Svege I, Nordsletten L, Fernandes L, and et al. Exercise therapy may postpone total hip replacement surgery in patients with hip osteoarthritis: a long-term follow-up of a randomized trial. Ann Rheum Dis 2015; 74:164–169.

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Design: Randomized clinical trial

Objective: To determine if exercise therapy in addition to patient education results in better long-term cumulative survival of the native hip from total hip replacement (THR) compared with patient education alone in patients with osteoarthritis (OA) of the hip.

Population /sample size/setting:

- A total of 109 patients with OA of the hip (59 females, 50 males, mean age 57.5 years) were recruited by one university hospital, one local hospital, one rehabilitation center, general medical practitioners, and by advertisement in a local newspaper in Oslo, Norway. Patients were randomized into one of 2 groups; the intervention group of patient education and supervised exercise therapy (PE+E) n=55, or the control group of patient education alone (PE) n=54.
- Study design was a long-term follow-up study of a single blind, randomized controlled trial.
- Inclusion criteria included age between 40 and 80 years, hip pain for at least 3 months, radiographically verified minimum joint space according to Danielsson's criterion (<4 mm for patients <70 years, <3 mm for patients >70 years) and Harris Hip Score between 60 and 95 points. Night pain and Harris Hip Score below 60 are used as criteria for THR. The patients included in the study were not candidates for THR at the time of inclusion, and none of them were on waiting lists for THR.
- Exclusion criteria included THR in the index joint, knee pain or knee OA, low back pain, rheumatoid arthritis, osteoporosis, cancer, cardiovascular disease unable to tolerate exercise, dysfunction in lower extremities due to accident or disease, pregnancy and not understanding Norwegian.

Methods/Interventions/Outcome Measures:

- Randomization was conducted by using a computer-generated randomization list and using sequentially numbered, sealed envelopes to assign treatment for patients consecutively by a research coordinator not involved in the patient assessment or interventions. The randomization sequence was concealed from the study collaborators until treatment was assigned. Allocation concealment was maintained until written informed consent was obtained, and baseline assessments and patient education sessions were completed. The outcome assessor was blinded to group allocation.
- Before randomization to either an exercise therapy group or a control group, all included patients in both groups were given the patient education program that consisted of 3 group sessions developed for patients with hip OA.

- The exercise therapy program was specifically designed for patients with hip OA and consisted of strengthening, flexibility and functional exercises. Patients in the intervention group performed the exercise program 2 to 3 times per week for 12 weeks, supervised by a physical therapist at least once weekly. Exercise compliance was based on training diaries filled in weekly by the patients during the 12-week intervention period. Attending at least 20 of a total of 24 sessions was defined as satisfactory adherence.
- Patients in the control group did not participate in the exercise therapy program, but did attend a 2-month follow-up visit at the physiotherapy clinic as part of the patient education program.
- The main outcome measure for this long-term follow-up was survival of the native hip from THR. At inclusion, all patients were instructed to report if and when they went through THR surgery during the project period. Data on THR was recorded at follow-ups 4, 10, 16 and 29 months after inclusion and by contacting all patients by telephone at the end of the study.
- Patients were followed until time of THR or until death, drop-out or the end of the study. The mean time from inclusion until the end of the study was 4.8 years, ranging from 3.6 to 6.1 years.
- The secondary outcome was the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) which was used to assess symptoms and functional limitations prior to THR surgery or at the end of the study. The WOMAC was filled in at baseline and at the 4, 10, 16 and 29-month follow-ups.
- Data on exercise training sessions per week was collected at baseline and at 4 months, data on engagement in strength training and flexibility training was collected at 16 and 29 months, and data on physical therapy treatment was collected at 10, 16 and 29 months.
- Time to THR was reported as a median and 95% confidence intervals (CI). Hazard ratios (HR) and 95% CIs were calculated to describe the risk for joint replacement therapy between groups.
- Data were analyzed according to intent-to-treat principle.

Results:

- Baseline characteristics and outcome measures were similar in the two intervention groups and displayed no significant differences between the groups.
- The patients completed a median of 20 exercise sessions over the 12-week period, with 53% completing ≥20 exercise sessions.
- Data on whether THR had been performed were obtained from 102 patients. A total of 41 patients in the exercise therapy group and 30 patients in the control group completed the WOMAC questionnaire at the 29-month follow-up.
- A total of 22 (40%) patients in the exercise therapy group and 31(57%) patients in the control group went through THR within the 3.6 to 6.1 years follow-up period. Estimated median time to THR was 5.4 (CI 4.5 to 6.2) years in the exercise therapy group and 3.5 (CI 2.3 to 4.6) years in the control group. The cumulative 6-year survival of the native hip to THR was 41% in the exercise therapy group compared with 25% in the control group ($p=0.034$).

- Participating in both exercise therapy and patient education had a protective effect against THR compared with patient education alone (HR=0.56, CI 0.32 to 0.96, p=0.036). The risk for hip replacement surgery was significantly higher for patients in the patient education only group compared to the exercise therapy and patient education group.
- At baseline, mean minimum joint space was 1.5±0.9 mm in patients who went through THR compared with 2.5±1.0 mm in the patients who did not ($p<0.01$).
- Over the 29-month follow-up period, the exercise therapy group had significantly better WOMAC physical function scores compared with the control group (p=0.004), but the between-group differences in the WOMAC pain (p=0.083) and WOMAC stiffness (p=0.112) scores did not reach statistical significance.
- At baseline there were no significant differences between patients who went through THR and patients who did not in either WOMAC pain (p=0.967), WOMAC stiffness (p=0.333) or WOMAC physical function (p=0.092). The 53 patients who underwent THR before the end of study did have worse preoperative scores in all WOMAC subscales over the 29-month follow-up period compared with the patients who did not go through THR ($p<0.01$).
- The number of self-reported exercise sessions per week was similar in the two groups during the 29 month follow-up period.

Authors' conclusions:

- Participating in both exercise therapy and patient education resulted in significantly higher 6-year cumulative survival of the native hip from THR compared with patient education only. The cumulative survival of the native hip was higher in the exercise therapy group from 1 year and throughout the follow-up period.
- The findings in this explanatory study show that participating in a 12-week exercise therapy program in addition to patient education can reduce the need for THR by 44% or postpone surgery in patients with hip OA.
- In this study, the patients who went through THR had poorer scores in the WOMAC subscales for pain, stiffness and physical function before THR compared with the patients who did not undergo THR. This supports the assumption that the patients who undergo THR surgery have more severe symptoms and functional limitations. Also, the patients who went through THR had smaller minimum joint space at baseline, suggesting that this clinical parameter is also a determinant of THR.
- In this study, the exercise therapy group demonstrated better results in WOMAC physical function compared with the control group over the complete 29-month follow-up period (p=0.004). In contrast, the differences in WOMAC pain (p=0.083) and WOMAC stiffness (p=0.112) did not reach statistical significance. This may indicate that the lower rate and longer time to THR in the exercise therapy group are due to better hip function, with or without the presence of pain.
- Fifty-three per cent of the patients in the exercise therapy group completed ≥20 exercise sessions during the 12-week intervention period and were thus regarded as exercise compliant.
- The findings of this study are only applicable for patients with symptomatic and radiographic hip OA, with mild to moderate symptoms, and it must be recognized that

patients recruited to non-surgical trials may have a stronger desire to avoid surgery compared with the general OA population.
- The results of this study support the recommendations stating that exercise therapy should be offered to patients with hip OA as first-line treatment.

Comments:

- In an earlier study, Pisters found that 20% of patients underwent THR in the exercise therapy group compared with 45% in the usual care control group with hip OA. The risk for THR within 5 years was 2.87 (95% CI 1.1 to 7.3) times higher in the usual care control group compared to the exercise therapy group. The control group in this study had a 1.80 times higher risk of THR. The somewhat smaller protective effect of exercise in this study may be due to the patients having both symptomatic and radiographic evidence of hip OA, whereas in the Pisters study, radiographic evidence of hip OA was not part of the inclusion criteria.
- Since a significant number of patients with symptomatic and radiographic hip OA undergo THR sometime during their lifetime, and rates of THR have increased steadily during the past four decades, the results of this study showing that exercise therapy enhances the survival of the native hip from THR is therefore important for reducing healthcare consumption costs and for patients who may want to avoid surgery and its potential complications.
- One limitation of the study was that no measurement or log on the continuation of the exercise therapy program after the 12-week intervention period was obtained. Self-reported outcomes such as physical activity and exercise lack validity due to recall bias and overestimation of time, frequency and intensity, so this data should be interpreted with caution. Nonetheless, better adherence to exercises has been shown to improve long-term results and so having this data could aid in interpreting the results. This could introduce measurement error and underestimate the effect.
- Another limitation of the study was that the criteria for when THR surgery was indicated were not specified prior to the start of the study. The criteria used for THR at various institutions may differ and so the symptom state may differ at time of surgery. Preoperative assessment of THR patients was also not conducted, and this information could have helped elucidate the differences between THR patients and non-THR patients.
- There is a possible risk of introducing attention or performance bias in the patient education and exercise group, since they received 12 more interactions with a physical therapist than the patient education group. The beneficial therapeutic effects of the patient education and exercise group 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 patient education and exercise group.

Assessment*:*

- This adequate study provides some evidence that 12 weeks of supervised exercise therapy in addition to patient education results in better long-term cumulative survival of the

native hip from total hip replacement (THR) compared with patient education alone in patients with osteoarthritis (OA) of the hip.

Reference:

- Pisters MF, Veenhof C, Schellevis FG, and et al. Long-term effectiveness of exercise therapy in patients with osteoarthritis of the hip or knee: a randomized controlled trial comparing two different physical therapy interventions. Osteoarthritis and Cartilage 2010; 18:1019-1026.