

Research

A Randomized Controlled Trial of Chiropractic Compared to Physical Therapy for Chronic Low Back Pain in Community Dwelling Geriatric Patients

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Abstract

Background: Chronic low back pain is the most frequently reported musculoskeletal condition in the elderly, affecting up to 50% of this age cohort. It is a leading falls related comorbidity and robust predictor of morbidity among the elderly.

Methods: This analysis of a randomized controlled trial evaluated the use of either chiropractic care (CC) or physical therapy (PT) as a treatment for geriatric patients with balance problems and with or without chronic low back pain. Of the one hundred and eighteen participants enrolled, sixty one participants (51.7%) were randomized into the CC group and fifty seven participants (48.3%) into the PT group. A pain questionnaire was administered at baseline, after 6 weeks of treatment, and again at week 12. University ethics committee approval was obtained and written informed consent was given.

Results: There was statistically significant reductions in pain for this intent-to-treat design mixed model analysis of variance (ANOVA) ($p < 0.05$) and Bonferroni correction ($p < 0.025$; 95% CI). The CC and PT groups had similar reductions at week 6 for Box 21 current pain scores (52.7%, 50.9%); Box 21 least pain scores (40.4%, 45.4%); Box 21 worst pain scores (42.1%, 37.2%); Box 21 usual pain scores (41.1%, 46.7%); and Box 21 number of days per week in pain scores (24.3%, 18.9%). There were no significant

between group effects.

Conclusion: There were statistically and clinically significant improvements in pain outcome measures in both the chiropractic care and physical therapy treatment groups at week six and at week twelve.

Trial registration: NCT02031562

Introduction

Chronic low back pain (cLBP) is the most frequently reported musculoskeletal condition in the elderly, affecting up to 50% of this age cohort. It is a leading falls related comorbidity and a robust predictor of morbidity among the elderly.¹⁻⁵ Fifty percent of community dwelling older adults experience sufficient pain to interfere with normal activities of daily living.^{6,7} Narcotic use for the management of chronic pain creates a special issue for the geriatric patient, including an increased risk of sedation, falls, and decreased renal function. Within the population of community-dwelling older adults, between 30% and 40% fall at least once per year and fall related injuries are a leading cause of hospitalization in the United States.^{8,9} Chronic pain by definition is a refractory, non resolving pain of at least 12 weeks duration and has repercussions for the elderly that differ from the younger adult. The effectiveness of non- pharmacological treatments for the geriatric patient is of special interest.^{10,23}

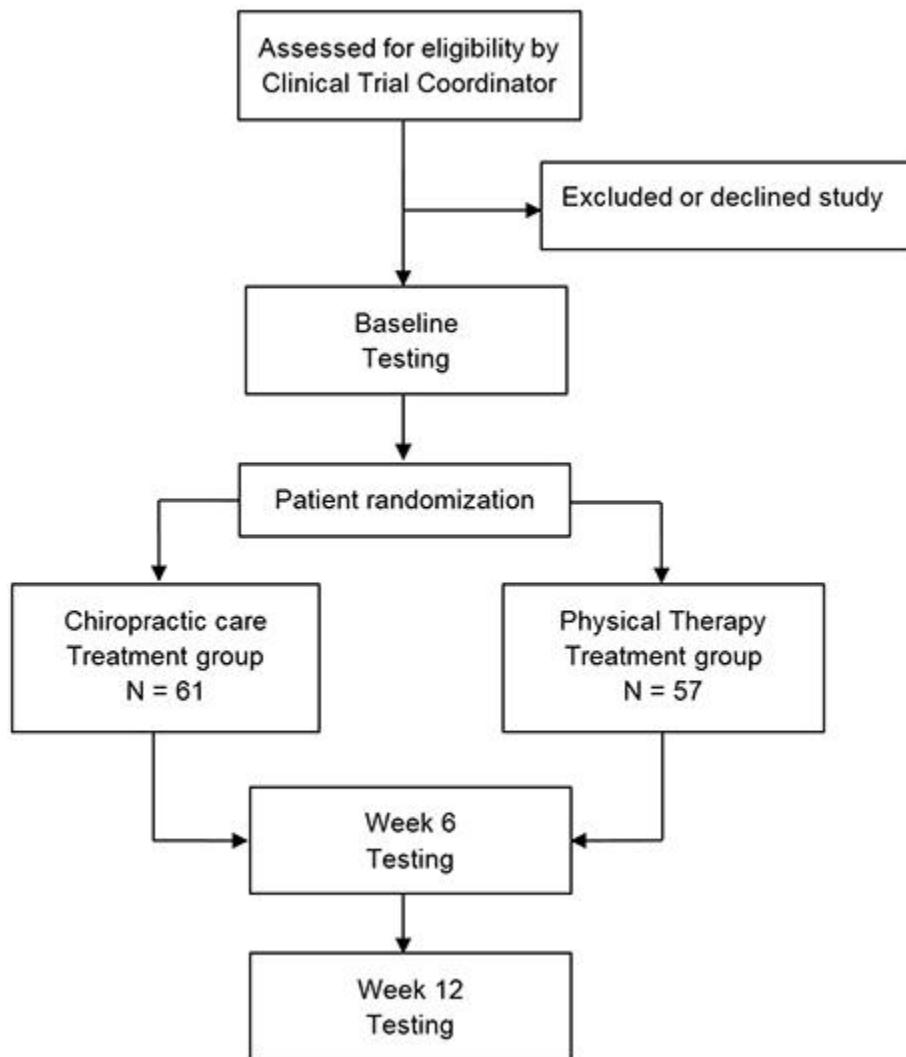
A multimodal approach of exercise¹¹, manual therapy¹², and behavioral modification programs¹² has been shown to be the most effective strategy for the management of cLBP in older adults. Hawk et al. published feasibility studies examining chiropractic as a treatment for chronic pain, dizziness, and balance problems in the elderly.^{13,14} A study by Schneider et al. reported that manual thrust style of manipulation demonstrated statistically significant short term but not long term reductions in low back pain.¹⁵ This paper reports on the changes in pain outcomes for a randomized controlled clinical trial which compared chiropractic care to physical therapy.

Methods

Participants between the ages of 60 to 85 years were randomly assigned into either a chiropractic care group or a physical therapy treatment group.

This analysis of a randomized controlled trial evaluated the use of either chiropractic care (CC) or physical therapy (PT) as a treatment for geriatric patients with balance problems and with or without chronic low back pain. Participants all reported balance problems with or without low back pain and were randomized using an online computer randomization program (www.random.org) to receive 6 weeks (12 - 18 visits) of either chiropractic or physical therapy treatments (**Figure 1**). This publication is an analysis of patients who reported cLBP in addition to their balance deficits. We are reporting the main data for the specific aim 1 examining pain outcomes.

Figure 1. Flow chart of assessment, testing, randomization, and treatment for study participants with cLBP.



This study was in collaboration with the Saint Louis University (SLU) Division of Geriatric Medicine and conducted at the SLU Biomedical and Healthcare Research Facility. Participants were recruited from the outpatient clinic and clinical practices of geriatric physicians in the Department of Internal Medicine, Division of Geriatric Medicine at Saint Louis University School of Medicine and through retirement centers, churches, grocery stores, community centers, and newspaper advertisements. A detailed and complete description of the methods of this RCT can be found in another publication.¹⁶ This study was in compliance with ethical standards for responsible human experimentation and the Helsinki

Declaration. Logan University and Saint Louis University School of Medicine ethics committee approval was obtained for this study and written consent was obtained from all study participants and CONSORT statement guidelines for collecting data were followed.

Eligibility

All participants were ambulatory community dwelling adults that were between the ages of 60-85 with self-reported balance problems. Balance problems are defined as the inability to keep one's center of gravity over the base of support during both static and dynamic situations. Participants in this analysis all reported a history of cLBP. Participants were ineligible if they had a history of recent neoplasm (excluding minor skin cancers), recent (< 6 months) orthopedic surgery or fracture, acute infectious disease, or non-mechanical low back pain, Meniere's disease, vertigo, vestibular disorders. Patients were also excluded who had unstable peripheral vascular disease and or cardiac disease requiring recent hospitalization (< 6 months) ago. Patients currently using antipsychotics, anxiolytics, and sedative/hypnotics, or with a recent history of substance abuse were also excluded. Patients that were receiving ongoing care by a chiropractor or physical therapist were not enrolled into the study.

Patient screening and consenting

Interested participants were screened by phone by the nurse coordinator for eligibility. Those who met the initial criteria were scheduled with the nurse coordinator who obtained medical and surgical history and demographic information. Medical records were reviewed by the geriatric physician and nurse coordinator prior to patient acceptance into the study. Written informed consent was obtained by the nurse trial coordinator after the study details were reviewed with participants. The participant demographic information and medical surgical history is shown in Tables 1 and 2.

Out of one hundred and sixty eight total participants, one hundred and eighteen participants (70.2%) reported cLBP. The presence of back pain had no effect on randomization and was identified at baseline testing with the 21 point box pain scale. Of those identified with cLBP, fifty seven participants (48.3%) were randomized into the physical therapy group and sixty one (51.7%) were randomized into the chiropractic care group.

Primary outcomes

Participants completed 21-point Box Scale self-reported pain questionnaire at baseline, after 6 weeks of care, and at 12 weeks. These were administered by an investigator blinded to participant treatment condition. Participants were specifically asked to comment on their cLBP. The 21-point box scale assesses participant's current amount of pain as well as the usual, least, and worst amount of pain experienced over the past week. The number of days participants reported pain over the last week is also recorded. The Box 21 scale uses a series of horizontal boxes labeled from 0-100 in 5-point increments with verbal anchors at 0 ("No Pain") and 100 ("Pain as bad as it could be"). This scale has been validated and is recommended for pain assessment in older adults.^{17,18}

Treatments

Both chiropractic and physical therapy treatments were provided at a research clinic established at the Saint Louis University School of Medicines' Center for Biomedical and Healthcare research. Evidence based practice guidelines for musculoskeletal pain was followed by the chiropractors and physical therapist in determining treatment options for each individual patient in the study.

Chiropractic was delivered two to three times a week for six weeks by a licensed chiropractic physician with at least five years' experience. Treatments lasted for approximately twenty five to thirty minutes and were based on standard examination findings, including orthopedic testing, range of motion assessment, and evaluation of pain or tenderness, changes in tissue asymmetry or misalignment. Chiropractic care was individualized and directed at restricted thoracic or lumbosacral spine joint segments or extremities to patient tolerance. It may include any combination of the following when clinically indicated, high-velocity, low-amplitude manipulation, low-velocity, variable-amplitude repetitive motion maneuvers (flexion-distraction therapy, low-velocity, low amplitude drop table manipulation, passive mobilization. Soft tissue therapies include the use of Proprioceptive Neuromuscular Facilitation stretching (PNF), Post-Isometric Exercise Relaxation Techniques (PIR), transverse friction massage, and passive stretching as needed. Physical therapy was delivered two to three times a week for six weeks by a licensed physical therapist with at least five years' experience and based on individual patient history, initial patient evaluation, and examination findings. Treatments lasted for approximately thirty to forty five minutes and techniques included any combination of the following treatment options: neuromuscular reeducation, muscle endurance and strength training exercises, flexibility stretches, interferential electrical stimulation, ultrasound, postural education, and home exercise program.

Data analysis and sample size

This randomized, controlled mixed-model design included a repeated measures variable for time (baseline, week 6, & week 12) and a between subjects variable for treatment (chiropractic vs. physical therapy). This analysis of the pain measures used in the study included an intention-to-treat design data analysis included a mixed-model analysis of variance (ANOVA) ($p < 0.05$) for each outcome measure, with a Bonferroni correction of $p < 0.025$ for main pain measures (SPSS Statistics version 20.0, IBM Corp., Somers, NY). At a power level of $1 - \beta = 0.80$, this study was sufficiently powered to detect a main effect of treatment group at effect sizes of $f > 0.19$ to evaluate the primary study outcome measures. The values of the f effect size are interpreted as follows: 0.10-0.24 is considered small effects, 0.25-0.39 is considered medium effects, and values > 0.40 are considered large effects.^{19,20} Data was screened prior to the main data analysis following standard procedures.²¹

Results

Participants between the ages of 60 to 85 were recruited and enrolled in the study between January 2010 and June 2013. In this analysis of a larger study, out of one hundred and eighteen participants with cLBP, one hundred and seven (90.6%) of them completed the treatment and the six week testing and ninety seven (82.2%) completed the twelve week testing. There were no treatment related adverse events in this study. Patient demographics including age, gender, ethnicity, years of education were equally distributed between treatment groups (**table 1**). Participants' medical and surgical histories were also balanced between treatment groups. Forty four percent of participants in both treatment groups reported a history of falls. Specific conditions relevant to low back pain were noted. Of the total group, thirty nine percent reported a history of orthopedic surgery, fifty nine percent reported a history of osteoarthritis, ten percent had a diagnosis of spinal stenosis, and eleven percent had a history of ruptured disc (**table 2**).

Table 1. Patient demographics at time of enrollment

Characteristics	Physical Therapy <i>n=57 (48.3%)</i>	Chiropractic Care <i>n=61 (51.7%)</i>	Total <i>n=118</i>
Age, mean (SD)	72.1 ± 6.8	71.8 ± 6.6	72.0 ± 6.7
Range (median)	60 – 85 (72.5)	60 - 85 (70.0)	60 - 85 (70)
Gender			
Male	26.3%	34.4%	30.5%
Female	73.7%	65.6%	69.5%
Ethnicity			
Caucasian	84.9%	92.9%	89.0%
African American	11.3%	7.1%	9.2%
Other	3.8%	0%	1.8%

Education, mean (SD)	16.7 ± 1.8	15.4 ± 2.4	16.0 ± 2.2
Exercised	69.6%	71.4%	70.6%

*Patient demographics by treatment groups and totals.
SD, standard deviation; education in years*

Table 2. Medical Surgical History

Medical Surgical History	Physical Therapy <i>n=57</i>	Chiropractic Care <i>n=61</i>	Total <i>n=118</i>
History of Falls	44.0%	44.6%	44.31%
Smoker History	46.2%	44.4%	45.3%
Smoker Current	13.5%	9.3%	11.3%
Hypertension	58.9%	64.4%	61.7%
Myocardial Infarction	3.6%	10.2%	7.0%
Congestive Heart Failure	7.1%	3.4%	5.2%
Non-Insulin Dependent Diabetes	23.2%	10.2%	16.5%
Peripheral Vascular Disease	1.8%	5.1%	3.5%
Deep Vein Thrombosis	1.8%	11.9%	7.0%
Stroke	1.8%	5.1%	3.5%

Peripheral Neuropathy	12.5%	11.9%	12.2%
Rheumatoid Arthritis	3.6%	1.7%	2.6%
Spinal Stenosis	8.9%	11.9%	10.4%
Osteoarthritis	69.6%	49.2%	59.1%
Ruptured Disc	17.9%	5.1%	11.3%
Head Injury	1.8%	3.4%	2.6%
Other Neurological Injury	3.6%	3.4%	3.5%
Head and Neck surgery	5.5%	6.9%	6.2%
Coronary artery bypass surgery	7.3%	15.5%	11.5%
Lung surgery	1.8%	(0.0%)	(0.9%)
Gastrointestinal surgery	5.5%	(13.8%)	(9.7%)
Orthopedic surgery	45.5%	(34.5%)	(39.8%)

Medical and surgical history reported by treatment groups and totals.

Primary pain outcomes

Chronic low back pain is a multifaceted problem with numerous comorbidities. To fully describe the study participants' pain, the 21 point Box scale was used to assess participant's current, least, worst, and usual pain, as well as the number of days in pain over the last week. The pain value means, standard deviations, Confidence Intervals (CI) and p values are listed in **table 3**.

Table 3. Chiropractic Care versus Physical Therapy Treatment in Older Adults with Low Back Pain.

Pain Scales & Treatment Condition*	Baseline	6 Weeks	12 Weeks	P-Value**
	Mean ± SD	Mean ± SD	Mean ± SD	
Box21 Scale: Pain at the Moment (0-100)				
Chiropractic Care	21.07±21.0	9.96±14.1	10.42±15.8	<.001 ^{a,b}
Physical Therapy	24.09±20.6	11.82±16.4	15.82±21.3	
Box21 Scale: least Pain Past Week (0-100)				
Chiropractic Care	12.17±15.0	7.25±13.5	7.05±13.3	<.001 ^a
Physical Therapy	11.61±15.6	6.34±11.6	9.91±17.0	
Box21 Scale: Worst Pain Past Week (0-100)				
Chiropractic Care	50.20±27.9	29.06±25.2	28.20±25.4	<.001 ^{a,b}
Physical Therapy	54.91±22.0	34.46±25.8	35.27±29.1	
Box21 Scale: Usual Pain Past Week (0-100)				
Chiropractic Care	30.53±20.3	17.99±18.6	17.18±18.5	<.001 ^{a,b}

Physical Therapy	33.00±19.5	17.59±16.0	18.73±19.5	
Box21 Scale: Days Pain Past Week (0-7)				
Chiropractic Care	5.97±1.7	4.52±2.6	4.25±2.6	<.001 ^{a,b}
Physical Therapy	5.45±2.3	4.42±2.3	4.60±2.7	

* A 2 X (3) mixed model analysis of variance was used to compare pain outcomes for treatment condition (chiropractic care versus physical therapy) by time (baseline, after 6 weeks of treatment, & 12 weeks [i.e., 6 weeks following the end of treatment]).

** There were no treatment condition main effects (all $p_s > .05$) and no treatment condition by time interaction effects

(all $p_s > .05$). P-values for the time main effect (baseline, 6 weeks, & 12 weeks) are shown in the table.

Time main effect comparisons (baseline vs. 6 weeks, baseline vs. 12 weeks, & 6 weeks vs. 12 weeks) were computed using a Bonferroni correction.

^a Baseline versus 6 weeks $p < .05$; ^b Baseline versus 12 weeks $p < .05$; ^c 6 weeks versus 12 weeks $p < .05$.

Analysis

This analysis of a larger study demonstrated significant improvements in the pain outcomes for the main effect of time. Both chiropractic care (CC) and physical therapy (PT) were efficacious for pain reduction. Statistically significant ($p < 0.001$; 95% CI) within group effects for pain reduction were seen in both treatment groups at week six and week twelve testing. However, there were no between group effects for either of the two follow up tests. Participants' pain was improved following 6 weeks of either treatment and the improvement was maintained 6 weeks after treatment was completed. Results met the Kolmogorov-Smirnov goodness of fit test for the normal distribution of data.

The mean 21-Point Box Scale scores for Pain at the Moment in the CC group at baseline were 21.07 ± 1.0 and for week six were 9.96 ± 14.1 ($P < 0.001$). The mean scores for the PT group at baseline were 24.09 ± 20.6 and at week six were 11.82 ± 16.4 ($P < 0.001$) (**Figure 2**). This represented a 52.7% reduction in pain in the CC group and a comparable 50.9% reduction in the PT group. The mean 21-Point Box Scale scores for the Least Amount of Pain in the Last Week in the CC group at baseline were 12.17 ± 15.0 and for week six were 7.25 ± 13.5 ($P < 0.001$). The mean scores for the PT group at baseline were 11.61 ± 15.6 and at week six were 6.34 ± 11.6 ($P < 0.001$) (**Figure 3**). This represented a 40.4% reduction in pain in the CC group and a similar 45.4% reduction in the PT group. The mean 21-Point Box Scale scores for the

Worst Amount of Pain in the Last Week in the CC group at baseline were 50.20 ± 27.9 and for week six were 29.06 ± 25.2 ($P < 0.001$). The mean scores for the PT group at baseline were 54.91 ± 22.0 and at week six were 34.46 ± 25.8 ($P < 0.001$) (**Figure 4**). This represented a 42.1% reduction in pain in the CC group and a 37.2% reduction in the PT group. The mean 21-Point Box Scale scores for the Usual Amount of Pain in the Last Week in the CC group at baseline were 30.53 ± 20.3 and for week six were 17.99 ± 18.6 ($P < 0.001$). The mean scores for the PT group at baseline were 33.00 ± 19.5 and at week six were 17.59 ± 16.0 ($P < 0.001$) (**Figure 5**). This represented a 41.1% reduction in pain in the CC group and a 46.7% reduction in the PT group. The mean 21-Point Box Scale scores for the Number of Days in Pain in the Last Week in the CC group at baseline were 5.97 ± 1.7 and for week six were 5.97 ± 1.7 ($P < 0.001$). The mean scores for the PT group at baseline were 5.45 ± 2.3 and at week six were 4.42 ± 2.3 ($P < 0.001$) (**Figure 6**). This represented a 24.3% reduction in days with pain in the CC group and 18.9% reduction in the PT group.

Figure 2. Box 21 Current Pain Scores for the two treatment groups at baseline, week 6, and week 12.

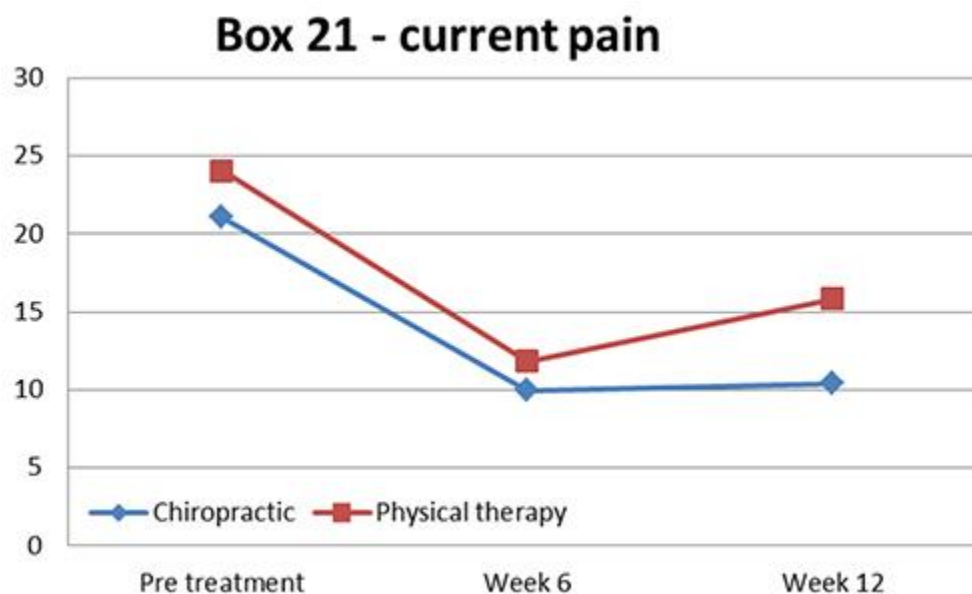


Figure 3. Box 21 Least Amount of Pain in the Last Week scores for the two treatment groups at baseline, week 6, and week 12.



Figure 4. Box 21 Worst Amount of Pain in the Last Week scores for the two treatment groups at baseline, week 6, and week 12.

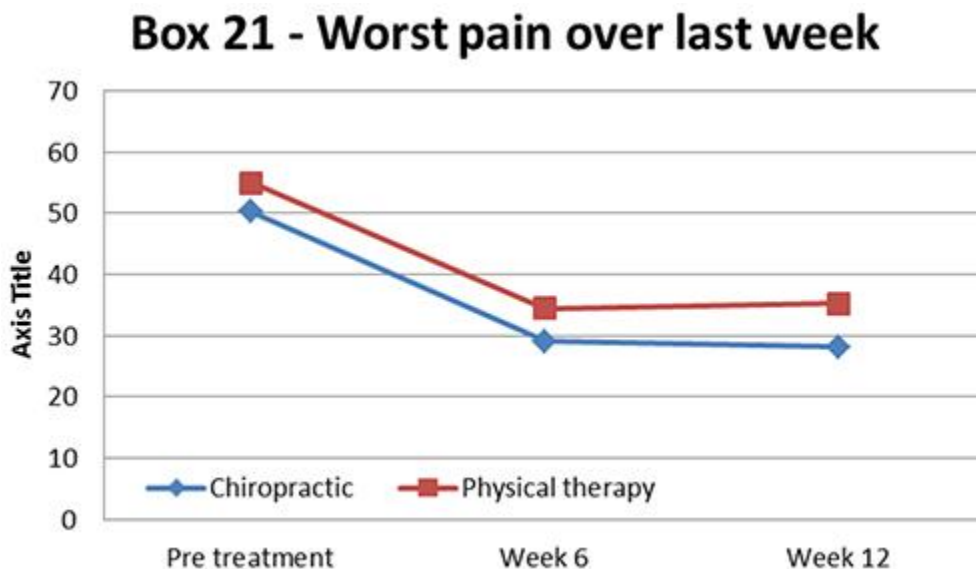


Figure 5. Box 21 Usual Pain in the Last Week scores for the two treatment groups at baseline, week 6, and week 12.

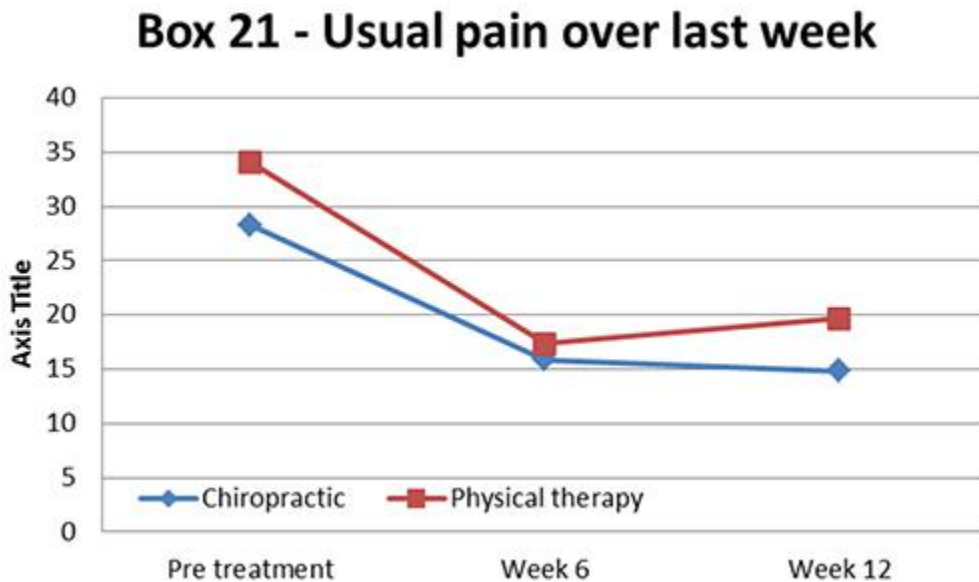
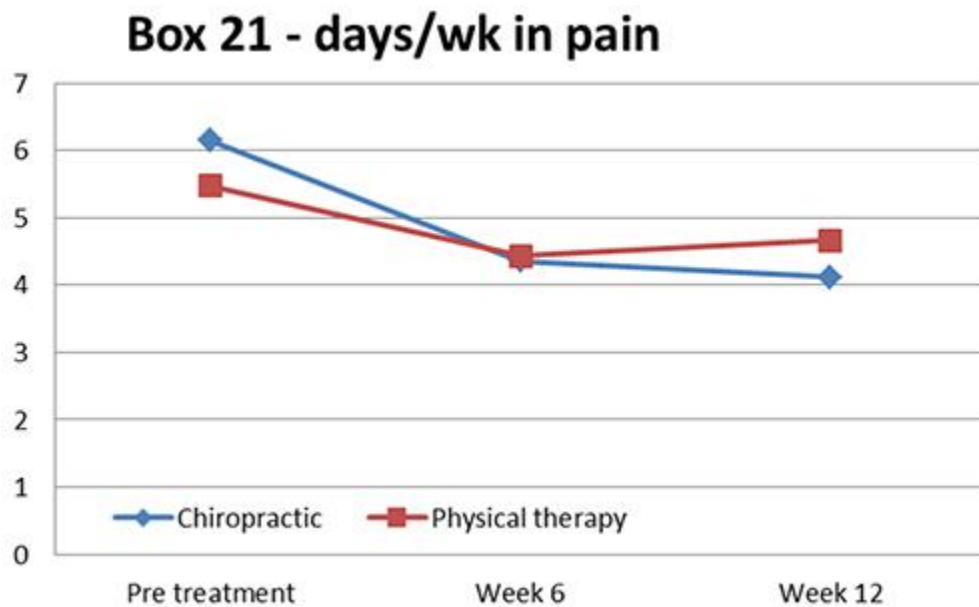


Figure 6. Box 21 Number of Days in Pain in the Last Week scores for the two treatment groups at baseline, week 6, and week 12.



Discussion

Chiropractic is underutilized in adults over the age of seventy, with only 4.6 percent of this age cohort choosing this treatment.²⁰ Similarly, studies on chronic pain and chiropractic in this age cohort also remain under represented.^{1,13} A direct comparison between chiropractic and physical therapy increases the evidence based care options for the geriatric patient.

This study shows statistically significant and clinically meaningful reductions (within group effects) in pain for both the chiropractic and PT treatment groups at six week and twelve week testing periods. However, there were no statistically significant between group effects indicating therapeutic equivalence. Similar reductions in participants' Box-21 scores for current, least, worst, usual pain, and number of days in pain over the last week at weeks six and twelve gave confidence in study results.

While it did not reach the level of statistical significance ($p > .05$), the CC group better maintained the levels of pain reduction at week 12 after six weeks with no care. This is visualized on the line plot graphs (figures 2-6) for each outcome measure. While the CC group line remained constant or even slightly decreased its slope after week six, the slope of the PT line exhibited a slight elevation in pain scores. This demonstrates that CC maintained pain reduction over a longer amount time compared to the PT treatment group. Larger sample sizes may show greater differences of this week twelve between group effects. As a hybrid pragmatic designed study, some commonalities between treatments may have existed, which could explain the lack of between group treatment effects.

The strengths of this study included equal randomization of age, gender, and medical and surgical history across both treatment groups. Additionally, the gender distribution in this study was comparable to that of the general geriatric population. The presence of cLBP was not a primary outcome in the original RCT and was not a factor in the randomization process. However, there were equivocal numbers of participants with cLBP in the CC and PT treatment groups. To ensure fidelity of care, all treatments were provided by the same chiropractor or physical therapist, both having previous experience focusing on geriatric care.

One limitation of this study was that some potential subjects had difficulty acquiring transportation to and from clinic sites and were unable to participate. Additionally, older adults who resided in long term care facilities, were home bound, or did not speak English were not represented in this study. Because patients were allowed to continue their usual medical care, pain medication such as NSAIDs and opiates were not controlled for. Between group differences in medical history (ruptured disc, diabetes and osteoarthritis) were not corrected for. Balancing the risk of single provider bias and fidelity of care between multiple providers is challenging. This study hoped to overcome both with well-defined treatment protocols. Due to the nature of the treatments, participants were not blinded to their group assignment.

Conclusion

Geriatric patients with cLBP who received chiropractic or physical therapy demonstrated similar reductions in pain. These statistically and clinically significant improvements extended six weeks beyond the end of care. Chiropractic and physical therapy are effective treatment options and should be considered for the management of cLBP in the geriatric population.

Consent

Written informed consent was obtained from all study participants. University ethics committee approval was obtained for this study.

Competing interests

The author(s) declare(s) that they have no competing interests.

Author's contributions

All authors contributed to this clinical trial and the manuscript. DE is the study principal investigator and program director. DE, JF & TM contributed to the study design. DE and KS reviewed the literature and created the first manuscript draft, TM was responsible for analysis and interpretation of data. All authors provided critical review and approved the final manuscript.

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