**Article Full Title**

Spinal manipulative therapy and exercise for older adults with chronic low back pain: a randomized clinical trial

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**Paper Abstract**

Background Low back pain (LBP) is a common disabling condition in older adults which often limits physical function and diminishes quality of life. Two clinical trials in older adults have shown spinal manipulative therapy (SMT) results in similar or small improvements relative to medical care; however, the effectiveness of adding SMT or rehabilitative exercise to home exercise is unclear. Methods We conducted a randomized clinical trial assessing the comparative effectiveness of adding SMT or supervised rehabilitative exercise to home exercise in adults 65 or older with sub-acute or chronic LBP. Treatments were provided over 12-weeks and self-report outcomes were collected at 4, 12, 26, and 52 weeks. The primary outcome was pain severity. Secondary outcomes included back disability, health status, medication use, satisfaction with care, and global improvement. Linear mixed models were used to analyze outcomes. The primary analysis included longitudinal outcomes in the short (week 4–12) and long-term (week 4–52). An omnibus test assessing differences across all groups over the year was used to control for multiplicity. Secondary analyses included outcomes at each time point and responder analyses. This study was funded by the US Department of Health and Human Services, Health Resources and Services Administration. Results 241 participants were randomized and 230 (95%) provided complete primary outcome data. The primary analysis showed group differences in pain over the one-year were small and not statistically significant. Pain severity was reduced by 30 to 40% after treatment in all 3 groups with the largest difference (eight percentage points) favoring SMT and home exercise over home exercise alone. Group differences at other time points ranged from 0 to 6 percentage points with no consistent pattern favoring one treatment. One-year post-treatment pain reductions diminished in all three groups. Secondary self-report outcomes followed a similar pattern with no important group differences, except satisfaction with care, where the two combination groups were consistently superior to home exercise alone. Conclusions Adding spinal manipulation or supervised rehabilitative exercise to home exercise alone does not appear to improve pain or disability in the short- or long-term for older adults with chronic low back pain, but did enhance satisfaction with care.

**NIH Risk of Bias Tool**

Quality Assessment of Controlled Intervention Studies

1. **Was the study described as randomized, a randomized trial, a randomized clinical trial, or an RCT**

Yes

1. **Was the method of randomization adequate (i.e., use of randomly generated assignment)?**

Yes

1. **Was the treatment allocation concealed (so that assignments could not be predicted)?**

No

1. **Were study participants and providers blinded to treatment group assignment?**

No

1. **Were the people assessing the outcomes blinded to the participants' group assignments?**

Yes

1. **Were the groups similar at baseline on important characteristics that could affect outcomes (e.g., demographics, risk factors, co-morbid conditions)?**

Yes

1. **Was the overall drop-out rate from the study at endpoint 20% or lower of the number allocated to treatment?**

Yes

1. **Was the differential drop-out rate (between treatment groups) at endpoint 15 percentage points or lower?**

Yes

1. **Was there high adherence to the intervention protocols for each treatment group?**

Yes

1. **Were other interventions avoided or similar in the groups (e.g., similar background treatments)?**

No

1. **Were outcomes assessed using valid and reliable measures, implemented consistently across all study participants?**

Yes

1. **Did the authors report that the sample size was sufficiently large to be able to detect a difference in the main outcome between groups with at least 80% power?**

Yes

1. **Were outcomes reported or subgroups analyzed prespecified (i.e., identified before analyses were conducted)?**

Yes

1. **Were all randomized participants analyzed in the group to which they were originally assigned, i.e., did they use an intention-to-treat analysis?**

Yes

**Key Finding #1**

All three treatment groups, spinal manipulative therapy (SMT) with home exercise plan (HEP), supervised exercise plan (SEP) with home exercise plan (HEP), and HEP alone, reduced pain in older adults with low back pain (LBP) by 30-40% after 12 weeks and by 25% after 52 weeks.

**Key Finding #2**

The addition of SMT or SEP to a standard HEP does not improve pain scores in both the short and long term for older adults with LBP.

**Key Finding #3**

The addition of SMT or SEP to a standard HEP enhanced the satisfaction with care for older adults with LBP compared to those with just a HEP alone.

**Key Finding #4**

**Please provide your summary of the paper**

This study was a randomized clinical trial that assessed the effectiveness of three separate treatment programs for reducing pain severity in older adults (65+) with low back pain (LBP). The three treatment programs were spinal manipulative therapy (SMT) combined with home exercise program (HEP), supervised exercise program (SEP) combined with HEP, and HEP alone. Each group received their form of treatment for 12 weeks and pain severity scores were assessed at 0, 4, 12, 26, and 52 weeks. Each group was comprised of approximately 80 participants. The authors of the study concluded that all three treatment programs reduced low back pain by 30-40% after 12 weeks and by 25% after 52 weeks. They further went on to conclude that the addition of SMT or SEP to a standard HEP does not improve pain scores for older adults with LBP in both the short and long term. Lastly, the authors concluded that while the addition of SMT or SEP to a HEP did not improve pain scores, it enhanced the satisfaction with care for the patients in those respective treatment groups.

**Please provide your clinical interpretation of this paper. Include how this study may impact clinical practice and how the results can be implemented.**

"While the authors concluded that SMT did not enhance patient outcomes for older adults with LBP, there were additional details worth considering to give this conclusion context. First, there was a limited description of what specific SMT techniques were used and how frequently each patient received the SMT treatment. While the article stated that SMT was used for 10-20min per session with a maximum frequency of 2x/week, it also stated that high velocity, low amplitude SMT was used “when possible”. This language indicates that the use of SMT was not always possible. Additionally, the article stated that low velocity, low amplitude SMT, flexion-distraction manipulation, and drop-table assisted SMT was utilized “if needed”. This language also indicates that these SMT strategies were not always utilized with patients. Other modalities listed within the SMT group were “light soft tissue massage, active and passive stretching, ischemic compression of tender points, ice, and heat.” Ultimately, it was not clear what specific manipulative interventions were performed and how frequently the patients received these interventions. There were also some slight differences in the demographics of the participants in each study group that were worth noting. The baseline percentage of patients awake at night due to LBP for the SMT+HEP group was 32% while the SEP+HEP and HEP alone groups were 21% and 18%, respectively. The baseline percentage of patients with traumatic onset of LBP for the SMT+HEP group was 27% while the SEP+HEP and HEP alone groups were 15% each. The baseline percentage of patients with a history of depression and anxiety for the SMT+HEP group was 16% while the SEP+HEP and HEP alone groups were 12% each. It is possible that these variables, being more prevalent for the SMT+HEP group, had an impact on how successful the SMT+HEP treatment program was.

Another noteworthy finding of the study was that there were no adverse events as a result of patients receiving SMT. This was an encouraging finding, indicating that SMT appears to be a safe intervention strategy for older adults with LBP.

Lastly, the authors made a recommendation for future research of evaluating LBP treatment strategies for older adults. Their recommendation was to focus not only on treatment strategies that address pain symptoms but to assess other areas such as biopsychosocial factors (i.e. self-efficacy, adaptive coping). This was a great recommendation for future research to assess other variables that have bearing on patient outcomes for older adults with LBP.