Spine

SPINE Volume 40, Number 4, pp 209-217

RANDOMIZED TRIAL

Comparison of Spinal Manipulation Methods and Usual Medical Care for Acute and Subacute Low Back Pain

A Randomized Clinical Trial

Michael Schneider, DC, PhD,* Mitchell Haas, DC, MA,† Ronald Glick, MD,‡ Joel Stevans, DC,§ and Doug Landsittel, PhD¶

Study Design. Randomized controlled trial with follow-up to 6 months.

Objective. This was a comparative effectiveness trial of manual-thrust manipulation (MTM) *versus* mechanical-assisted manipulation (MAM); and manipulation *versus* usual medical care (UMC).

Summary of Background Data. Low back pain (LBP) is one of the most common conditions seen in primary care and physical medicine practice. MTM is a common treatment for LBP. Claims that MAM is an effective alternative to MTM have yet to be substantiated. There is also question about the effectiveness of manipulation in acute and subacute LBP compared with UMC.

Methods. A total of 107 adults with onset of LBP within the past 12 weeks were randomized to 1 of 3 treatment groups: MTM, MAM, or UMC. Outcome measures included the Oswestry LBP Disability Index (0–100 scale) and numeric pain rating (0–10 scale). Participants in the manipulation groups were treated twice weekly during 4 weeks; subjects in UMC were seen for 3 visits during this time. Outcome measures were captured at baseline, 4 weeks, 3 months, and 6 months.

Results. Linear regression showed a statistically significant advantage of MTM at 4 weeks compared with MAM (disability = −8.1, $P = 0.009$; pain = −1.4, $P = 0.002$) and UMC (disability = −6.5, $P = 0.032$; pain = −1.7, $P < 0.001$). Responder analysis, defined as 30% and 50% reductions in Oswestry LBP Disability Index scores revealed a significantly greater proportion of responders at 4 weeks in MTM (76%; 50%) compared with MAM (50%; 16%) and UMC (48%; 39%). Similar between-group results were found for pain: MTM (94%; 76%); MAM (69%; 47%); and UMC (56%; 41%). No statistically significant group differences were found between MAM and UMC, and for any comparison at 3 or 6 months.

Conclusion. MTM provides greater short-term reductions in self-reported disability and pain scores compared with UMC or MAM.

Key words: low back pain, spinal, manipulation, usual medical care, chiropractic, mechanical-assisted manipulation, manual-thrust manipulation, pain, disability.

Level of Evidence: 2

Spine 2015;40:209–217

From the *School of Health and Rehabilitation Sciences, Clinical and Translational Science Institute, University of Pittsburgh, Pittsburgh, PA; †Center for Outcomes Studies, University of Western States, Portland, OR; ‡Department of Psychiatry and Physical Medicine and Rehabilitation, University of Pittsburgh School of Medicine, Center for Integrative Medicine at UPMC Shadyside, Pittsburgh, PA; §School of Health and Rehabilitation Sciences University of Pittsburgh, Pittsburgh, PA; and ¶Department of Medicine and Department of Biostatistics, Clinical & Translational Science Institute, Center for Research on Health Care Data Center, University of Pittsburgh, Pittsburgh, PA.

Acknowledgment date: August 25, 2014. Revision date: October 31, 2014. Acceptance date: November 3, 2014.

The device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication.

The National Institutes of Health, National Center for Complementary and Alternative Medicine (NIH/NCCAM) grant no. R00 AT004196 funds were received in support of this work.

Relevant financial activities outside the submitted work: consultancy, expert testimony, grants, payment for lecture, royalties, payment for development of educational presentations.

Address correspondence and reprint requests to Michael Schneider, DC, PhD, School of Health and Rehabilitation Sciences, Clinical and Translational Science Institute, University of Pittsburgh, Bridgeside Point 1, 100 Technology Dr, Ste 210, University of Pittsburgh, Pittsburgh, PA 15219; E-mail: mjs5@pitt.edu

DOI: 10.1097/BRS.0000000000000724

Low back pain (LBP) is among the most common medical ailments and an important public health issue. Approximately, 50% of US working-age adults experience LBP each year[1] with a quarter of US adults reporting an episode of back pain in the previous 3 months.[2] Back pain is the most common cause of disability for persons younger than 45 years and one of the most common reasons for office visits to primary care physicians in the United States[3,4] as well as Europe and Australia.[5–7]

Spinal manipulative therapy (SMT) is used by chiropractors, physical therapists, and osteopathic physicians for the treatment of acute LBP. The most recent Cochrane Review concluded that SMT was no more effective than inert interventions, sham SMT, or usual medical interventions.[8] A recent meta-analysis using Bayesian methods concluded that the effectiveness of SMT is equivocal.[9] However, other guidelines and systematic reviews have shown moderate effectiveness of manual SMT for the care of acute LBP.[10–13]

Systematic reviews have focused on manual-thrust manipulation (MTM) and are not generalizable to mechanical-assisted manipulation (MAM) methods. MTM is still the most common type of manipulation used by chiropractors. However, surveys of the chiropractic profession during the past decade have shown a trend toward increased utilization of mechanical manipulation devices. These devices are now the second most common type of manipulation used by American chiropractors.[14–16] The most popular mechanical device used by chiropractors is the Activator Instrument (Activator Methods International Ltd., Phoenix, AZ).

Mechanical devices are promoted as safe and effective alternatives to manual manipulation, yet there is a lack of high-quality trials to support this claim. A few clinical studies[17–21] compared Activator Instrument with MTM with equivocal results, but none of these trials compared Activator Instrument with usual medical care (UMC). The purpose of this study was to compare the effectiveness of MTM and MAM, and to compare both types of manipulation with UMC for the treatment of acute and subacute LBP.

MATERIALS AND METHODS

Design Overview

This was a prospective, randomized clinical trial evaluating the comparative effectiveness of manual and mechanical types of spinal manipulation and UMC for treatment of acute and subacute LBP. This study was approved by the University of Pittsburgh Institutional Review Board (PRO10040327); written informed consent was obtained from all study participants. We followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines for reporting randomized trials (http://www.consort-statement.org/) and provided a CONSORT flow diagram (Figure 1).

Setting and Participants

The study was conducted between November 2010 and March 2013 at the UPMC Center for Integrative Medicine in Pittsburgh. Participants were required to have a new LBP episode within the previous 3 months, be at least 18 years of age, and speak/understand English. To prevent floor effects, minimum levels of self-reported pain (3 on 0–10 scale) and disability (20 on 0–100 scale) were also required. Participants also agreed to be randomized, attend 2 office visits per week for 4 weeks, and co-operate with follow-up data collection.

Exclusion criteria included the following: (1) chronic LBP (>3-mo duration); (2) previous chiropractic, medical, or physical therapy treatment for the current LBP episode; (3) radicular features including leg pain distal to the knee, numbness/weakness of the lower leg, or positive nerve root tension/neurological signs; (4) contraindications to spinal manipulation, including: previous history of metastatic cancer, severe osteoporosis, fracture or instability, or prolonged anticoagulant or oral steroid use; or (5) current use of prescription pain medications. Participants were permitted to take over-the-counter medications for back pain.

Randomization and Blinding

Randomization was conducted using a rank-based adaptive allocation design[22] to balance groups on baseline pain, disability, and treatment expectation. Randomization was computer generated remotely *via* a data center Web site after baseline examination so that allocation was concealed until the moment of randomization. The participants or treating clinicians were not blinded to the treatment assignment.

Informed consent and baseline examinations to determine eligibility were performed by a chiropractor with 10 years of clinical experience; he did not provide treatment. A research co-ordinator with 20 years of clinical trials experience was responsible for overseeing randomization and data collection procedures. She maintained a secure randomization master file that linked personal identifying information with a unique research identity. The principal investigator was blinded to the treatment assignment and had no interaction with research participants. The principal investigator was also blinded to the tasks of data collection and the primary data analysis. These tasks were conducted by the research co-ordinator (collection) and biostatistician (analysis), who were not blinded to group allocation.

Study Interventions

1. *Manual-thrust manipulation*: Participants were given high-velocity low-amplitude thrust manipulation in the side posture position by a licensed chiropractor. Segmental levels where manipulation was applied were determined using standard chiropractic methods of static and motion palpation.[23]
2. *Mechanical-assisted manipulation*: Participants were given MAM in the prone position by a certified Activator Methods chiropractor using the Activator IV Instrument (FDA approval no. K003185; Activator Methods International Ltd.). Segmental levels where the manipulation was applied was determined by using palpation and the Activator method of leg length analysis.[24]
3. *Usual medical care*: Participants were seen by a medical physician, board certified in physical medicine and rehabilitation. These participants were told that most new episodes of back pain are typically self-limiting, were prescribed over-the-counter analgesic and nonsteroidal anti-inflammatory drugs medications, given advice to stay physically active and avoid prolonged bed rest. This protocol is consistent with current clinical guidelines for the management of nonspecific LBP in primary care practice.[25]

All participants were treated during the course of 4 weeks. The 2 manipulation groups attended 8 office visits (~15 min each), twice per week for 4 weeks, a typical chiropractic treatment schedule. Chiropractors typically consider the lower thoracic, lumbar, and sacroiliac joints as 1 kinetic chain, and therefore we permitted them to perform manipulation in any

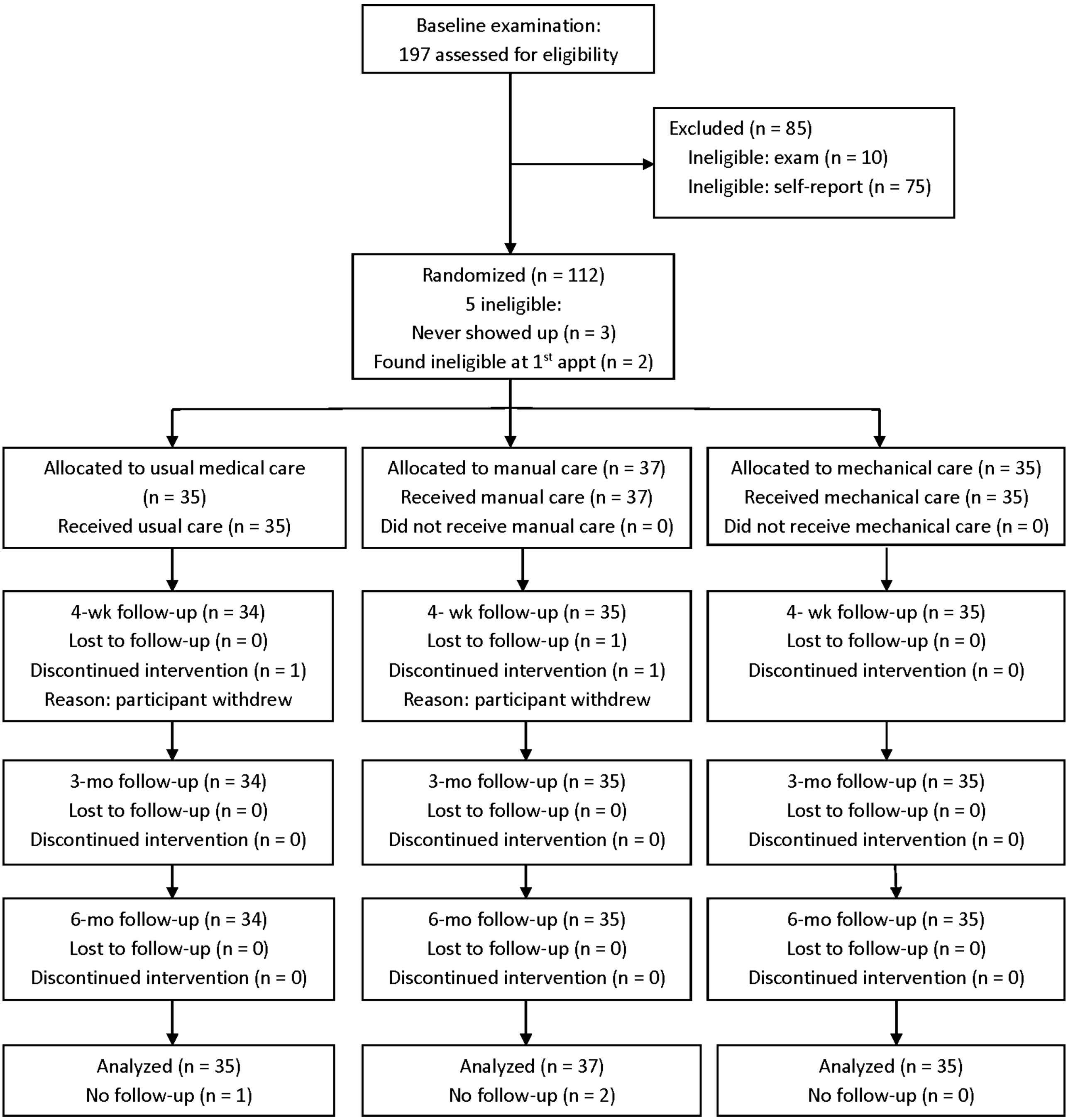

Figure 1. CONSORT study participant flow diagram.

of these regions because they it deemed necessary. No manipulation of other spinal or peripheral joints was permitted. If manipulation was not indicated on any particular visit, the patient was given reassurance and dismissed without treatment that day. The UMC group attended a total of 3 office visits; an initial visit (~30 min) with follow-up visits (~15 min each) at 2 and 4 weeks. After the 4-week assessment, participants were free to pursue rehabilitation or manipulative treatment.

The same clinician provided all care within each treatment group: a single physical medicine and rehabilitation physician provided all UMC; a single chiropractor provided all MTM, and a single chiropractor provided all MAM. Each of the treating clinicians had more than 15 years of clinical experience and provided strong enthusiasm for his respective treatment approach. Participants in all 3 treatment arms received a copy of the same educational booklet[26] from their clinician, providing information about proper posture and movements during activities of daily living.

Outcomes and Follow-up

The primary outcome measure was the Oswestry LBP Disability Index (OSW). It has been widely used in LBP research and is considered to be a valid/reliable measure of functional impairment.[27] The OSW score ranges from 0 to 100, with higher numbers representing higher levels of self-reported disability. The secondary outcome was a self-reported pain-intensity scale, computed as the mean of 3 numeric pain rating scales: current pain, worst pain in the past 24 hours, and average pain during the past week.[28] The 3 individual 0 to 10 scales were anchored by 0 indicating "no pain" and 10 indicating "unbearable pain." Outcomes were assessed at baseline, 4 weeks, 3 months, and 6 months. Additional baseline variables included demographics, physical examination findings, fear avoidance beliefs questionnaire,[29] and treatment credibility-expectation questionnaire.[30]

Statistical Analysis

The primary analysis was linear regression[31] with OSW score as the dependent variable, treatment group as the independent variable, and forced covariate adjustments for baseline OSW score, pain, and treatment expectation (used in the randomization algorithm). Comparison of MTM with MAM was specified *a priori* as the single primary comparison; therefore, no adjustments were made for multiple comparisons. Secondary associations included comparisons of MTM with UMC and MAM with UMC. The analysis was repeated using pain as the dependent variable.

Longitudinal trends were evaluated using a mixed model[32] with a random intercept to account for within-patient correlations, and using separate linear models fit to the 3-month and the 6-month outcomes. The same covariates were included in the models.

Participants who achieved at least 30% or 50% decreases in an outcome were considered to be responders with "moderate" or "substantial" improvement, respectively.[33,34] The proportions of responders in each treatment group were compared using logistic regression with the previously described covariate adjustments.

All analyses were conducted as intention-to-treat with participants in their originally assigned group. For missing follow-up data, the outcome measure was imputed using the prediction from a participant-specific regression of available outcomes at baseline and later time points. Sensitivity analyses were run without imputed data. Stata version 12 (Stata Corp., College Station, TX) was used for all statistical analyses.

Sample size was determined a priori by power analysis that indicated the need for 105 participants (n = 35 per group) to achieve 80% power for detecting a 10-point difference between groups in OSW score (primary outcome) at an α level of 0.05. This was based upon a conservative estimate of the minimal clinically important difference for OSW score and using a standard deviation of 14 points.[35,36]

RESULTS

After telephone screening, 197 potentially eligible people underwent a baseline examination, 112 were randomized, and 107 received treatment (Figure 1). Of the 40 participants allocated to medical care, 2 were subsequently found ineligible and 3 never began treatment. Baseline variables were successfully balanced across the 3 groups (Table 1). Mean participant disability (39.9) and pain (5.7) were moderate in intensity. No adverse events were reported.

Primary and Secondary Analysis

Outcomes, within-group changes and between-group comparisons with standard deviations and/or 95% confidence intervals are found in Table 2. The primary comparison at 4 weeks showed significantly reduced disability for MTM *versus* MAM, with an adjusted mean difference (Δ) of −8.1, P = 0.009. Comparison of MTM with UMC showed a similar result ($\Delta = -6.5$, $P = 0.032$). Comparison of MAM with UMC showed a nonsignificant difference ($\Delta = 1.5$, $P = 0.609$). Excluding missing data led to very similar results.

For pain scores, the adjusted mean difference between MTM and MAM was −1.4 ($P = 0.002$). MTM again showed a significant reduction in pain *versus* UMC ($\Delta = -1.7$, $P < 0.001$). However, there was no significant difference between MAM in comparison with UMC ($\Delta = -0.3$, $P = 0.480$). All results were similar after excluding all missing data.

Longitudinal Analysis

The longitudinal profiles portraying group differences in disability and pain over time are plotted in Figures 2 and 3. For disability, there were no statistically significant differences between groups in the repeated measures model: the adjusted mean differences were −3.5 ($P = 0.308$) for MTM *versus* MAM; −2.5 ($P = 0.461$) for MTM *versus* UMC; and 1.0 ($P = 0.778$) for MAM *versus* UMC. None of the tests at the 3 or 6-month time points were statistically significant (Table 2).

For pain, the adjusted mean differences were as follows: −1.1 (P = 0.0.047) for MTM *versus* MAM; −1.2 ($P = 0.039$) for MTM *versus* UMC; and 0.04 ($P = 0.940$) for MAM *versus* UMC. Although the repeated-measures model demonstrated statistically significant differences in the 2 comparisons with MTM, the individual regressions at the 3-month and 6-month time points showed no significant results (Table 2).

Sensitivity analysis showed that exclusion of missing data led to similar adjusted mean differences between groups for the longitudinal analysis of both disability and pain. There were no statistically significant group differences for disability as explained in the earlier text. For pain, the repeated-measures analysis was also statistically significant for MTM *versus* UMC. However, the 6-month analysis was significant for MTM *versus* MAM in contrast to the analysis with imputed data.

Responder Analysis

Table 3 and Figure 4 display the disability responder analysis at 4 weeks. Seventy-six percent of the MTM group achieved at least a 30% reduction in disability compared with approximately 50% of the MAM ($P = 0.013$) or UMC ($P = 0.024$) groups; MAM was not significantly different from UMC ($P = 0.804$). Fifty percent of the manual group achieved at least a 50% reduction compared with 16% of the MAM ($P = 0.001$) and 39% of the UMC ($P = 0.267$) groups; MAM was significantly worse than UMC ($P = 0.015$) for this outcome.

TABLE 1. Demographic and Baseline Clinical Characteristics for Research Participants				
Variable	Overall (N = 107)	Medical (n = 35)	Manual (n = 37)	Mechanical (n = 35)
Oswestry Low Back Pain Disability Index, mean (SD)	33.9 (9.2)	33.9 (8.1)	33.1 (9.6)	34.6 (10.0)
Numeric pain rating scale score, mean (SD)	5.7 (1.4)	5.7 (1.3)	5.5 (1.3)	6.0 (1.4)
FABQ, mean (SD)	32.9 (16.8)	33.0 (17.8)	32.7 (15.3)	33.0 (18.6)
Age, mean (SD) (yr)	41.1 (14.3)	41.3 (11.6)	41.4 (15.3)	40.4 (15.9)
BMI, no. (%)	28.8 (6.8)	27.4 (5.9)	28.8 (7.7)	30.3 (6.5)
Treatment expectancy, mean (SD)				
Manual	41.9 (8.6)	41.4 (7.8)	41.7 (8.4)	42.5 (9.8)
Mechanical	39.2 (10.1)	38.1 (10.4)	39.7 (9.3)	39.7 (10.7)
Medical	31.8 (12.4)	33.3 (13.0)	31.3 (11.6)	30.8 (12.8)
Sex, no. (%)				
Female	67 (62.6)	21 (60.0)	25 (67.6)	21 (60.0)
Male	40 (37.4)	14 (40.0)	12 (32.4)	14 (40.0)
Race, no. (%)				
Caucasian	67 (62.6)	22 (62.9)	23 (62.2)	22 (62.9)
African American	29 (27.1)	11 (31.4)	9 (24.3)	9 (25.7)
Asian	4 (3.7)	2 (5.7)	2 (5.4)	0 (0.0)
Other	7 (6.5)	0 (0.0)	3 (8.1)	4 (11.4)
Occupation, no. (%)				
Homemaker/student/other	49 (45.8)	11 (31.4)	17 (45.9)	21 (60.0)
Employed	58 (54.2)	24 (68.6)	20 (54.1)	14 (40.0)
Smoking, no. (%)				
No	49 (45.8)	20 (57.1)	15 (40.5)	14 (40.0)
Yes	21 (19.6)	4 (11.4)	11 (29.7)	6 (17.1)
Quit	37 (34.6)	11 (31.4)	11 (29.7)	15 (42.9)
General health, no. (%)				
Poor/fair	7 (6.6)	2 (5.7)	2 (5.6)	3 (8.6)
Good/very good/excellent	99 (93.4)	33 (94.3)	34 (94.4)	32 (91.4)
Exercise, no. (%)				
No	39 (36.8)	11 (31.4)	15 (44.4)	12 (34.3)
Yes	67 (63.2)	24 (68.6)	20 (55.6)	23 (65.7)
Previous chiropractic treatment, no. (%)				
No	58 (54.7)	18 (51.4)	22 (61.1)	18 (51.4)
Yes	48 (45.3)	17 (48.6)	14 (38.9)	17 (48.6)
Previous mechanical treatment, no. (%)				
No	38 (79.2)	13 (76.5)	11 (78.6)	14 (82.4)
Yes	10 (20.8)	4 (23.5)	3 (21.4)	3 (17.6)
Previous manual treatment, no. (%)				
No	1 (2.1)	0 (0.0)	1 (7.1)	0 (0.0)
Yes	47 (97.9)	17 (100.0)	13 (92.9)	17 (100.0)
Comorbidities, no. (%)				
None	64 (59.8)	24 (68.6)	21 (56.8)	19 (54.3)
1	29 (27.1)	8 (22.9)	10 (27.0)	11 (31.4)
> 1	14 (13.1)	3 (8.6)	6 (16.2)	5 (14.3)

Disability and pain outcomes by treatment group and time.

FABQ indicates fear avoidance beliefs questionnaire; BMI, body mass index; SD, standard deviation.

TABLE 2. Data Sections: Disability and Pain Outcomes; Within-Group Changes from Baseline (Outcome − Baseline); and Adjusted Between-Group Differences in Improvement From Baseline

	Baseline	4 wk	3 mo	6 mo
Outcome, mean ± SD				
Disability (0–100 scale)				
Manual	33.1 ± 9.6	17.4 ± 12.3	18.6 ± 14.9	19.8 ± 13.9
Mechanical	34.6 ± 10.0	24.9 ± 13.3	24.1 ± 14.4	23.4 ± 16.1
Medical	33.9 ± 8.1	24.2 ± 13.2	22.7 ± 14.3	22.1 ± 15.6
Pain (0–10 scale)				
Manual	5.5 ± 1.3	1.9 ± 1.5	2.7 ± 2.3	2.5 ± 2.0
Mechanical	6.0 ± 1.4	3.3 ± 2.0	3.9 ± 2.4	4.2 ± 2.8
Medical	5.7 ± 1.3	3.8 ± 2.4	3.9 ± 2.3	3.4 ± 2.6
Outcome − baseline, ([mean ± SD (95% CI])				
Disability				
Manual		−16.0 ± 14.1	−14.7 ± 16.3	−12.7 ± 14.1
		(−20.9 to −11.1)	(−20.5 to 8.9)	(−17.9 to −7.4)
Mechanical		−8.9 ± 11.9	−10.3 ± 15.4	−11.0 ± 15.7
		(−13.2 to −4.6)	(−15.8 to −4.7)	(−16.7 to −5.3)
Medical		−9.5 ± 14.4	−11.3 ± 15.8	−10.9 ± 17.4
		(−14.6 to −4.4)	(−16.9 to −5.7)	(−17.4 to −4.6)
Pain				
Manual		−3.7 ± 1.5	−2.9 ± 2.3	−2.9 ± 2.0
		(−4.2 to −3.1)	(−3.7 to −2.0)	(−3.7 to −2.2)
Mechanical		−2.6 ± 1.6	−2.1 ± 1.9	−1.8 ± 2.2
		(−3.2 to −2.0)	(−2.8 to −1.4)	(−2.6 to −1.0)
Medical		−1.9 ± 2.2	−1.8 ± 1.9	−2.2 ± 2.6
		(−2.7 to −1.1)	(−2.5 to −1.2)	(−3.1 to −1.2)
Adjusted group differences, mean (95% CI)				
Disability				
Manual-mechanical		−8.1 (−14.0 to −2.1)*	−2.9 (−9.9 to 4.0)	0.4 (−10.2 to 11.0)
Manual-medical		−6.5 (−12.5 to −0.6)*	−2.6 (−9.5 to 4.4)	1.4 (−9.1 to 12.0)
Mechanical-medical		1.5 (−4.4 to 7.5)	0.4 (−6.6 to 7.3)	1.0 (−9.6 to 11.6)
Pain				
Manual-mechanical		−1.4 (−2.2 to −0.5)*	−0.9 (−2.1 to 0.3)	−1.2 (−3.2 to 0.7)
Manual-medical		−1.7 (−2.5 to −0.8)*	−1.0 (−2.2 to 0.2)	−0.9 (−2.9 to 1.1)
Mechanical-medical		−0.3 (−1.2 to 0.6)	−0.2 (−1.4 to 1.1)	0.3 (−1.6 to 2.3)

Results of responder analyses.

These data are presented for the 3-study interventions: manual-thrust manipulation (n = 37), mechanical-assisted manipulation (n = 35), and usual medical care (n = 35). A negative sign indicates within-group improvement or an advantage for the first group in adjusted group differences. Data were collected before treatment at baseline, and then again at 4 wk, 3 mo, and 6 mo after onset of treatment. The primary comparison was the covariate-adjusted difference between manual-thrust and mechanical-assisted manipulation in disability scores at 4 wk.

$^*P < 0.05$.

SD indicates standard deviation; CI, confidence interval.

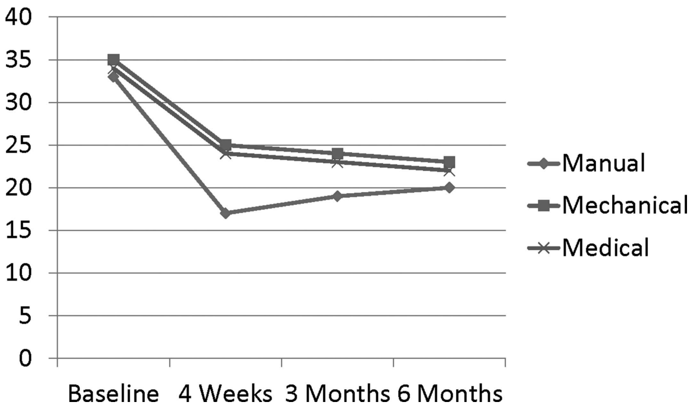

Figure 2. Line plots showing adjusted mean Oswestry Low Back Pain Disability Index scores (disability) for the 3 treatment groups at 4 time points.

Table 3 and Figure 5 show that 94% of the MTM group achieved greater than 30% reduction in pain compared with 69% of MAM (*P* = 0.009) and 56% of UMC (*P* = 0.002). Seventy-six percent of the MTM group attained more than 50% reduction in pain compared with 47% of MAM (*P* = 0.008) and 41% of UMC (*P* = 0.006). The comparisons between MAM and UMC were not significant.

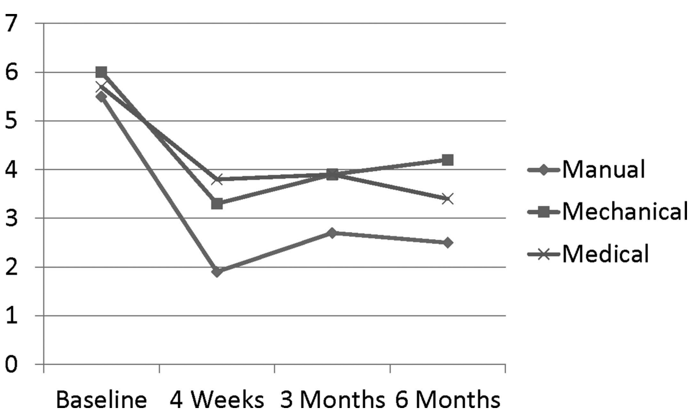

Figure 3. Line plots showing adjusted mean numeric pain rating scores (pain) for the 3 treatment groups at 4 time points.

DISCUSSION

Treatment for acute and subacute LBP is a classic example of preference-sensitive care,[37] where several effective treatment options exist for a specific condition and all should be offered to the patient. Guidelines from the American College of Physicians and the American Pain Society recommend that patients with nonspecific LBP should be provided with nonsteroidal anti-inflammatory drugs and "watchful waiting," which emphasizes spontaneous recovery and prompt return to normal activity.[10,38] Although this approach is reasonable and the general prognosis for acute back pain is favorable, some patients may actually have preference for nonpharmacological therapies including spinal manipulation.

Our primary analysis showed that the MTM group achieved a statistically significant short-term reduction in disability compared with the UMC group (and MAM). The magnitude of the treatment effect size and clinical significance are relatively modest, but still relevant to patients with back pain. Manipulation should be offered as an effective therapeutic option to patients within the context of preference-sensitive care, allowing the patient to make an informed choice that reflects their individual values and preferences. It has been found that treatment options that align with patient preferences lead to enhanced patient satisfaction.[39]

One reason for the observed advantage of MTM may be the characteristics of our study population; we only included patients with recent onset of LBP that had localized lumbar/buttock pain provoked by palpation, and did not have pain distal to the knee. This was by design, because previous research has found that these characteristics represent key clinical findings in a subgroup of patient with LBP that are likely to respond well to spinal manipulation and can be helpful in guiding shared decision making.[40–43]

TABLE 3. Data Obtained After Dichotomizing the Within-Person Changes in Outcomes From Baseline to 4 wk

Outcome	Manual (%)	Mechanical (%)	Medical (%)
Week 4	76	50	48
≥30% reduction disability (OSW)			
Week 4	50	16	39
≥50% reduction disability (OSW)			
Week 4	94	69	56
≥30% reduction pain (NPR)			
Week 4	76	47	41
≥50% reduction pain (NPR)			

The percentages listed in the table reflect the proportion of patients within each group that achieved at least a 30% or 50% reduction in clinical outcomes. These levels of outcome reductions are considered "moderate improvement" and "substantial improvement," respectively.[27,28]

OSW indicates Oswestry Low Back Pain Disability Index; NPR, numeric pain rating.

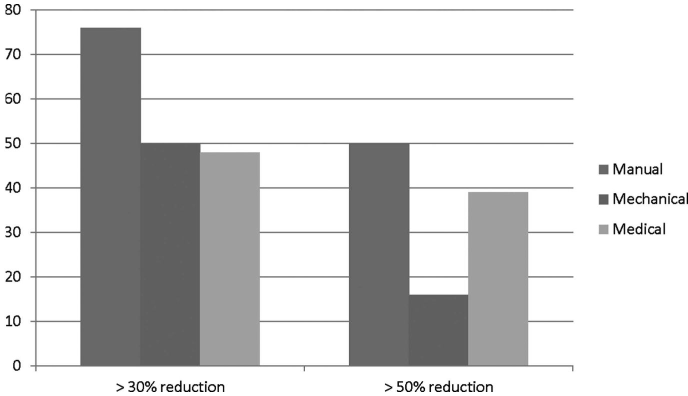

Figure 4. Bar plots showing percentages of subjects in each treatment group who had at least 30% and 50% reductions in Oswestry Low Back Pain Disability Index score from baseline to 4 weeks. y-axis indicates percentage of treatment responders.

An important finding from our study was the significant advantage of MTM over MAM on reductions in both disability and pain scores (Table 2). Also, the MTM group had at least 25% more responders for both outcomes and levels of improvement compared with the MAM group (Table 3). These findings contradict the assumption of therapeutic equivalence between these 2 methods of manipulation. This is another important factor to consider when advising patients on the manipulation treatment options available for LBP.

There were several limitations to our study. We could not determine what portion of the healing response was attributable to natural history, direct treatment effect, and/or nonspecific factors, because there was no natural-history control. This was a single-center study with a modest sample size. It was not possible to blind participants and providers to treatment group. Each type of treatment was delivered by a single clinician, and it is possible that part of the treatment response was due to indirect contextual factors related to participant-provider interaction, rather than the direct effect of the treatment alone. This has been noted in a randomized trial of care provided by chiropractors for chronic LBP.[44]

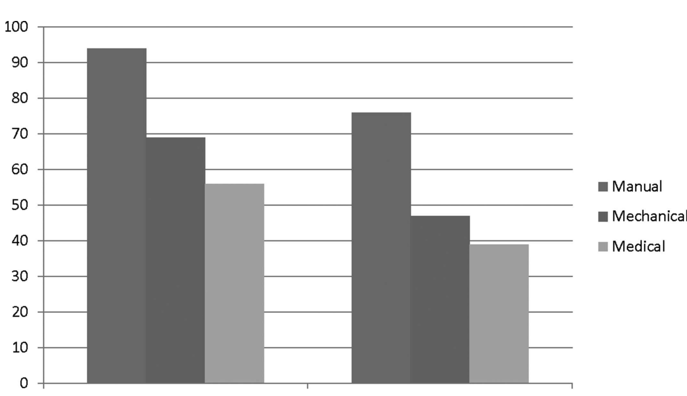

Figure 5. Bar plots showing percentages of subjects in each treatment group who had at least 30% and 50% reductions in numeric pain rating score from baseline to 4 weeks. y-axis indicates percentage of treatment responders.

Participants had 8 treatments with the chiropractors but only 3 with the medical doctor, creating a differential in clinical time/attention between participants and their providers. However, this difference is generalizable to the "real world" setting; a recent analysis of the Medicare Expenditure Panel Survey data revealed that the average number of chiropractic and medical visits were 8 and 2, respectively.[45] Also, the doctor-patient encounter was found to be a poor mediator between number of assigned visits to a chiropractor and clinical outcomes.[44]

CONCLUSION

MTM led to greater short-term reductions in self-reported pain and disability than MAM or UMC. These changes were both statistically significant and clinically meaningful. The benefit seen at end-of-intervention was no longer statistically significant at 3 or 6 months. No adverse outcomes were reported. MTM should be considered an effective short-term treatment option for patients with acute and subacute LBP. MAM and UMC seem similar in effect; both lead to decreased pain and disability, but their value compared with natural history was not evaluated in this study.

➢ Key Points

- ❑ Patients in all 3 treatment arms showed clinical improvement at 4 weeks, 3 months, and 6 months.
- ❑ Significantly more patients in the manual-thrust manipulation group achieved moderate (≥30%) or substantial (≥50%) reductions in self-reported disability and pain scores at 4 weeks.
- ❑ Between-group differences are no longer statistically significant at 3 months or 6 months.
- ❑ These results contradict prior assumptions of therapeutic equivalence between manual thrust and mechanical-assisted types of manipulation.
- ❑ Manipulation is an effective treatment for short-term relief of acute and subacute LBP.

References

1. Andersson GB. Epidemiological features of chronic low back pain. *Lancet* 1999;354:581–5.
2. Hart LG, Deyo R, Cherkin D. Physician office visits for low back pain. Frequency, clinical evaluation, and treatment patterns from a US National Survey. *Spine* 1995;20:11–9.
3. Deyo RA, Tsui-Wu YJ. Descriptive epidemiology of low-back pain and its related medical care in the United States, 1987. *Spine* 1987;12:264–8.
4. Cunningham LS, Kelsey JL. Epidemiology of musculoskeletal impairments and associated disability. *Am J Public Health* 1984;74:574–9.
5. Palmer KT, Walsh K, Bendall H, et al. Back pain in Britain: comparison of two prevalence surveys at an interval of 10 years. *BMJ* 2000;320:1577–8.

6. Santos-Eggimann B, Wietlisbach V, Rickenbach M, et al. One-year prevalence of low back pain in two Swiss regions: estimates from the population participating in the 1992–1993 MONICA project. *Spine* 2000;25:2473–9.
7. Walker BF, Muller R, Grant WO. Low back pain in Australian adults: prevalence and associated disability. *J Manipulative Physiol Ther* 2004;27:238–44.
8. Rubinstein SM, Terwee CB, Assendelft WJ, et al. Spinal manipulative therapy for acute low back pain: an update of the Cochrane review. *Spine* 2013;38:E158–77.
9. Menke JM. Do manual therapies help low back pain?: a comparative effectiveness meta-analysis. *Spine* 2014;39:E463–72.
10. Chou R, Qaseem A, Snow V, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med* 2007;147:478–91.
11. Chou R, Huffman L. Nonpharmacologic therapies for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians Clinical Practice Guideline. *Ann Intern Med* 2007;147:492–504.
12. Bronfort G, Haas M, Evans R, et al. Evidence-informed management of chronic low back pain with spinal manipulation and mobilization. *Spine J* 2008;8:213–25.
13. Lawrence OJ, Meeker W, Branson R, et al. Chiropractic management of low back pain and low back-related leg complaints: a literature synthesis. *J Manipulative Physiol Ther* 2008;31:659–74.
14. Christensen MG, Morgan DR. *Job Analysis of Chiropractic*. Greeley, CO: National Board of Chiropractic Examiners; 1993.
15. Christensen MG, Kerkhoff D, Kollash MW. *Job Analysis of Chiropractic*. Greeley, CO: National Board of Chiropractic Examiners; 2000.
16. Christensen MG, Kollash M, Ward R, et al. *Job Analysis of Chiropractic*. Greeley, CO: National Board of Chiropractic Examiners; 2005.
17. Yurkiw D, Mior S. Comparison of two chiropractic techniques on pain and lateral flexion in neck pain subjects: a pilot study. *Chiropr Tech* 1996;8:155–62.
18. Wood TG, Colloca CJ, Mathews R. A pilot randomized clinical trial on the relative effect of instrument (MFMA) *versus* manual (HVLA) manipulation in the treatment of cervical spine dysfunction. *J Manipulative Physiol Ther* 2001;24:260–71.
19. Gemmell HA, Jacobson BH. The immediate effect of Activator *vs*. Meric adjustment on acute low back pain: a randomized controlled trial. *J Manipulative Physiol Ther* 1995;18:453–6.
20. Shearer KA, Colloca C, White H. A randomized clinical trial of manual *versus* mechanical force manipulation in the treatment of sacroiliac joint syndrome. *J Manipulative Physiol Ther* 2005;28:493–501.
21. Schneider MJ, Brach J, Irrgang J, et al. Mechanical *versus* manual manipulation for low back pain: an observational cohort study. *J Manipulative Physiol Ther* 2010;33:193–200.
22. Stigsby B, Taves DR. Rank-minimization for balanced assignment of subjects in clinical trials. *Contemp Clin Trials* 2010;31:147–50.
23. Bergmann TF, Peterson DH. *Chiropractic Technique: Principles and Procedures*. 3rd ed. St Louis, MO: Mosby; 2011.
24. Fuhr AW, Green JR, Colloca CJ, et al. *Activator Methods Chiropractic Technique*. St Louis, MO: Mosby-Year Book; 1997.
25. Koes BW, van Tulder M, Lin C, et al. An updated overview of clinical guidelines for the management of nonspecific low back pain in primary care. *Eur Spine J* 2010;19:2075–94.
26. Schneider MJ, Farrell P. *Preventing Low Back Pain and Injury*. Minneapolis, MN: OPTP Inc.; 2003.
27. Fairbank JC, Pynsent PB. The Oswestry Disability Index. *Spine* 2000;25:2940–53.
28. Von Korff M, Deyo RA. Back pain in primary care: Outcomes at 1 year. *Spine* 1993;18:855–62.
29. Waddell G, Newton M. A fear-avoidance beliefs questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. *Pain* 1993;52:157–68.
30. Smeets RJ, Beelen S, Goossens ME, et al. Treatment expectancy and credibility are associated with the outcome of both physical and cognitive behavioral treatment in chronic low back pain. *Clin J Pain* 2008;24:305–15.
31. Rosner B. *Fundamentals of Biostatistics*. 7th ed. Boston, MA: Brooks/Cole, Cengage Learning; 2011.
32. Rabe-Hesketh S, Skrondal A. *Multilevel and Longitudinal Modeling Using Stat*. 1st ed. College Station, TX: Stata Press; 2005.
33. Dworkin RH, Turk DC, Wyrwich KW, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT Recommendations. *J Pain* 2008;9:105–21.
34. Dworkin RH, Turk DC, McDermott MP, et al. Interpreting the clinical importance of group differences in chronic pain clinical trials: IMMPACT recommendations. *Pain* 2009;146:238–44.
35. Fritz JM, Irrgang JJ. A comparison of a modified Oswestry Disability Questionnaire and the Quebec Back Pain Disability Scale. *Phys Ther* 2001;81:776–88.
36. Hagg O, Fritzell P, Nordwall A. The clinical importance of changes in outcome scores after treatment for chronic low back pain. *Eur Spine J* 2003;12:12–20.
37. Wennberg JE. *Tracking Medicine*. New York, NY: Oxford University Press; 2010.
38. Bigos S, Bower O, Braen G, et al. *Acute Low Back Problems in Adults. Clinical Practice Guideline No. 14*. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, US Department of Health and Human Services; 1994.
39. Eisenberg DM, Post DE, Davis RB, et al. Addition of choice of complementary therapies to usual care for acute low back pain: a randomized controlled trial. *Spine* 2007;32:151–8.
40. Flynn TP, Fritz J, Whitman JM, et al. A clinical prediction rule for classifying patients with low back pain who demonstrate short-term improvement with spinal manipulation. *Spine* 2002;27:2835–43.
41. Childs JD, Fritz J, Flynn T, et al. A clinical prediction rule to identify patients with low back pain most likely to benefit from spinal manipulation: a validation study. *Ann Intern Med* 2004;141:920–8.
42. Cleland JA, Fritz J, Kulig K, et al. Comparison of the effectiveness of three manual physical therapy techniques in a subgroup of patients with low back pain who satisfy a clinical prediction rule: a randomized clinical trial. *Spine* 2009;34:2720–9.
43. Brennan GP, Fritz J, Hunter S, et al. Identifying subgroups of patients with acute/subacute "nonspecific" low back pain: results of a randomized clinical trial. *Spine* 2006;31:623–31.
44. Haas M, Vavrek D, Neradilek MB, et al. A path analysis of the effects of the doctor- patient encounter and expectancy in an open-label randomized trial of spinal manipulation for the care of low back pain. *BMC Complement Altern Med* 2014;14:16.
45. Davis MA, Sirovich BE, Weeks WB. Utilization and expenditures on chiropractic care in the United States from 1997 to 2006. *Health Serv Res* 2010;45:748–61.