

**Poulsen E, Hartvigsen J, Christensen HW, and et al. Patient education with or without manual therapy compared to a control group in patients with osteoarthritis of the hip. A proof-of-principle three-arm parallel group randomized clinical trial. Osteoarthritis and Cartilage 2013; 21:1494-1503.**

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**Design:** Randomized clinical trial

**Objective:** To determine the effectiveness of a patient education (PE) program with or without the added effect of manual therapy (MT) compared to a minimal control intervention (MCI) in reducing pain among people with symptomatic hip osteoarthritis.

**Population /sample size/setting:**

- 111 patients aged age 40 to 80 years of age with clinical and radiographic unilateral hip osteoarthritis (OA) were recruited from a single-center university hospital setting and were randomly assigned to 1 of 3 groups: 1) patient education program (PE) (n = 37, mean age = 65.5), 2) patient education program + manual therapy (PE+MT) (n = 38, mean age = 65.8), or 3) minimal control intervention (MCI) (n = 36, mean age = 62.5).
- Study design was a randomized, assessor blinded, three-arm parallel group controlled trial with a 6-week intervention and follow-up, and long term follow-ups at 3 and 12 months.
- Inclusion criteria included unilateral hip pain >3 months' duration, age 40 to 80 years, radiographic hip OA, and ability to speak and read Danish.
- Exclusion criteria included patients who had had manual therapy within the previous 12 months, patients who rated their pain severity as 1 or 2 on the primary outcome 11-box numerical rating scale (NRS), since improvement would not be measurable, and patients with polyarthritis, defined as having OA-like symptoms from more than 3 anatomic areas.

**Interventions/Methods:**

- The randomization sequence with block sizes of three, 6 or 9 was computer generated by a person not otherwise involved in the study and opaque envelopes were generated by yet another person not otherwise involved in the trial. On the day of allocation, a number of sealed opaque envelopes matching the number of patients scheduled were generated and each patient selected an envelope following completion of patient-reported outcome measures on the baseline questionnaire.
- The PE program included two individual sessions and three group sessions and was taught by a physiotherapist with experience in orthopedic rehabilitation. Each patient received a sheet of paper with recommendations for activities of daily living (ADL) and home stretching exercises related to balance and hip mobility which were to be performed daily. Power point presentations and anatomic models were used as teaching aids to teach hip anatomy. Advice was given on keeping an active lifestyle and activities like swimming, cycling and walking were recommended. Discussions were initiated on self-management of pain including which tissue is pain sensitive and what signifies pain.

- Manual therapy (MT) was administered by a chiropractor (author) with 20 years of clinical experience and 10 years of specific clinical and research interest in patients with hip OA. MT was scheduled twice a week for 15 to 25 minutes for the 6-week intervention period and treatment was individualized to each patient depending on examination findings. MT includes 3 different manual therapies: trigger point release therapy (TPPR), muscular stretching by muscle energy technique (MET) and joint manipulation. TPPR is given to obtain desensitization and muscular relaxation of trigger points through digital mechanical pressure. The aim of the MET is to obtain muscle relaxation and improve ROM through stretching. The aim of joint manipulation is to affect hip musculature and joint capsule through forceful distraction also known as high volume low amplitude (HVLA) thrusts. At end range of joint movement, the joint is distracted and an HVLA thrust is applied using manual force. The force and speed applied should be of a sufficient magnitude aimed at cavitation of the joint.
- The MCI group was given written advice on a home stretching program derived from the PE program by the project nurse, together with a 5 to 10 minute instruction. Patients were advised not to initiate or alter their use of pain medication or other treatment. The project nurse was not involved in the assessment of patients.
- Physical exams were performed by a blinded assessor and questionnaires were completed by participants at baseline and at 3 and 12 months. Patients were instructed not to reveal group allocation to the assessor, but blinding was not confirmed for all patients.
- The main analyses followed the intention-to-treat principle analyzing all patients “as randomized” including those who received hip surgery between 6 weeks and 12 months.
- Sample-size estimation calculations were based on detecting a 17-point difference in pain severity with a 2-sided 5% significance level, and 80% power. A sample size of 30 per group was determined. Allowing for drop-outs, total sample size was estimated to include a minimum of 106 patients.
- Only the comparisons PE vs MCI and PE + MT vs MCI with respect to the main outcome were considered as confirmative, and the comparison PE vs PE + MT was considered as explorative.
- Adherence, adverse events, co-interventions, and medication use were collected during treatment and via questionnaires administered during follow-up.

### **Main outcome measures:**

- One primary outcome variable was included (self-reported) to measure hip pain severity rated on an 11-box NRS (numeric rating scale) after 6 weeks of intervention. Patients were asked to rate the worst pain experienced during the previous week. Patients were followed for one year. Zero represents no pain and 11 is the worst possible pain.
  - The minimal clinically important difference (MCID) is estimated to be 15 points, but this study conservatively used 17 points.
- Secondary outcomes were;
  - Hip disability and Osteoarthritis Outcome Score (HOOS) range 0 to 100, worst to best;
  - patients’ perceived global effect of interventions, percentage in each group having classified themselves as improved;
  - passive hip range of motion (ROM);

- use of pain medication at 12 months;
  - hip replacement surgery within the 12 month follow-up period.
- At 6 weeks follow-up, nine patients (8.1%) had withdrawn from the study. One patient from the PE group, and 4 each from the other 2 groups.
  - The between-group differences for changes in pain were not significantly different. At the primary end point (6 weeks), no overall statistically significant differences were found between all three groups for mean pain severity (PE: 5.3 [SD 2.3], PE + MT: 3.4 [SD 2.4], MCI: 5.3 [SD 1.7],  $P = 0.058$ ).
  - For the pair-wise comparison, the PE + MT group achieved a 1.9 points greater pain reduction compared to the MCI (95% CI = 0.9 to 2.9). No difference was found between the PE and MCI groups (95% CI = -1.0 to 1.0). Effect size for the PE + MT minus the MCI group was 0.92 (95% CI = 0.41 to 1.42) and for the PE minus the MCI group, 0.02 (-0.49 to 0.46).
  - At 12 months, the statistically significant difference favoring PE + MT was maintained.
  - Differences between all three groups were significant for the HOOS subscales pain, function in sport, and hip-related quality of life (QoL), but not for the subscales of symptoms and function in daily living (ADL). All HOOS subscales demonstrated clinically relevant and statistically significant superiority for the PE + MT group when compared to the MCI group: 17 points (95% CI 11 to 23) for Pain; 13 points (95% CI 5 to 20) for Symptoms; 14 points (95% CI 7 to 22) for ADL; 17 points (95% CI 8 to 25) for Sport, and 13 points (95% CI 6 to 20) for QoL. Mean differences between PE and MCI were small and not statistically significant. Effect sizes for HOOS subscales for PE + MT minus MCI ranged between 0.75 and 1.08. For ROM measurements, neither overall nor pair-wise comparisons were statistically significant.
  - The exploratory analysis of the difference between PE and PE + MT groups at 6 weeks showed that the PE + MT group was able to reduce pain severity with a clinically relevant difference of 1.9 points compared to PE alone (95% CI = 0.8 to 2.9). The effect size was 0.79 (95% CI = 0.30 to 1.27) showing statistically significant and clinically relevant reductions in pain. The same pattern was demonstrated for all HOOS subscales with effect sizes ranging from 0.72 to 0.97.
  - For patients' perceived global effect of intervention at 6 weeks, 76.5% of patients in the PE + MT group had classified themselves as improved compared to 22.2% in the PE group, and 12.5% in the MCI group.

### **Authors' conclusions:**

- The results of this clinical trial demonstrated that a 6-week patient education and manual therapy (PE and MT) intervention did confer a statistically significant and clinically relevant pain reduction with a large effect size when compared to the control group receiving a minimal intervention of home stretching in patients with hip osteoarthritis.
- No difference in reducing pain was found when comparing PE alone to the minimal intervention (MCI).
- For primary care patients with OA of the hip, a combined intervention of MT and PE was more effective than a MCI.
- The effectiveness of manual therapy in reducing pain in people with hip OA may be explained by the physical components of joint manipulation (forceful traction), opposed to just mobilization.

- Pain reduction and improvement in all of the HOOS subscales in the group receiving PE + MT was also demonstrated.
- Future trials should determine the optimal frequency and dose of manual therapy, and compare manual therapy to patient education alone.

**Comments:**

- The primary outcome measure of pain severity was clearly stated a priori.
- There is a possible risk of introducing attention or performance bias in the PE + MT group, since they received 12 more sessions than the PE alone group, and 17 more sessions than the MCI group. The beneficial therapeutic effects of the PE + MT intervention are likely due to both the specific effects of the intervention itself and the non-specific effects of the extra attention received during the additional sessions. Thus, the non-specific effects could inflate the overall effect size in the PE + MT group.
- Since no differences were found between the PE and MCI groups at any follow-up, this may demonstrate the lack of effectiveness of patient education programs on pain and function for hip OA patients.
- No measurement or log of the PE program recommended daily home stretching exercises or any other exercises or activities were completed as part of this study. This could introduce measurement error and underestimate the effect in the PE group. However, recommending exercise and supervised exercise are not the same.
- A performance based measure of physical function as a secondary outcome for hip OA should have been incorporated in this study to provide a better overall effect of manual therapy.
- Since the study was not powered to compare the PE and PE + MT interventions, the main results on this comparison could not formally be tested in a confirmative manner. Because this was an important comparison to include, the study should have incorporated adequate power or sample size to evaluate this comparison confirmatively.
- Both the patient education and the manual therapy were administered by only one therapist/chiropractor, limiting the external validity of the study.

**Assessment:**

There is some evidence that a 6-week patient education and manual therapy (PE and MT) intervention is more effective in reducing pain in patients with hip osteoarthritis than a control group receiving a minimal intervention of home stretching.