

TITLE: Evaluation of two different methods of teaching self-management strategies to patients with symptomatic knee osteoarthritis

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**Title:** Evaluation of two different methods of teaching self-management strategies to patients with symptomatic knee osteoarthritis

**Principal Investigator:** Dr. James Wyss, MD

**Condition or Intervention to be studied:** The condition being studied is self-management education for patients who have symptomatic knee osteoarthritis (OA) and are scheduled for a hyaluronic acid (HA) injection.

**Research questions/specific aims:** This is a pilot study to evaluate two different teaching methods of self-management education to patients receiving an HA injection for symptomatic knee OA. The main goal is to see if the study can be feasibly conducted. Feasibility will be determined by availability of the fellows/residents to administer the assigned teaching method to the potential patient (if they are unavailable 70% of the time, then the study will be deemed to be not feasible). The other goals are to obtain information on the following:

1. Patient satisfaction with their assigned teaching methods.
2. Education methods that are preferred by patients.
3. Provider (fellows and residents) satisfaction with their assigned teaching methods.
4. Teaching methods that are preferred by fellows and residents.

**Hypothesis:** We hypothesize that the study can be feasibly conducted, and that patient satisfaction with assigned teaching method 2 (education handout + 5-minute explanation) will be higher than patient satisfaction with assigned teaching method A (educational handout only, no explanation).

**Primary outcome:**

1. Patient satisfaction with their assigned teaching method (0-10 scale; 0=not satisfied; 10=most satisfied) – assessed at 1 and 3 months post-injection
2. Provider (fellow, resident) satisfaction with their assigned teaching method (0-10 scale; 0=not satisfied; 10=most satisfied) – assessed at 1 and 3 months post-injection

**Secondary outcomes:**

1. Patient preference regarding teaching method – assessed at 1 and 3 months post-injection
2. Provider preference regarding teaching method – assessed at 1 month post-injection
3. Quality of education on post-injection care – assessed at 1 and 3 months post-injection
4. PROMIS-10 – assessed at 1 and 3 months post-injection

**Background:** Symptomatic knee OA is a condition that is characterized by frequent pain to the joint and affects approximately 10 million adults in the United States.<sup>1</sup> By age 60, the lifetime risk of being diagnosed with symptomatic knee OA is 9.29%.<sup>2</sup> Increases in symptomatic knee OA pain have been associated with higher BMI, greater comorbidity, and lower level of education.<sup>3</sup> For patients who do not want to have surgery, treatment options include pharmacologic injections, physical therapy, and medications, with the goal of relieving symptoms, improving quality of life, and restoring physical function. Regardless of treatment type, achieving the abovementioned goals requires self-management.

In 2003, the EULAR consensus stated that patient education should be provided to patients with symptomatic knee OA to help them understand and self-manage their condition.<sup>4</sup>

However, there is a lack of consensus on the best teaching methods to educate our patients with symptomatic knee OA on self-management strategies. Different physician practices within a department or across different departments utilize different strategies to accomplish these goals. Many provide direct doctor-to-patient teaching that may occur during an office visit (one-on-one) or with a small group. Others may rely on educational handouts or other forms of individual education that are given to patients. Some utilize both methods of teaching, and others rely on physical therapists to provide this education to their patients as part of their physical therapy program. There are many other teaching methods, and variations of previous methods also exist.<sup>5</sup>

Numerous studies on different patient education methods in various patient populations have been conducted.<sup>6</sup> Both the content and delivery of education materials are essential to having a successful method. Whether one method is effective depends largely on the patient's self-efficacy, ability to understand the materials, and willingness to cooperate.<sup>7,8</sup> This is especially key to having success with self-management protocols. Any stress that may result from an ineffective education tool can also adversely affect a patient's outcomes.<sup>7</sup> In the general OA population, Hansson et al. demonstrated an increase in self-perceived health in patients who participated in an OA-targeted patient education program (5 group sessions) compared to patients who did not participate in the program.<sup>9</sup> However, no differences in self-efficacy were observed, and patient satisfaction was not assessed. A review by Brand et al. in 2013 showed improvements in self-efficacy with regard to decreasing pain in arthritis patients receiving self-management education, although these effect sizes were very small and likely not statistically significant in some cases.<sup>8</sup> Again, many of these studies did not assess patient satisfaction. Recently, the development of video-based patient education tools was tested in patients with knee osteoarthritis (both symptomatic and not), rheumatoid arthritis, and osteoporosis. The results showed increases in disease knowledge, and patients appeared to be more aware about taking their medications.<sup>10</sup> Future advances in patient education are likely to incorporate multimedia tools as a way to better engage the patient.

With all this being said, studies that are focused on patient education involving self-management methods in the symptomatic knee OA population are lacking. A literature search revealed one study looking at the effects of an 8-week multimodal treatment program that improved symptoms of symptomatic knee OA. Patient education was a component of the treatment program, but whether it specifically contributed to symptom improvement is unknown.<sup>11</sup> Given the degree of disability that these patients live with on a daily basis, clarifying the proper method of self-management education is important. This pilot study aims to take the first step at evaluating two different methods of teaching: one involving a written handout that's given to the patient for him/her to read at home, and one involving the same written handout that is explained to the patient by the provider. Future studies will evaluate other commonly utilized methods of teaching, as well as longer periods of follow-up.

1. Lawrence RC, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States, part II. *Arthritis Rheum.* 2008 Jan;58(1):26-35.
2. Losina E, et al. Lifetime risk and age of diagnosis of symptomatic knee osteoarthritis in the US. *Arthritis Care Res.* 2013 May;65(5).
3. Bastick AN, et al. Defining knee pain trajectories in early symptomatic knee osteoarthritis in primary care: 5-year results from a nationwide prospective cohort study (CHECK). *Br J Gen Pract.* 2016 Jan;66(642):e32-9.
4. Jordan KM, et al. EULAR Recommendations 2003: an evidence-based approach to the management of knee osteoarthritis: report of a task force of the standing committee for

international clinical studies including therapeutic trials (ESCISIT). *Ann Rheum Dis.* 2003 Dec;62(12):1145-55.

5. Schrieber L, et al. Patient education. *Best Prac Res Clin Rheum.* 2004;18(4):465-476.
6. Friedman AJ, et al. Effective teaching strategies and methods of delivery for patient education: a systematic review and practice guideline recommendations. *J Cancer Educ.* 2011 Mar;26(1):12-21.
7. Koehn CL, et al. Patient education and self-management of musculoskeletal diseases. *Best Prac Res Clin Rheum.* 2008;22(3):395-405.
8. Brand E, et al. Arthritis self-efficacy scale scores in knee osteoarthritis: a systematic review and meta-analysis comparing arthritis self-management education with or without exercise. *J Orthop Sports Phys Ther.* 2013 Dec;43(12):895-910.
9. Hansson EE, et al. Effect of an education programme for patients with osteoarthritis in primary care – a randomized controlled trial. *BMC Musculoskelet Dis.* 2010;11:244.
10. Lopez-Olivo MA, et al. Development and pilot testing of multimedia patient education tools for patients with knee osteoarthritis, osteoporosis, and rheumatoid arthritis. *Arthritis Care Res.* 2017.
11. Miller LE, et al. An 8-week multimodal treatment program improves symptoms of knee osteoarthritis: a real-world multicenter experience. *Pragmat Obs Res.* 2013;4:39-44.

**Study design:** Randomized controlled clinical trial

**Enrollment target:** 24

**Inclusion criteria:**

1. Age 18+
2. Diagnosis of symptomatic knee OA
3. Scheduled for an HA injection into the knee
4. Fellow/resident is available to administer assigned teaching method

**Exclusion criteria:**

1. Patients who are already enrolled in the study
2. Non-English speaking

**Study procedures:** Patients who have symptomatic knee OA and are coming in for an HA injection will be approached for the study. At the time of consent, patients will be told that they will be receiving educational materials, and that the study will be focusing on outcomes in patients who receive educational materials. Details related to the two teaching methods will only be revealed to the patients at the 3-month follow-up, in order to prevent any bias in their responses. The primary investigator and research assistant will be blinded to the randomization group.

Enrolled patients will be randomized to receive one of two teaching methods:

1. A written handout will be given to the patient, and the patient will be asked to read the handout at home and call back with any questions or clarifications.
2. A written handout will be given to the patient, and key information will be explained to the patient with time for questions and answers (approximately 5 min).

The written handout includes a description of knee OA, treatment options for knee OA, and instructions for the self-management of knee OA.

During the icing period post-injection, a fellow or resident will return to the exam room and administer either teaching method 1 or 2 to the patient (depending on the randomization assignment). The same written handout will be given to every patient. The explanation of key information will be standardized as much as possible to prevent against large variations in teaching methods among fellows and residents.

At 1 month following the educational handout/session, the fellows and residents will be surveyed regarding their satisfaction with the teaching method and if they would have preferred to teach the information in a different manner.

At 1 month and 3 months following the educational handout/sessions, patients will be asked the following questions:

1. On a scale of 0-10, with 0=not satisfied and 10=most satisfied, please rate your satisfaction with the education you received on the day of your injection.
2. Would you have preferred a different method of receiving education? If yes, what method?
3. Did the education you received help with the care of your osteoarthritis? If yes, please explain how it helped.
4. PROMIS-10 questionnaire (also administered at baseline, after consent)

**Sample size analysis and statistical analysis plan:** As recommended by Julius,<sup>1</sup> this pilot study will have a sample size of 12 per group (24 total). If deemed feasible, results from this study will be used to design larger, future studies.

Descriptive statistics will be employed for this pilot study. Patient/provider satisfaction results will be summarized as mean with standard deviation or median with 1<sup>st</sup> and 3<sup>rd</sup> quartiles. Patient/provider preference results (yes/no) will be presented as counts and percentages. Whether the education helped with the patient's care of OA (yes/no) will also be presented as counts and percentages. PROMIS-10 scores will be summarized as mean with standard deviation or median with 1<sup>st</sup> and 3<sup>rd</sup> quartiles. Comparisons between continuous or categorical variables will be assessed using the Student's t-test or Chi-square test, respectively.

1. Julius SA. Sample size of 12 per group rule of thumb for a pilot study. *Pharmaceut Statist.* 2005 Oct;4(4):287-291.

12. Lawrence RC, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States, part II. *Arthritis Rheum*. 2008 Jan;58(1):26-35.

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14. Losina E, et al. Lifetime risk and age of diagnosis of symptomatic knee osteoarthritis in the US. *Arthritis Care Res.* 2013 May;65(5).
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