Bennell KL, Egerton T, Martin J, and et al. Effect of Physical Therapy on Pain and Function in Patients With Hip Osteoarthritis A Randomized Clinical Trial. Journal of the American Medical Association 2014;311(19):1987-1997.

Critique author: Linda Metzger 2-20-15

Design: Randomized clinical trial

Objective: To determine if a 12-week multimodal physical therapy program, including manual therapy, exercise, and education, leads to greater improvements in pain and physical function than sham physical therapy among people with symptomatic hip osteoarthritis.

Population /sample size/setting:

- 100 community volunteers aged 50 years of age or older with radiographically confirmed hip osteoarthritis (OA) participated in the study and were randomly assigned to 1 of 2 groups, an active intervention group (n = 49, mean age = 64.5) or a sham intervention group (n = 53, mean age = 62.7).
- Study design was a randomized, participant and assessor blinded, parallel-group, placebo-controlled trial with a 12-week intervention and a 24-week follow-up after that.
- Inclusion criteria included 50 years of age or older, hip osteoarthritis fulfilling the American College of Rheumatology classification criteria of pain and radiographic changes, pain in the groin or hip for more than 3 months, average pain intensity in the past week of 40 or higher on a 100 mm visual analogue scale (VAS), and at least moderate difficulty with daily activities.
- Exclusion criteria included hip or knee joint replacements or both, planned lower limb surgery, physical therapy, chiropractic treatment or prescribed exercises for hip, lumbar spine, or both in the past 6 months, walking continuously more than 30 minutes daily, and regular structured exercise more than once a week.

Interventions:

- After baseline assessment, those eligible were randomized in permuted blocks of varying size using a computer-generated random numbers table, stratified by physical therapist, to receive either active or sham treatment. Allocations were sealed in opaque, consecutively numbered envelopes by an independent person not involved in recruitment and kept in a central locked location. The envelopes were picked by an individual not involved in the study.
- Eight physical therapists in 9 private clinics were trained to deliver both treatments. Treatment fidelity was assessed by observation of sessions and completion of treatment notes. The physical therapists were not blinded.
- All participants attended 10 individual treatment sessions over 12 weeks; twice in the first week. The initial 2 sessions were 45 to 60 minutes in duration. The remaining sessions were 30 minutes.
- The active intervention consisted of 1) manual therapy techniques including hip thrust manipulation, hip lumbar spine mobilization, deep tissue massage, and muscle stretches, 2) 4 to 6 home exercises performed 4 times/wk, including strengthening of the hip abductors and quadriceps, stretching, range of motion, and functional balance and gait

drills, 3) education and advice, and 4) provision of a walking stick if appropriate. During the 6-month follow-up, participants were instructed to perform unsupervised home exercises 3 times weekly.
- The sham intervention included inactive ultrasound and inert gel lightly applied to the anterior and posterior hip region by the unblinded therapist. This group received no exercise instructions and no manual therapy. During the 6-month follow-up, participants were asked to gently apply the gel for 5 minutes 3 times weekly.
- Participants were assessed by the same blinded assessor at baseline and at 13 weeks and were mailed questionnaires at 36 weeks.
- Adherence, adverse events, co-interventions, and medication use were collected via log book during treatment and via questionnaires administered during follow-up.

Main outcome measures:

- Two primary outcome variables were included (self-reported) to measure hip pain and function at week 13.
    - Overall average hip pain intensity in the past week was rated using a 100 mm VAS, for which 0 mm represented no pain and 100 mm, the worst pain possible. The minimal clinically important difference (MCID) was 18 mm.
    - Physical function was measured using the 17-item Western Ontario and McMaster Universities Osteoarthritis Index physical function subscale with hip-specific questions with scores ranging from 0 representing no difficulty to 68, extreme difficulty. The MCID was 6 units.
- Secondary outcomes were pain and function at week 36. Additional secondary outcomes included impairments, physical performance, global change, psychological status, and quality of life at weeks 13 and 36.
- Sample-size estimation calculations were based on detecting a 6-point difference in physical function on the WOMAC with a 2-sided 5% significance level, and 80% power. A sample size of 50 per group was determined.
- Three patients in each group were lost to follow-up and did not complete the 13 week assessment. A total of 83 (81%) participants completed week 36 measurements. Primary analyses were performed with 49 subjects in the active group and 53 subjects in the sham group.
- At baseline, there was no statistically significant difference between participant characteristics in either group or for the pain and function outcome variables.
- The between-group differences for changes in pain were not significantly different. The mean (SD) baseline overall pain score in the active group was 58.8 mm (13.3) and the week-13 score, 40.1 mm (24.6). For the sham group, the baseline overall pain score was 58.0 mm (11.6) and the week-13 score, 35.2 mm (21.4), for a mean difference of 6.9 mm in favor of sham treatment (95% CI, −3.9 to 17.7).
- No between-group differences existed for physical function. The baseline function score for the active group was 32.3 (9.2) and the week-13 score, 27.5 (12.9). The baseline function score for the sham group was 32.4 (8.4) and the week-13 score, 26.4 (11.3) for a mean difference of 1.4 units in favor of sham therapy (95% CI, −3.8 to 6.5) at week 13.
- For within group change scores, both groups showed statistically significant and clinically relevant improvements in pain. The active group improved a mean of 17.7 mm and the sham treatment group, 22.9 mm. For function, the active group improved a mean

of 5.2 units and the sham treatment group, 5.5 units. These within group improvements for function did not quite meet the MCID criteria for clinical relevance.

- For the secondary outcomes at weeks 13 or 36, no significant between-group differences were observed.
- Forty-one of 49 patients (84%) in the active group and 42 of 53 subjects (79%) in the sham treatment group attended all 10 treatment sessions. The active group attended an average of 9.6 sessions and the sham group attended an average of 9.4 sessions.
- Adherence to home exercise or gel application was good. In the active group, 85% of subjects performed an average of 3.4 home exercise sessions during the first 13 weeks. During weeks 13 to 26, 68% of the active group performed their home exercises an average of 2 times a week. For the sham group during weeks 13 to 26, 76% of subjects applied their gel an average of 2.3 times a week.

Authors' conclusions:

- **T**he results of this clinical trial demonstrated that a 12-week multimodal physical therapy treatment typical of current practice for people with symptomatic hip osteoarthritis did not confer additional benefits over a realistic sham treatment that controlled for the therapeutic environment, therapist contact time, and home tasks. Both groups showed significant improvements in pain and function following treatment.
- One possible explanation for these findings includes a type II error. Statistical power (80% for physical function and higher for pain) was adequate to detect clinically relevant differences if these had been present. Observed between-group differences favored the sham group and the 95% confidence intervals indicated it was unlikely that any important benefit of active treatment was missed.
- The absence of significant between-group differences despite the use of skilled therapists and excellent adherence rates to home exercise (85%), suggest that the active physical therapy program was truly ineffective. Multimodal interventions are common in physical therapy, and both exercise and manual therapy were included based on current evidence supporting their individual benefit.
- Another explanation for the study results may be that the participants may not have performed the home program to the same intensity as the supervised program.
- We know that a greater number of therapist contacts improve outcomes. It is not known whether a more intensive physical therapy protocol may have been more effective than sham treatment.
- These results question the benefits of a multimodal physical therapy program for this patient population.

Comments:

- This was a well-designed randomized controlled trial.
- Primary outcome measures were clearly stated.
- It is possible that the results of this study could be explained by type II error, such as some major undetected difference in the population of the 2 groups. However, baseline pain and physical function levels were virtually identical. It appears that the active group may actually be less active than the sham group based on several characteristics. The active group was on average almost 2 years older, had symptoms on average 6 months longer, and were slightly heavier (1.2 kg). Only 35% of the active group was employed compared to 53% in the sham group. For all types of past treatment involving exercise (muscle strengthening, aerobic exercise, range of motion, stretching, and aquatic exercise), the active group was much less likely to have participated.

- If the participants in the active group did not perform the home program to the same intensity as the supervised program, this could have diminished the effect size of exercise and contributed to the negative results of the study.
- The rigorous methodology used in this study avoided the possible biases of trials that measure subjective patient-reported outcomes. This trial minimized potential for bias by including a credible sham treatment, concealing treatment allocation, and blinding the participants, outcome assessor, and biostatistician. Participants also had radiographically confirmed hip osteoarthritis. Previous positive trials that were not placebo-controlled with an adequate sham intervention that also failed to blind participants were likely to overestimate the treatment benefit. This study did not overestimate the effect of the intervention. This may be another explanation for this study's negative findings.
- Evidence in the past may have supported both exercise and manual therapy for hip OA, but two more recent randomized controlled trials agree with this study and have found that combining exercise and manual therapy does not add benefits and may even have an adverse interaction effect in hip osteoarthritis. Perhaps combining manual and exercise therapy necessitates reducing the dose of both in order to fit into a fixed clinic visit time. This compromise might have reduced the efficacy of the multimodal program. The active physical therapy program may not have adequately targeted and changed physical impairments, such as muscle weakness and restricted range that are often associated with hip pain and dysfunction.
- The improvements observed in the sham group and the fact that patients with hip osteoarthritis not undergoing treatment showed little change over similar time frames, suggests that a credible and effective sham intervention was used. The sham intervention included 10 individual sessions with an attentive therapist and treatment that involved skin stimulation and touch. These components, together with a quality therapeutic relationship and a more patient-focused communication style (e.g. listening,) may have enhanced the sham intervention more than the active intervention, since in the active intervention the therapists' focus on content delivery may have reduced the time available for this enhanced relationship. We know that the therapeutic relationship can influence outcomes such as pain and function. Thus both active and sham physical therapy may have contained different therapeutic elements that resulted in similar clinical improvements.
- Lack of therapist blinding is a potential limitation of the trial. Also, the absence of more blinding than expected by chance among participants at the final follow-up assessment is a potential limitation. However, these potential biases would likely favor the active group.

Assessment*:*

This adequate study provides some evidence that a 12-week multimodal physical therapy program, consisting of a combination of manual therapy, exercise, and education, provides no additional reductions in pain or improvements in physical function than sham physical therapy among people with hip osteoarthritis.

References:

- French HP, Cusack T, Brennan A, et al. Exercise and manual physiotherapy arthritis research trial (EMPART) for osteoarthritis of the hip: a multicenter randomized controlled trial. *Arch Phys Med Rehabil*. 2013;94(2):302-314.
- Abbott JH, Robertson MC, Chapple C, et al; MOA Trial team. Manual therapy, exercise therapy, or both, in addition to usual care, for osteoarthritis of the hip or knee. *Osteoarthritis Cartilage*. 2013;21(4):525-534.