**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**

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 measures 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).

**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)?**

Yes

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)?**

Cannot Determine, Not Reported, or Not Applicable

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?**

Cannot Determine, Not Reported, or Not Applicable

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

No

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**

Distributing supervised exercise therapy sessions over the course of 1 year, in the form of 8 initial sessions in the first 2 months, then 4 booster sessions at 5, 8, and 11 months, improved outcomes at 1 year compared with delivery of 12 consecutive sessions of supervised exercise therapy within 2 months, without additional therapist contact time.

**Key Finding #2**

The addition of 12 sessions of individually tailored manual therapy to 12 sessions of supervised exercise therapy, delivered over 2 months, also improved outcomes at 1 year, while also requiring additional therapist time.

**Key Finding #3**

However, providing manual therapy distributed over 12 months using booster sessions in addition to supervised exercise therapy did not provide incremental benefit at 1 year compared with delivery of 12 consecutive sessions of supervised exercise therapy alone, and required additional therapist time.

**Key Finding #4**

Further research is required to establish the incremental benefits of booster sessions and/or manual therapy in addition to exercise therapy.

**Please provide your summary of the paper**

This study shows that providing manual therapy or booster sessions (which includes sessions of supervised therapy provided at time intervals separated from the consecutive sessions of the initial episode of care, with intervening periods of no supervised therapy provision) paired with exercise therapy had more benefits than just exercise therapy alone. Overall results showed the decreased pain disability gauged 1-year post-trial was attributed to these results [after 12 sessions of manual therapy on top of exercise therapy]. Similarly manual therapy paired with exercise therapy and standard care for treating knee OA also was more beneficial than just standard medical care for OA. When looking specifically at time spent doing each intervention, the study shows that keeping exercise and manual therapy intervention times the same poses additional benefits.

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

Although there are added benefits to a PT providing exercise and manual therapy, time must be a considered factor when making the decision to implement both interventions. This could require the PT to have more sessions with the patient (i.e. time with the patient) to be able to provide both types of therapy to the same degree and get the additional benefits mentioned in this study.