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A comparison of spinal manipulation methods and usual medical care for acute and sub-acute low back pain: a randomized clinical trial

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Abstract

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 sub-acute LBP, as compared to UMC.

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Methods—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 to 100 scale) and numeric pain rating (0 to 10 scale). Participants in the manipulation groups were treated twice weekly over 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 to MAM (disability = −8.1, p = .009; pain = −1.4, p = .002) and UMC (disability = −6.5, p = .032; pain = −1.7, p < .001). Responder analysis, defined as 30% and 50% reductions in Oswestry scores revealed a significantly greater proportion of responders at 4 weeks in MTM (76%; 50%) compared to 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.

Conclusions—MTM provides greater short-term reductions in self-reported disability and pain scores compared to UMC or MAM.

Keywords

Low back pain; spinal; manipulation; usual medical care; chiropractic; mechanical assisted manipulation; manual thrust manipulation; pain; disability

Low back pain (LBP) is amongst the most common medical ailments and an important public health issue. Approximately 50% of U.S. working-age adults experience LBP each year[1] with a quarter of U.S. adults reporting an episode of back pain in the previous 3 months.[2] Back pain is the most common cause of disability for persons under the age of 45 and 1 of the most common reasons for office visits to primary care physicians in the U.S.[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 over 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, 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 to MTM with equivocal results, but none of these trials compared Activator 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 sub-acute 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 sub-acute 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 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 cooperate with follow-up data collection.

Exclusion criteria included: 1) chronic LBP (> 3 months 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 website following baseline examination so that allocation was concealed until the moment of randomization. It was not possible to blind participants or treating clinicians to 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 coordinator 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 ID. The principal investigator (PI) was blinded and had no interaction with research participants. The PI was also blinded during the tasks of data collection and the primary data analysis. These

tasks were conducted by the research coordinator (collection) and biostatistician (analysis), who were not blinded to group allocation.

Study Interventions

1. Manual-Thrust Manipulation (MTM)—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 (MAM)—Participants were given mechanical-assisted manipulation in the prone position by a certified Activator Methods chiropractor using the Activator IV Instrument (FDA approval # K003185, Manufacturer: Activator Methods International Ltd., Phoenix, AZ). 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 (UMC)—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 NSAID medications, given advice to stay physically active and avoid prolonged bed-rest. This protocol is consistent with current clinical guidelines for the management of non-specific LBP in primary care practice.[25]

All participants were treated over the course of 4 weeks. The 2 manipulation groups attended 8 office visits (~15 mins each), twice per week for 4 weeks, a typical chiropractic treatment schedule. Chiropractors typically consider the lower thoracic, lumbar, and sacroiliac joints as one kinetic chain, and therefore we permitted them to perform manipulation in any of these regions as they 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 mins) with follow-up visits (~15 mins 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 PM&R physician provided all UMC; a single chiropractor provided all MTM, and a single chiropractor provided all MAM. Each of the treating clinicians had over 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. It has been widely used in LBP research and is considered to be a valid/reliable measure of functional impairment.[27] The Oswestry 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 over 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 Oswestry score as the dependent variable, treatment group as the independent variable, and forced covariate adjustments for baseline Oswestry, pain, and treatment expectation (used in the randomization algorithm). Comparison of MTM to MAM was specified a-priori as the single primary comparison; therefore, no adjustments were made for multiple comparisons. Secondary associations included comparisons of MTM to UMC and MAM to 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 Oswestry score (primary outcome) at an alpha level of 0.05. This was based upon a conservative estimate of the minimal clinically important difference for Oswestry score and using a standard deviation of 14 points.[35,36]

RESULTS

After telephone screening, 197 potentially eligible people received 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-groups comparisons with SDs 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 to UMC showed a similar result (Δ = −6.5, p=0.032). Comparison of MAM to UMC showed a non-significant difference (Δ = 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 (Δ = −1.7, p<0.001). However, there was no significant difference between MAM in comparison to UMC (Δ = −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: −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 above. 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 3 and Figure 5 show that 94% of the MTM group achieved greater than 30% reduction in pain compared to 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

to 47% of MAM (p=0.008) and 41% of UMC (p=0.006). The comparisons between MAM and UMC were not significant.

DISCUSSION

Treatment for acute and sub-acute 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 NSAIDS and "watchful waiting" which emphasizes spontaneous recovery and prompt return to normal activity.[38,39] Although this approach is reasonable and the general prognosis for acute back pain is favorable, some patients may actually have preference for non-pharmacological 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 which reflects their individual values and preferences. It has been found that treatment options which align with patient preferences lead to enhanced patient satisfaction.[40]

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 LBP patients that are likely to respond well to spinal manipulation and can be helpful in guiding shared decision making.[41–44]

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 to 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 non-specific 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.[45]

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 recently analysis of the Medicare Expenditure Panel Survey data revealed that the average number of chiropractic and medical visits were 8 and 2, respectively.[46] Also, the doctor-patient encounter was found to be a poor mediator between number of assigned visits to a chiropractor and clinical outcomes.[45]

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 sub-acute LBP. MAM and UMC appear similar in effect; both lead to decreased pain and disability, but their value compared to natural history was not evaluated in this study.

Acknowledgments

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 # 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.

ABBREVIATIONS

LBP	Low Back Pain
MTM	Manual Thrust Manipulation
MAM	Mechanical Assisted Manipulation
SMT	Spinal Manipulative Therapy
UMC	Usual Medical Care

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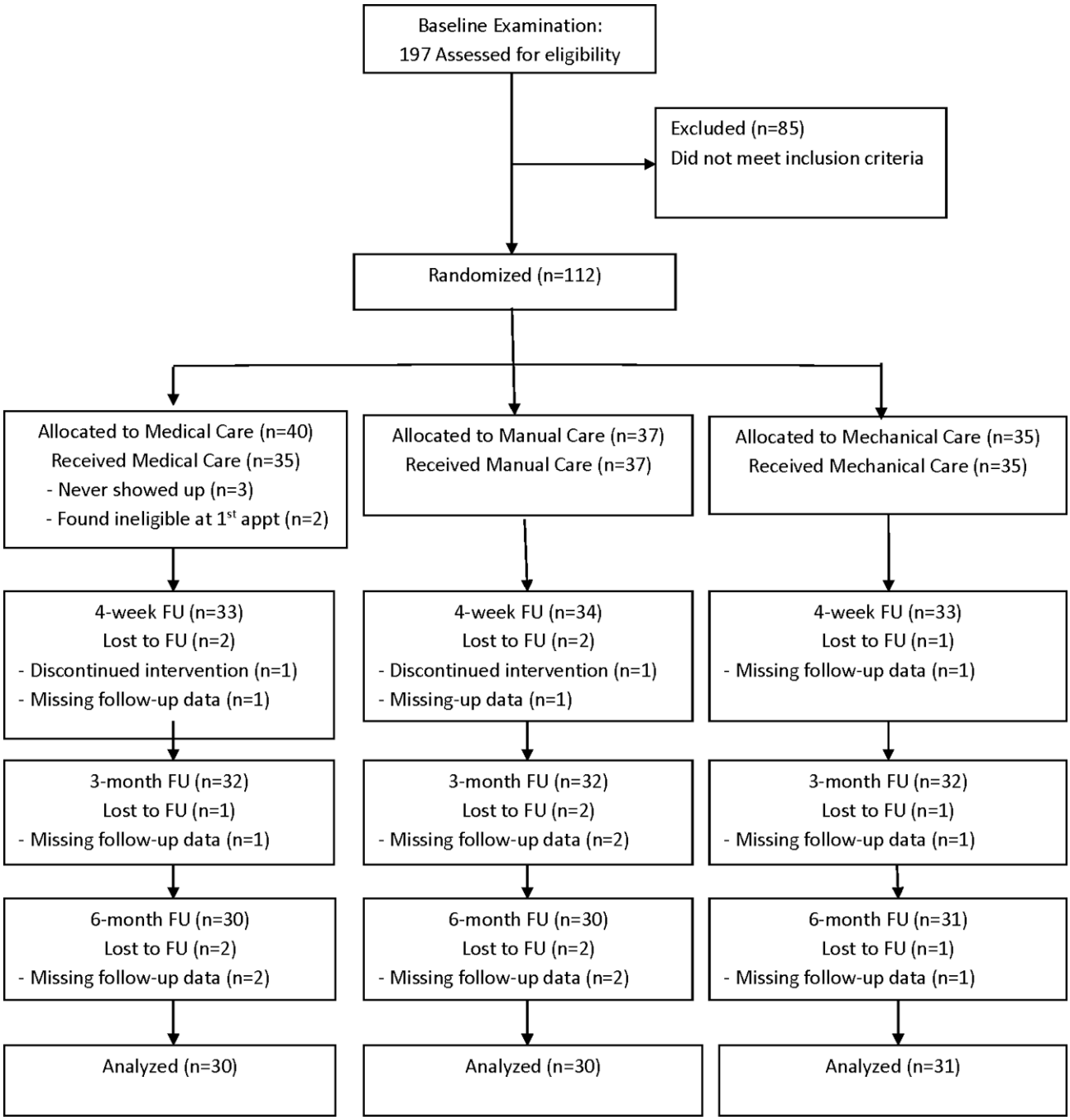

Figure 1.
CONSORT study participant flow diagram.

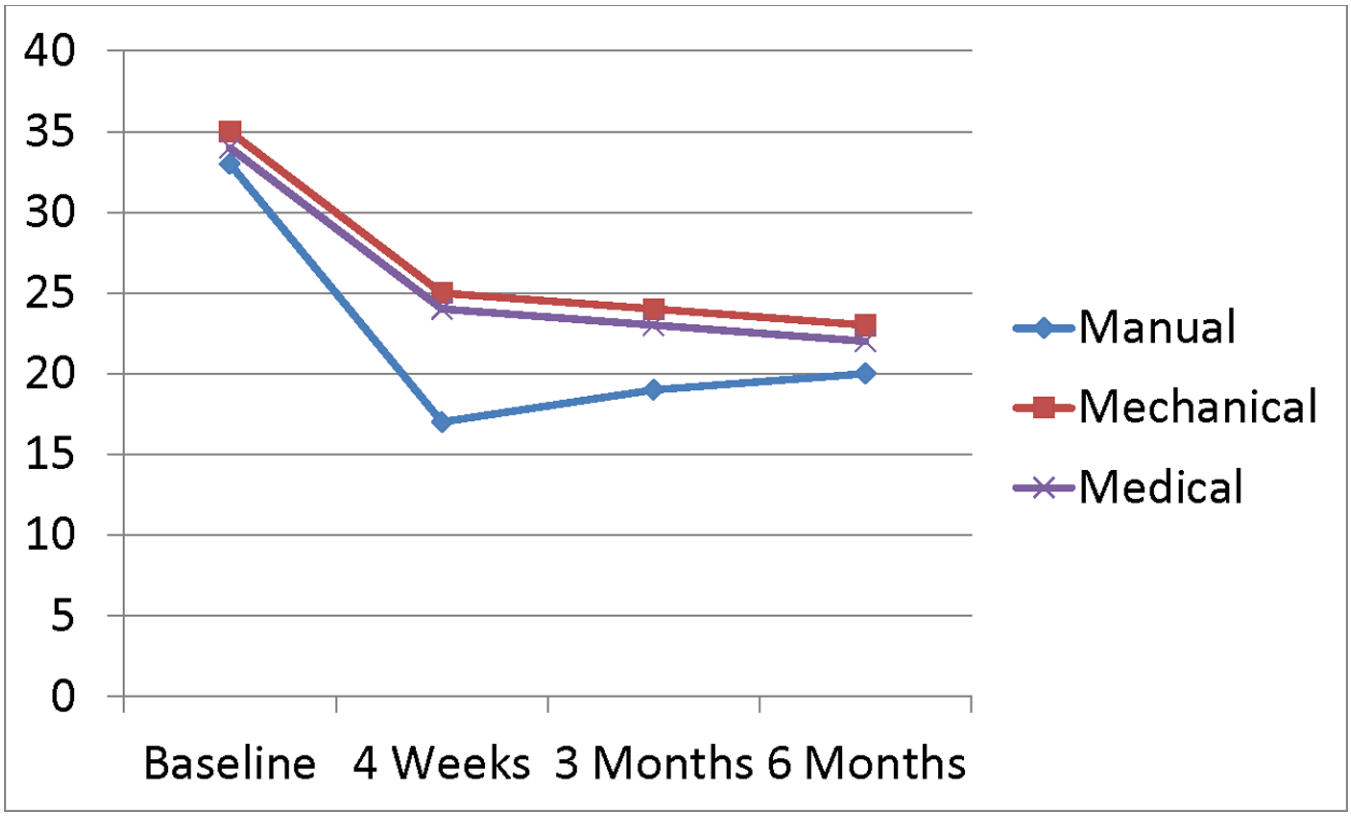

Figure 2.
Line-plots showing adjusted mean Oswestry scores (disability) for the 3 treatment groups at 4 time points.

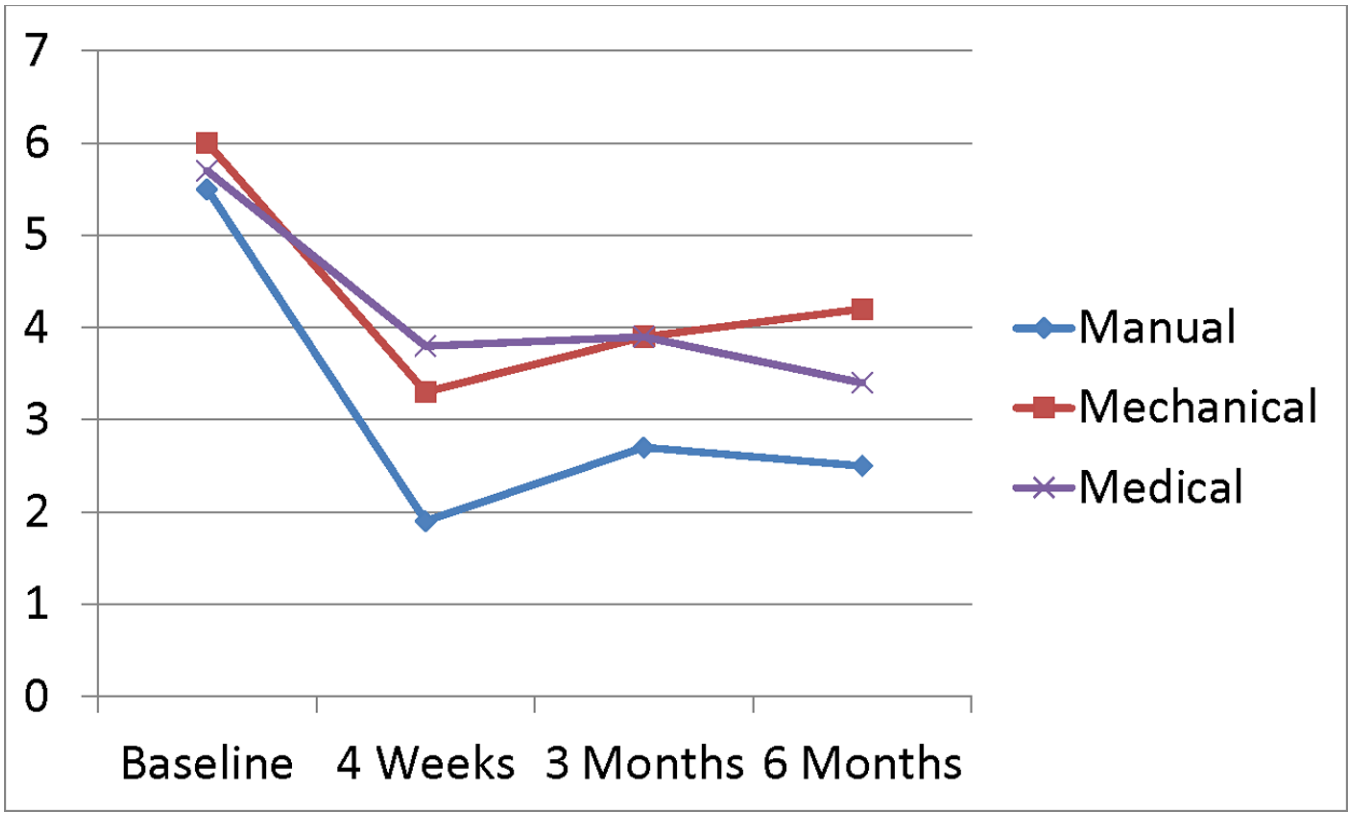

Figure 3.
Line-plots showing adjusted mean Numeric Pain Scores (pain) for the 3 treatment groups at 4 time points.

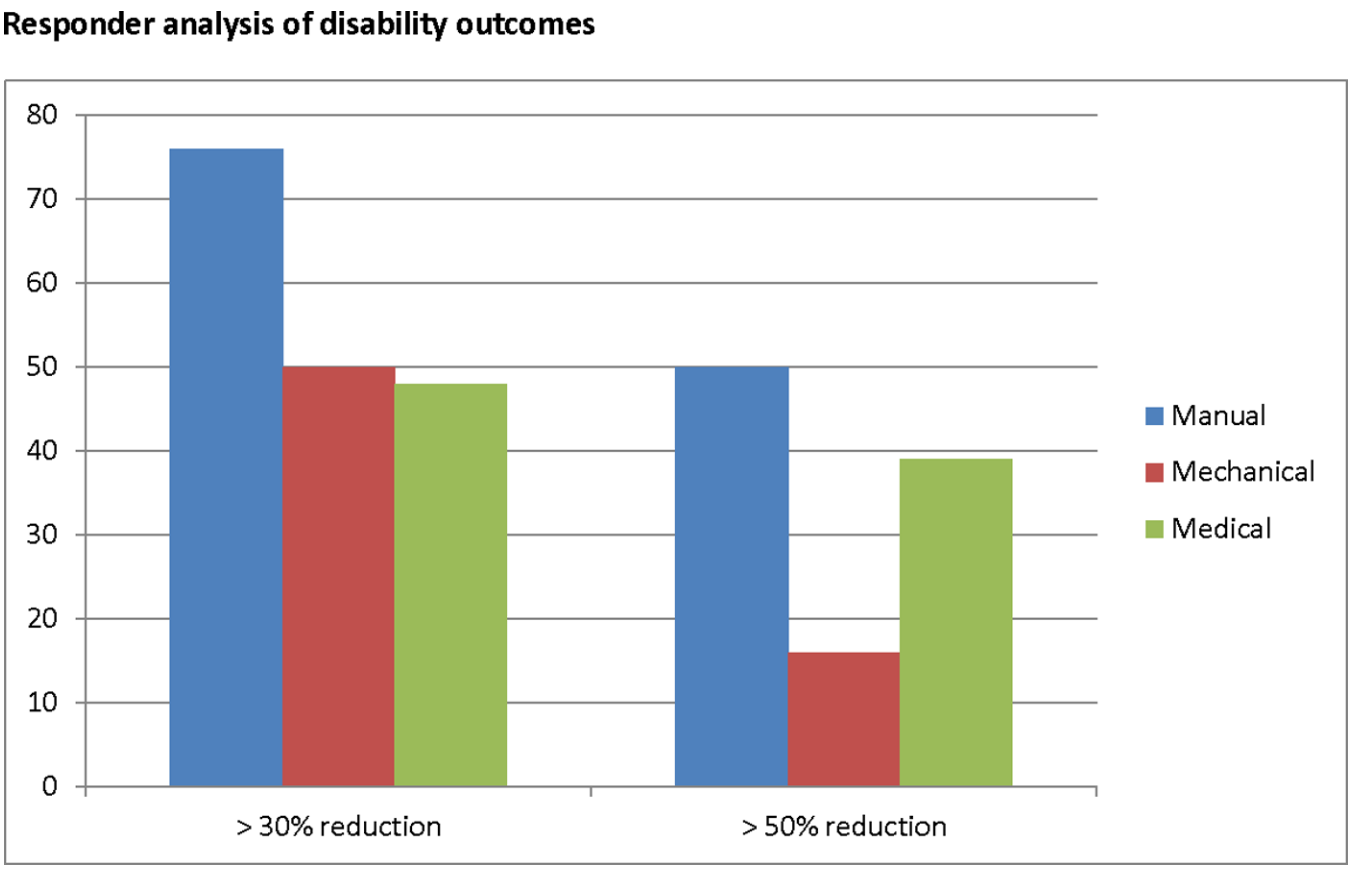

Figure 4.

Bar-plots showing percentages of subjects in each treatment group who had at least 30% and 50% reductions in Oswestry score (disability) from baseline to four weeks. Y axis indicates percentage of treatment responders.

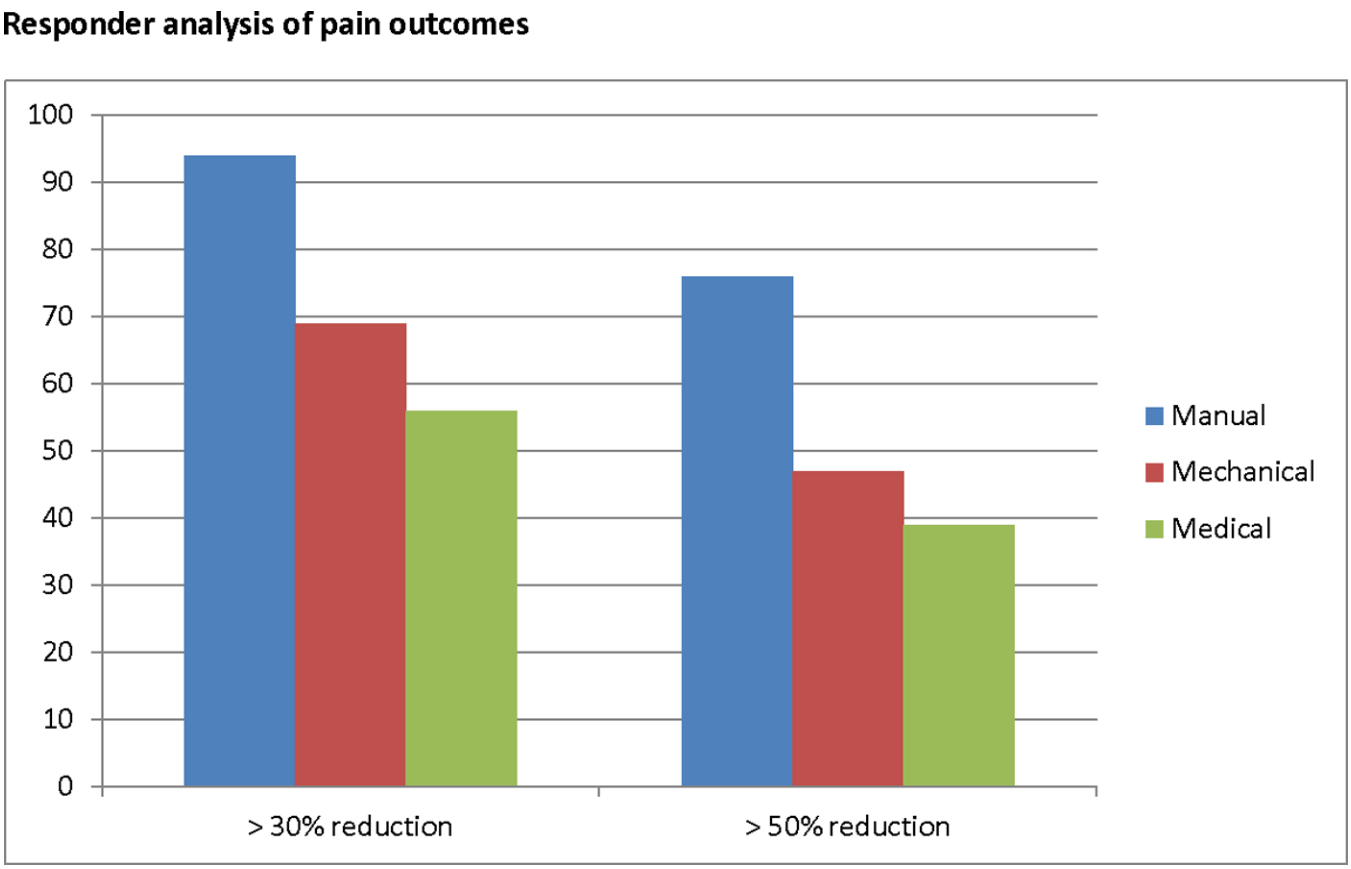

Figure 5.

Bar-plots showing percentages of subjects in each treatment group who had at least 30% and 50% reductions in Numeric Pain score from baseline to four weeks. Y axis indicates percentage of treatment responders.

Table 1

Demographic and baseline clinical characteristics for research participants.

Variable	Overall (N=107)	Medical (n=35)	Manual (n=37)	Mechanical (n=35)
	Mean (sd) or n(%)	Mean (sd) or n(%)	Mean (sd) or n(%)	Mean (sd) or n(%)
Oswestry	33.9 (9.2)	33.9 (8.1)	33.1 (9.6)	34.6 (10.0)
Numeric Pain Rating	5.7 (1.4)	5.7 (1.3)	5.5 (1.3)	6.0 (1.4)
Fear Avoidance Beliefs (FABQ)	32.9(16.8)	33.0(17.8)	32.7(15.3)	33.0(18.6)
Age (yrs)	41.1 (14.3)	41.3 (11.6)	41.4 (15.3)	40.4 (15.9)
BMI (%)	28.8 (6.8)	27.4 (5.9)	28.8 (7.7)	30.3 (6.5)
Treatment Expectancy				
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)
Gender				
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				
White	67 (62.6%)	22 (62.9%)	23 (62.2%)	22 (62.9%)
Black /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				
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	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				
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	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%)
Prev. Chiropractic Treatment				
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%)
Prev. Mechanical Treatment				
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%)
Prev. Manual Treatment				
No	1 (2.1%)	0 (0.0%)	1 (7.1%)	0 (0.0%)

Variable	Overall (N=107)	Medical (n=35)	Manual (n=37)	Mechanical (n=35)
	Mean (sd) or n(%)	Mean (sd) or n(%)	Mean (sd) or n(%)	Mean (sd) or n(%)
Yes	47 (97.9%)	17 (100.0%)	13 (92.9%)	17 (100.0%)
No. of Co-morbidities				
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%)

Table 2
Disability and Pain outcomes by treatment group and time

This table has three data sections: 1) disability and pain outcomes; 2) within-group changes from baseline (outcome minus baseline); and 3) adjusted between-group differences in improvement from baseline. These data are presented for the three 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 pre-treatment at baseline, and then again at 4 weeks, 3 months, and 6 months post onset of treatment. The primary comparison was the covariate-adjusted difference between manual-thrust and mechanical-assisted manipulation in disability scores at 4 weeks.

	Baseline	4 weeks	3 month	6 month
1.Outcome [mean ± SD]				
Disability (0 to 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 to 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
2. Outcome minus baseline [mean ± SD (95%CI)]				
Disability				
Manual		−16.0 ± 14.1 (−20.9,−11.1)	−14.7 ± 16.3 (−20.5, 8.9)	−12.7 ± 14.1 (−17.9, −7.4)
Mechanical		−8.9 ± 11.9 (−13.2,−4.6)	−10.3 ± 15.4 (−15.8, −4.7)	−11.0 ± 15.7 (−16.7, −5.3)
Medical		−9.5 ± 14.4 (−14.6,−4.4)	−11.3 ± 15.8 (−16.9, −5.7)	−10.9 ± 17.4 (−17.4, −4.6)
Pain				
Manual		−3.7 ± 1.5 (−4.2,−3.1)	−2.9 ± 2.3 (−3.7, −2.0)	−2.9 ± 2.0 (−3.7, −2.2)
Mechanical		−2.6 ± 1.6 (−3.2,−2.0)	−2.1 ± 1.9 (−2.8, −1.4)	−1.8 ± 2.2 (−2.6, −1.0)
Medical		−1.9 ± 2.2 (−2.7,−1.1)	−1.8 ± 1.9 (−2.5, −1.2)	−2.2 ± 2.6 (−3.1, −1.2)
3. Adjusted group differences [mean (95% CI)				
Disability				
Manual – Mechanical		−8.1 (−14.0, −2.1)*	−2.9 (−9.9, 4.0)	0.4 (−10.2, 11.0)
Manual – Medical		−6.5 (−12.5, −0.6)*	−2.6 (−9.5, 4.4)	1.4 (−9.1, 12.0)
Mechanical – Medical		1.5 (−4.4, 7.5)	0.4 (−6.6, 7.3)	1.0 (−9.6, 11.6)
Pain				
Manual – Mechanical		−1.4 (−2.2, −0.5)*	−0.9 (−2.1, 0.3)	−1.2 (−3.2, 0.7)
Manual – Medical		−1.7 (−2.5, −0.8)*	−1.0 (−2.2, 0.2)	−0.9 (−2.9, 1.1)
Mechanical – Medical		−0.3 (−1.2, 0.6)	−0.2 (−1.4, 1.1)	0.3 (−1.6, 2.3)

SD, standard deviation; CI, confidence interval.

* $p < .05$.

Table 3

Results of responder analyses

These data were obtained after dichotomizing the within-person changes in outcomes from baseline to 4-weeks. 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].

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

OSW: Oswestry Low Back Pain Disability Index; NPR: Numeric Pain Rating.