**Article Full Title**

The Incremental Effects of Manual Therapy or Booster Sessions in Addition to Exercise Therapy for Knee Osteoarthritis: A Randomized Clinical Trial

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**Paper Abstract**

Abstract: Study Design A factorial randomized controlled trial

Objectives: To investigate the addition of manual therapy to exercise therapy for the reduction of pain and increase of physical function in people with knee osteoarthritis (OA), and whether "booster sessions" compared to consecutive sessions may improve outcomes.

Background: The benefits of providing manual therapy in addition to exercise therapy, or of distributing treatment sessions over time using periodic booster sessions, in people with knee OA are not well established.

Methods: All participants had knee OA and were provided 12 sessions of multimodal exercise therapy supervised by a physical therapist. Participants were randomly allocated to 1 of 4 groups: exercise therapy in consecutive sessions, exercise therapy distributed over a year using booster sessions, exercise therapy plus manual therapy without booster sessions, and exercise therapy plus manual therapy with booster sessions. The primary outcome measure was the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC score; 0-240 scale) at 1-year follow-up. Secondary outcome measured were the numeric pain rating scale and physical performance tests Results Of 75 participants recruited, 66 (88%) were retained at 1-year follow-up. Factorial analysis of covariance of the main effects showed significant benefit from booster sessions (P = .009) and manual therapy (P = .023) over exercise therapy alone. Group analysis showed that exercise therapy with booster sessions (WOMAC score, -46.0 points; 95% confidence interval [CI]: -80.0, -12.0) and exercise therapy plus manual therapy (WOMAC score, -37.5 points; 95% CI: -69.7, -5.5) had superior effects compared with exercise therapy alone. The combined strategy of exercise therapy plus manual therapy with booster sessions was not superior to exercise therapy alone.

Conclusion: Distributing 12 sessions of exercise therapy over a year in the form of booster sessions was more effective than providing 12 consecutive exercise therapy sessions. Providing manual therapy in addition to exercise therapy improved treatment effectiveness compared to providing 12 consecutive exercise therapy sessions alone. Trial registered with the Australian New Zealand Clinical Trials Registry (ACTRN12612000460808).

Level of Evidence Therapy, level 1b-. J Orthop Sports Phys Ther 2015;45(12):975–983. Epub 28 Sep 2015. doi:10.2519/jospt.2015.6015

**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)?**

Yes

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?**

No

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**

Providing manual therapy as an adjunct to exercise therapy over a course of 12 consecutive sessions resulted in superior outcomes in pain and self-reported disability at 1-year follow up when compared to 12 consecutive sessions of exercise therapy alone.

**Key Finding #2**

Providing exercise therapy with 2 booster sessions at 5 months, 1 at 8 months, and 1 at 11 months had superior benefits in self-reported disability and 30-second sit-to-stand at 1-year follow-up compared to those who received 12 consecutive sessions of exercise therapy alone.

**Key Finding #3**

The results of this study did not find superior outcomes for the group that received both manual therapy and booster sessions when compared to the group that received exercise therapy alone.

**Please provide your summary of the paper**

This article provides a comparison via a randomized controlled trial of 4 different treatment groups over 12 sessions: exercise alone, exercise with manual therapy, exercise with booster sessions, and exercise with manual therapy utilizing booster sessions. The main objective of the article was to determine the effectiveness of manual therapy as an adjunct to exercise therapy over 1-year if the treatment strategy of using booster sessions at 5 months (2 sessions), 8 months (1 session), and 11 months (1 session) was utilized. The article uses multiple functional, self-reported functional, and self-reported pain outcome measures and utilizes tools for data analysis that are validated for RCTs to determine that the exercise with booster sessions group and the exercise with manual therapy without booster sessions group had statistically significant improvements in functional and self-reported pain and function outcome scores when compared to the reference group of exercise alone. The study did not find any statistically significant benefit for the exercise with manual therapy group that used booster sessions when compared to the exercise alone group. The article states that the small sample size may not have been able to prevent the possibility of this outcome being reached by chance and encourages further investigation of this treatment type using larger sample sizes.

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

While this paper includes a very small sample size that may not necessarily be representative of the general population that has knee OA (especially when considering the exclusion criteria and how many people may have the conditions included in those criteria), it does add to the breadth of research that supports the use of manual therapy as an adjunct to exercise therapy especially when considering patients' views of their own outcomes. It also supports the use of booster sessions instead of consecutive sessions when using exercise therapy in order to maintain the progress the therapist has made with a patient in their initial time with them. Using these booster sessions, therapists can monitor maintenance of patient health and progress with their condition over a longer period of time so that positive functional and pain-related outcomes may persist for longer periods of time. This article does not disprove the potential for the utilization of booster sessions of exercise and manual therapy, but instead presents a category of research and practice that may be important for therapists and researchers to consider investigating and utilizing in the future. Larger sample size groups may in the future show this treatment type and plan to be more effective upon further investigation, and it may be beneficial for certain patients to have the option of manual therapy along with exercise therapy utilizing the booster session model of care.