**Article Full Title**

Exercise, manual therapy, and use of booster sessions in physical therapy for knee osteoarthritis: a multi-center, factorial randomized clinical trial

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**Paper Abstract**

Objective: (1) Do treatment effects differ between participants receiving manual therapy (MT) with exercise compared to subjects who don't, (2) are treatment effects sustained better when participants receive booster sessions compared to those who don't over a one year period in subjects with knee osteoarthritis (KOA)? Design: Multi-center, 2 x 2 factorial randomized clinical trial. 300 participants with knee OA were randomized to four groups: exercise-no boosters (Ex), exercise-with boosters (Ex+B), manual therapy+exercise-no boosters (MT+Ex), manual therapy+exercise-with boosters (MT+Ex+B). The primary outcome was the Western Ontario and McMaster osteoarthritis index (WOMAC) at 1 year. Secondary outcomes included knee pain, physical performance tests, and proportions of participants meeting treatment responder criteria. Results: There were no differences between groups on the WOMAC at 1 year or on any performance-based measures. Secondary analyses indicated a) better scores on the WOMAC and greater odds of being a treatment responder at 9 weeks for participants receiving MT, b) greater odds of being a treatment responder at 1 year for participants receiving boosters. Exploratory interaction analysis suggested knee pain decreases for participants receiving boosters and increases for participants not receiving boosters from 9 weeks to 1 year. Conclusions: MT or use of boosters with exercise did not result in additive improvement in the primary outcome at 1 year. Secondary outcomes suggest MT may have some short term benefit, and booster sessions may improve responder status and knee pain at 1 year. However, the role of booster sessions remains unclear in sustaining treatment effects and warrants further study. Clinical trials: gov (NCT01314183).

**NIH Risk of Bias Score:** 11/14

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

Yes

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

Yes

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

Yes

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

Yes

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

Yes

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

Yes

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

Yes

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

Yes

**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

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

Yes

**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 Findings of the Study:**

1. There was no difference between treatment groups on the Western Ontario and McMaster osteoarthritis index (WOMAC) at 1 year.
2. Combining manual therapy with exercise showed some short-term improvement (9 weeks) in WOMAC scores.
3. Booster sessions may improve responder status based on the Osteoarthritis Research Society International responder criteria (OARSI).

**Reviewer Summary:**

This study placed participants into 4 groups: exercise no booster sessions, exercise with booster sessions, manual therapy and exercise no booster sessions, and manual therapy and exercise with booster sessions. The primary outcome measure used was the WOMAC and secondary outcomes included the timed-up and go, 30-second chair rise, and the 40-meter walk test. This study found no differences, on the WOMAC, between groups at the 1-year follow-up. However, they did find some short-term improvements at the 9-week session in the WOMAC for participants receiving manual therapy. This suggests that there may be positive short-term effects associated with manual therapy as compared to exercise alone. Interestingly, they found that booster sessions at 5-, 8-, and 11-months improved responder status on the OARSI which shows that booster sessions may help sustain therapeutic effects. Further studies are needed to investigate the effectiveness of booster sessions that include manual therapy.

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

This study did not find a difference between groups on their primary outcome at the 1-year follow-up, but there was an improvement at the 9-week session. This may suggest that manual therapy is more beneficial in the short-term and needs to be maintained over time, but further research is needed on the effects of manual therapy in booster sessions.