to be smaller in groups with higher baseline scores.

Similarly, the existence of a variety of payment systems and costing methodologies complicates direct comparisons of cost results from different studies. Our use of Medicare payments to estimate treatment costs may have contributed to our finding of low treatment costs relative to studies that have used charges, prices paid by private insurers, or other methods. Mean annual treatment costs of study-provided and outside care across the different SMT doses ranged from $315 to $897. While these costs are broadly comparable to those reported by Herman et al[67] for the cost of naturopathic care for LBP, other studies have reported substantially higher costs, especially if treatment involved surgery. Martin et al[68] found through analysis of a nationally representative sample that patients with back and neck problems had mean costs of $6,096 in 2005. The minimum cost of lumbar surgery has been estimated at $15,000.[69]

Using patient reports of health at specific time points or during specific periods to estimate health in intervening periods is common in cost analyses, and we employ this approach to compute DFDs for the complete 1 year duration of the study.[31, 66, 70] However, it remains possible that this extrapolation may introduce an unknown bias into our estimates. We similarly use patient reports of health care utilization and activity restriction in 4-week periods preceding the 6, 12, 18, 24, 39, and 52-week time points to estimate annual treatment and lost productivity costs. The possibility of conservative bias due to extrapolation cannot be ruled out. Our estimates of the cost of productivity lost due to LBP are also conservative. Using mean as opposed to median wages to estimate the cost of each hour of productivity lost would have increased these costs by approximately 30%. Attributing a full workday (8 hours) of lost productivity to each day when a patient was kept from usual activities due to LBP would have compounded the increase by another third. The cost analyses which yield results slightly more favorable to doses SMT 12 and SMT 18 are not statistically significant.

CONCLUSION

SMT showed a modicum of benefit in LBP and LBP-related disability without increasing costs from a societal prospective (treatment costs and productivity together). Inference regarding cost is preliminary because of low statistical power. The SMT 12 group had the most PFDs and DFDs compared to SMT 0. SMT 12 was also favored when looking at predicted mean costs but the incremental cost of SMT interventions depended upon the characteristics of patients being treated. Specifically, for patients who were likely to have high costs, the SMT 12 intervention was cost decreasing (but not statistically significant). This report adds to the evidence that a dose of 12 SMT treatments appears to be reasonable for use in a comparative effectiveness trial.

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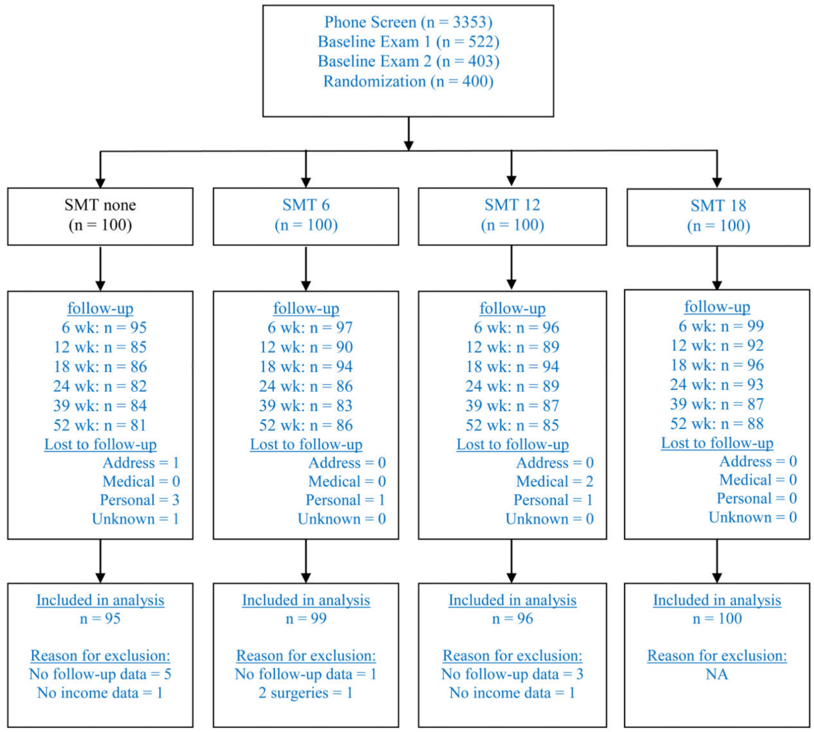

Figure 1.
Study Flowchart

Table 1

Estimated costs calculated from RVUs.

CPT code	Description	estimated cost
99213	office/outpatient visit with an established patient, the most commonly reported physician service (primary care)	$62.35
98941	chiropractic manipulation	$33.90
97124	massage therapy	$22.72
99245	surgeon/neurologist - office consultation	$226.50
90806	psychologist/psychiatrist - individual therapy in office, 45–50 minutes	$87.64
	naturopath/homeopath, physical and occupational therapist, acupuncturist, nurse practitioner, and “other health care provider”	same as DC visit
99283	emergency department visit	$190.59

Table 2

Baseline patient characteristics*

Variable	SMT 0	SMT 6	SMT 12	SMT 18
Demographic				
Age (years)	40.9 (14.1)	41.4 (14.8)	41.8 (14.0)	41.2 (13.8)
Male	51%	51%	51%	48%
Non-white or Hispanic	14%	18%	11%	16%
Married	37%	28%	41%	36%
College degree	58%	63%	51%	53%
Annual income<$20,000	31%	27%	19%	28%
Smoker	17%	13%	6%	8%
Confidence in treatment success (0 extremely doubtful – 6 extremely certain)				
Spinal manipulation (6-point Likert scale)	3.6 (1.2)	3.8 (1.1)	3.7 (1.2)	3.8 (1.1)
Light massage (6-point Likert scale)	3.4 (1.2)	3.5 (1.2)	3.4 (1.2)	3.5 (1.2)
Previous treatment experience				
Spinal manipulation	71%	70%	74%	72%
Massage	52%	56%	43%	54%
Baseline health				
Pain (100-point MVK scale)	52.2 (16.3)	51.0 (18.2)	51.6 (17.5)	51.5 (16.8)
Disability (100-point MVK scale)	45.2 (21.8)	44.8 (24.0)	46.1 (23.4)	45.2 (21.8)
QALY score (EQ-5D)	0.76 (0.11)	0.74 (0.11)	0.76 (0.09)	0.77 (0.07)
Costs (4 wks preceding baseline)				
Treatment ($)	5.5 (13.5)	15.2 (69.2)	8.0 (28.0)	11.7 (34.7)
Treatment + cost of lost productivity($)	599.0 (645.8)	546.1 (591.0)	553.1 (603.5)	533.7 (581.4)

*Mean (SD) or %.

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Table 3

Cost comparisons for treatment and lost productivity*

	Observed unadjusted mean (SD)				Adjusted cost ratio‡ [95% CI]					
	SMT 0	SMT 6	SMT 12	SMT 18	SMT 6 vs SMT 0		SMT 12 vs SMT 0		SMT 18 vs SMT 0	
Treatment costs in preceding 4 weeks ($)										
0 wk	6 (14)	15 (69)	8 (28)	12 (35)						
6 wk	4 (20)	6 (21)	4 (16)	10 (74)	1.08	[0.81, 1.45]	0.93	[0.69, 1.25]	0.88	[0.65, 1.17]
12 wk	23 (47)	52 (152)	13 (29)	32 (102)	0.94	[0.58, 1.52]	0.85	[0.52, 1.39]	0.77	[0.47, 1.25]
18 wk	17 (42)	33 (111)	18 (50)	16 (66)	1.01	[0.65, 1.58]	1.00	[0.64, 1.57]	0.66	[0.42, 1.03]
24 wk	21 (38)	44 (147)	37 (100)	25 (57)	1.06	[0.65, 1.72]	1.16	[0.70, 1.90]	0.78	[0.48, 1.27]
39 wk	32 (72)	62 (170)	36 (87)	26 (50)	1.16	[0.69, 1.95]	1.34	[0.79, 2.28]	0.94	[0.56, 1.59]
52 wk	34 (71)	49 (103)	36 (111)	25 (84)	1.01	[0.60, 1.68]	1.11	[0.66, 187]	0.68	[0.41, 1.13]
Total	128 (166)	255 (516)	134 (223)	113 (162)	1.19	[0.67, 2.11]	1.12	[0.63, 2.01]	0.75	[0.42, 1.33]
Estimated total annual cost of treatment†										
	315 (419)	623 (1299)	361 (631)	287 (390)	1.15	[0.63, 2.11]	1.18	[0.64, 2.18]	0.78	[0.43, 1.43]
Cost of treatment plus lost productivity in preceding 4 weeks ($)										
0 wk	599 (646)	546 (591)	553 (604)	534 (581)						
6 wk	198 (444)	125 (241)	111 (217)	103 (331)	0.99	[0.50, 1.95]	0.54	[0.27, 1.07]	0.46	[0.24, 0.91]
12 wk	312 (517)	266 (462)	181 (270)	221 (350)	0.81	[0.40, 1.63]	0.62	[0.31, 1.26]	0.61	[0.30, 1.23]
18 wk	164 (413)	215 (429)	164 (361)	185 (422)	0.99	[0.50, 1.96]	0.99	[0.49, 2.00]	0.78	[0.39, 1.56]
24 wk	328 (581)	270 (512)	271 (397)	248 (351)	0.89	[0.44, 1.79]	1.74	[0.85, 3.53]	1.37	[0.68, 2.75]
39 wk	240 (414)	318 (515)	233 (412)	220 (395)	0.97	[0.48, 1.96]	0.91	[0.44, 1.85]	0.69	[0.34, 1.39]
52 wk	320 (531)	352 (612)	185 (330)	221 (427)	0.62	[0.31, 1.27]	0.50	[0.24, 1.03]	0.55	[0.27, 1.11]
Total	1594 (2312)	1453 (1813)	1169 (1357)	1109 (1282)	0.87	[0.51, 1.50]	0.91	[0.52, 1.59]	0.64	[0.37, 1.10]
Estimated total annual cost of treatment plus lost productivity†										
	3815 (5384)	3583 (4511)	2991 (3544)	2838 (3282)	0.91	[0.57, 1. 45]	1.02	[0.63,1.64]	0.90	[0.56, 1.44]

* Excludes cost of study-provided treatment. Costs of study-related spinal manipulative therapy over the entire year were: $203 for SMT 6; $407 for SMT 12; and $ 610 for SMT 18.

† Includes imputed costs for weeks not covered by patient reports.

‡The adjusted cost ratio is the geometric mean cost for the treatment group divided by the geometric mean costs for the control group adjusted for group differences in baseline covariates. (Adjusted cost ratio − 1) × 100% equals the percentage increase or decrease of treatment group costs compared to the control group (SMT 0) costs. For example, in the last line of the table, annual costs of treatment plus lost productivity were 0.91 times that of SMT 6, 1.02 times that of SMT 12, and 0.90 times that of SMT 18 compared to patients in the SMT 0 group.

Table 4

Regression models for LBP-related disability-free days and costs*

Variable	Pain Free Days (N=389; R^2=0.34) Regression Coefficient [95% CI]	P	Disability Free Days (N=389; R^2=0.38) Regression Coefficient [95% CI]	P	Log Annual Cost of Treatment (N=388; R^2=0.40) Regression Coefficient [95% CI]	P	Log Annual Cost of Treatment and Lost Productivity (N=388; R^2=0.44) Regression Coefficient [95% CI]	P
Intercept	326.5 [241.5,411.6]	<.001	304.6 [231.4,377.9]	<.001	6.2 [4.3, 8.1]	<.001	6.0 [3.5, 8.5]	<.001
Intervention (Reference category—SMT 0)								
SMT 6	16.8 [−3.9, 37.6]	0.111	12.8 [−5.1, 30.6]	0.160	−0.1 [−0.6, 0.4]	.683	0.1 [−0.5, 0.7]	.649
SMT 12	22.9 [1.8, 44.0]	0.033	19.4 [1.3, 37.5]	0.036	0.0 [−0.5, 0.5]	.936	0.2 [−0.5, 0.8]	.605
SMT 18	18.4 [−2.3, 39.1]	0.081	12.3 [−5.5, 30.1]	0.174	−0.1 [−0.6, 0.4]	.668	−0.2 [−0.9, 0.4]	.428
Socio-demographic								
Age	−0.2 [−0.7, 0.4]	0.513	−0.2 [−0.7, 0.3]	0.367	0.0 [0.0, 0.0]	.020	0.0 [0.0, 0.0]	.611
Male	5.8 [9.4, 21.0]	0.452	0.7 [−12.4, 13.8]	0.918	−0.2 [−0.6, 0.1]	.207	−0.4 [−0.8, 0.1]	.086
White non-Hispanic	−11.6 [−32.6, 9.5]	0.281	−3.5 [−21.6, 14.6]	0.705	0.3 [−0.2, 0.8]	.196	0.0 [−0.6, 0.6]	.983
Married	−4.4 [−21.1, 12.3]	0.605	2.2 [−12.2, 16.6]	0.761	0.1 [−0.2, 0.5]	.467	0.2 [−0.3, 0.7]	.362
College-educated	−5.9 [−21.2, 9.4]	0.447	1.5 [−11.6, 14.7]	0.819	0.3 [0.1, 0.6]	.133	0.6 [−0.1, 1.0]	.016
Low income (<$20,000)	−1.7 [−20.4, 16.9]	0.855	1.3 [−14.7, 17.4]	0.872	0.2 [−0.2, 0.6]	.370	−0.1 [− 0.6, 0.5]	.766
Smoker	−18.0 [−42.2, 6.2]	0.145	3.1 [−23.9, 17.7]	0.770	0.1 [−0.5, 0.6]	.786	0.0 [−0.7, 0.7]	.975
Previous Treatment Experience								
Spinal Manipulation	12.9 [−5.5, 31.3]	0.168	−2.2 [−18.0, 13.6]	0.785	0.1 [−0.3, 0.5]	.608	0.3 [−0.3, 0.8]	.302
Massage	−3.6 [−20.0, 12.9]	0.669	2.8 [−11.4, 17.0]	0.698	0.2 [−0.1, 0.6]	.228	0.5 [0.0, 1.0]	.036
Confidence in Treatment								
SMT vs. massage (baseline)	0.6 [−9.0, 10.2]	0.900	3.5 [−4.7, 11.7]	0.404	0.1 [−0.2, 0.3]	.631	0.0 [−0.2, 0.3]	.736
Baseline health								
Pain (100-point scale)	−2.7 [−3.3, −2.0]	<.001	−0.5 [−1.0, 0.1]	0.083	0.0 [0.0, 0.0]	.125	0.0 [0.0, 0.0]	.206
Disability (100-point scale)	−0.0 [−0.5, 0.5]	0.943	−1.4 [−1.8, −1.0]	<.001	0.0 [0.0, 0.0]	.005	0.0 [0.0, 0.0]	.102
QALY (EQ-5D, range −0.109 to 1	106.9 [24.5,189.4]	0.011	104.5 [33.5,175.5]	0.004	−3.3 [−5.1, −1.4]	.001	−3.7 [−6.1, −1.3]	.003
Costs (4 wks prior to enrollment)								
Treatment	N.A.		N.A.		0.4 [0.3, 0.5]	<.001	N.A.	
Treatment & lost productivity	N.A.		N.A.		N.A.		0.3 [0.2, 0.5]	<.001

N.A.-- Not Applicable.

*Table 4 does not include study costs of study treatment as these are non-stochastic, additive, and could bias the multiplicative log model if included. There was no variability in study treatment costs. Note that study treatment costs are added into Table 5.

Table 5

Predicted mean costs and incremental effects of predictors

					Incremental Cost($) of Dose change to				Incremental Costs ($) due the following:			
Patient type	**Group**	**Predicted Mean costs ($)**	**Incremental cost per PFD compared to SMT 0 ($)**	**Incremental cost per DFD compared to SMT 0 ($)**	**SMT 6**	**SMT 12**	**SMT 18**	**Smoking**	**14-year (1 SD) increase in age**	**22-point (1 SD) increase in baseline disability score**	**$30 (1 SD) increase in treatment costs in the 14 days preceding enrollment**	**$600 (1 SD) increase in treatment and lost productivity costs in the 14 days preceding enrollment**
Annual cost of treatment												
Profile M*	SMT 0	596	N.A.	N.A.	317	123	345	123	34	192	119	N.A.
Profile M*	SMT 6	914	19	25	N.A.	−194	28	161	44	251	156	N.A.
Profile M*	SMT 12	720	5	6		N.A.	222	107	29	167	104	N.A.
Profile M*	SMT 18	941	19	28			N.A.	110	30	173	107	N.A.
Profile L†	SMT 0	61	N.A.	N.A.	154	195	401	12	3	20	47	N.A.
Profile L†	SMT 6	215	9	12	N.A.	41	246	16	4	25	61	N.A.
Profile L†	SMT 12	255	9	10		N.A.	206	11	3	17	41	N.A.
Profile L†	SMT 18	461	22	33			N.A.	11	3	18	42	N.A.
Profile H‡	SMT 0	3,551	N.A.	N.A.	1,217	−271	39	733	202	1,147	487	N.A.
Profile H‡	SMT 6	4,768	72	95	N.A.	−1,488	−1,178	956	263	1,496	635	N.A.
Profile H‡	SMT 12	3,280	−12	−14		N.A.	310	635	175	994	422	N.A.
Profile H‡	SMT 18	3,590	2	3			N.A.	657	181	1,028	436	N.A.
Annual cost of treatment and lost productivity												
Profile M*	SMT 0	3,492	N.A.	N.A.	734	94	476	536	764	1,601	N.A.	825
Profile M*	SMT 6	4,226	44	57	N.A.	−640	−258	627	894	1,875	N.A.	966
Profile M*	SMT 12	3,586	4	5		N.A.	381	519	740	1,551	N.A.	799
Profile M*	SMT 18	3,968	26	39			N.A.	546	779	1,632	N.A.	841
Profile L†	SMT 0	1,637	N.A.	N.A.	416	152	439	251	358	750	N.A.	387
Profile L†	SMT 6	2,053	25	33	N.A.	−264	23	294	419	879	N.A.	453

Patient type	Group	Predicted Mean costs ($)	Incremental cost per PFD compared to SMT 0 ($)	Incremental cost per DFD compared to SMT 0 ($)	Incremental Cost($) of Dose change to SMT 6	SMT 12	SMT 18	Incremental Costs ($) due the following: Smoking	14-year (1 SD) increase in age	22-point (1 SD) increase in baseline disability score	$30 (1 SD) increase in treatment costs in the 14 days preceding enrollment	$600 (1 SD) increase in treatment and lost productivity costs in the 14 days preceding enrollment
Profile L†	SMT 12	1,789	7	8		N.A.	287	243	347	727	N.A.	375
Profile L†	SMT 18	2,076	24	36			N.A.	256	365	765	N.A.	394
Profile H‡	SMT 0	15,422	N.A.	N.A.	2,777	−277	710	2,366	3,373	7,071	N.A.	3,643
Profile H‡	SMT 6	18,200	165	217	N.A.	−3,055	−2,067	2,771	3,951	8,282	N.A.	4,267
Profile H‡	SMT 12	15,145	−12	−14		N.A.	988	2,292	3,268	6,851	N.A.	3,530
Profile H‡	SMT 18	16,133	39	58			N.A.	2,412	3,439	7,210	N.A.	3,715

N.A.-- Not Applicable: retransformed profiles include additive cost of study treatment.

* Profile M (patient characteristics reflective of the mean) — 41 year-old, college-educated, non-white or Hispanic, unmarried, non-smoking female with no previous massage or chiropractic treatment, differential treatment confidence score 0, and baseline pain, disability and QALY scores of 51, 45, and 0.76, respectively. She had treatment costs of $35, and treatment plus lost productivity costs of $600 in the 4 wks preceding study enrollment.

† Profile L (variables one standard deviation away from mean predicted to lower costs) — 27 year-old, non-white or Hispanic, unmarried, low-income, non-smoking male with no previous massage or chiropractic treatment, differential treatment confidence score 0, and baseline pain, disability and QALY scores of 60, 30, and 0.85, respectively. He had treatment costs of $5, and treatment plus lost productivity costs of $200 in the 4 wks preceding study enrollment.

‡ Profile H (variables one standard deviation away mean predicted to raise costs) --55 year-old, college-educated, white non-Hispanic, married, non-smoking female with prior massage and chiropractic treatment, differential treatment confidence score 1, and baseline pain, disability and QALY scores of 40, 55, and 0.65, respectively. She had treatment costs of $55 and treatment plus lost productivity costs of $1200 in the 4 wks preceding study enrollment.