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.

Critique author: Linda Metzger 6-3-15

Design: Randomized clinical trial

Objective: To determine if 12 weeks of behavioral graded activity (BGA) results in better long-term effectiveness (5 years after inclusion) than usual exercise therapy (UC; usual care) in patients with osteoarthritis (OA) of the hip or knee.

Population /sample size/setting:

- A total of 200 patients with OA of the hip or knee (154 females, 46 males, mean age 65 years, 97 patients in the BGA intervention group and 103 patients in the UC control group) were recruited by 87 participating physiotherapists from the region of Utrecht in the Netherlands and by articles about the study in local newspapers.
- Study design was a long-term follow-up study single blind cluster, randomized controlled trial.
- Inclusion criteria included OA of the hip or knee according to the clinical criteria of the American College of Rheumatology, and 50 to 80 years of age.
- Exclusion criteria included complaints in less than 10 out of 30 days; treatment for these complaints with exercise therapy in the preceding 6 months; indication for hip or knee replacement within 1 year; contraindication for exercise; inability to understand the Dutch language; and a low level of limitations in activities.

Methods/Interventions/Outcome Measures:

- Cluster randomization was performed at the level of the 72 participating physiotherapy practices. The participating practices were randomly assigned to one of the two treatment groups by means of a computer generated random sequence table. Allocation was concealed.
- Behavioral graded activity (BGA) is an exercise program/behavioral treatment integrating operant behavioral principles, self-regulation principles and additional booster sessions. BGA is an individually tailored exercise program in which patients' most problematic physical activities are gradually increased in a time-contingent way to improve impairments limiting the performance of these activities. The ultimate goal is integration of these exercises and activities in patients' daily living, so that patients get a more physically active lifestyle. The treatment period was 12-weeks with a maximum of 18 sessions, followed by 5 pre-set booster sessions in weeks 18, 25, 34, 42, and 55. After the 12-week treatment period, physiotherapists advised patients to maintain exercising and performing the activities at home. The additional booster sessions consisted of evaluating, motivating (stimulating exercise adherence) and repeating the main treatment message.

- The physical therapists in the UC control group treated the patients with hip and/or knee OA according to the Dutch physical therapy guideline which emphasizes information and advice, exercise therapy, and encouragement of a positive coping strategy. It recommends maintaining exercising at home after discharge. The treatment period was a maximum of 18 sessions within 12 weeks.
- Both BGA and UC were given individually by physical therapists in primary care trained on the allocated treatment.
- X-rays of the hip and/or knee were scored for each patient according to the Kellgren and Lawrence scale.
- Primary outcome measures were pain in the last 48 hours and physical function, both assessed using the WOMAC, and patient global assessment (PGA).
- Secondary outcome measures were patient-oriented physical function, physical performance, health care utilization, and the number of joint replacement surgeries.
- Assessments for all primary and secondary outcome measures took place at baseline before the exercise intervention, 3, 9, 15 and 60 months' follow-up performed by a researcher blinded to treatment assignment. The patients were instructed not to mention their allocation.
- Data were analyzed according to intent-to-treat principle.
- Estimated sample size was 200 patients total yielding a power of 80% to detect small to medium-sized effects (effect-size =0.2-0.4) in the outcome measures of pain and physical functioning, at two-sided significance level of 0.05 given a maximum loss to follow-up of 20%.

Results:

- Baseline characteristics and outcome measures of the groups displayed no significant differences between the groups, but the UC control may have consisted of patients with more severe OA. The UC control group consisted of a larger percentage (45% vs 35%) of patients with symptoms lasting greater than 5 years and a larger percentage of patients with moderate to severe OA for both the knee (61% vs 52%) and the hip (97% vs 86%).
- The 60 months' follow-up assessment was completed by 76 BGA patients and 73 UC patients (149 total).
- Fifty-five physical therapists treated the patients included in this study.
- At 60 months' follow-up, 35% of the UC patients and 28% of the BGA patients were still adherent to the recommended home exercises (OR = 0.69 [0.3-1.4]).
- In the long-term (60 months' follow-up), patients in both treatment groups improved on all primary outcome measures. The differences between treatment groups in pain (-0.18, 95% CI = -1.7-1.4), physical function (-1.92, 95% CI = - 6.5 to 2.6) and PGA (OR =0.67, CI = 0.3 to 1.4) were small and not statistically significant. Similar results were found on most secondary outcome measures at 60 months' follow-up.
- The only significant difference between treatment groups was that a greater percentage of the patients in the UC group (25 patients, 24.3%) underwent a joint replacement surgery during the study period compared to 14 (14.4%) patients in the BGA group. The risk for joint replacement surgery was significantly higher for patients treated with UC compared to BGA (hazard ratio = 2.10, 95% CI = 1.1- 4.1) and even more pronounced when the analysis included only patients with hip OA (hazard ratio = 2.87, 95% CI = 1.1- 7.3). No

differences were found in the risk for joint replacement surgery between treatment groups in patients with only knee OA (hazard ratio = 1.11, 95% CI = 0.4- 2.8).

Authors' conclusions:

- Both treatment groups showed beneficial effects in the long-term. No significant differences between treatment groups were found on the primary outcome measures of pain, physical function, and PGA at 5 years follow-up, as well as in patients with only hip OA or in patients with only knee OA.
- In patients with hip OA, BGA resulted in the long-term in less joint replacement surgeries than UC.
- In patients with hip OA, it is possible that the positive results of UC on pain and physical function at 15 and 60 months' follow-up were biased by a larger number of patients who underwent joint replacement surgery during the study period compared to the BGA group. The differences between groups would have been more in favor of BGA on all outcome measures, if the positive effects of joint replacement surgery in patients in the UC group could have been eliminated in the 9 to 60 months' follow-ups.
- The reduced risk for joint replacement surgery in BGA patients with hip OA may be due to the beneficial effects of BGA in the 3-9 months' time period on pain and physical function, and are thus large enough to postpone joint replacement surgery.
- The results of this study could be biased by the number of patients which were lost to follow-up, which was 26% at the long-term 5 year follow-up, but the non-response analysis showed similar baseline characteristics for responders and non-responders.
- More research is needed to confirm the study findings that indicate that BGA reduces the risk for joint replacement surgeries compared to UC in patients with hip OA.

Comments:

- It is interesting to note that the UC patients were more adherent to the recommended home exercises at the end of 5 years than the patients in the BGA group.
- This study lacked adequate power to detect any small to medium size between group differences. The lost to follow-up rate at 5 years' follow-up (26%) was higher than expected (20%) and only 149 patients were followed until 5 years' follow-up. This was smaller than the sample size of 160 required to detect a small to medium effect-size (0.2-0.4) in the outcome measures of pain and physical functioning.
- The greater number of joint replacements in the UC group may have been due to a larger number of patients in this group compared with the BGA group with severe OA at baseline. Even though no statistically significant differences were found between groups at baseline, slightly more patients in the UC group had a longer duration of OA symptoms and slightly more had moderate to severe OA based on radiological evidence.

Assessment*:*

- This adequate study provides some evidence that 12 weeks of behavioral graded activity does not result in better long-term effectiveness in reducing pain or improving function at 5 years than usual exercise therapy in patients with osteoarthritis (OA) of the hip or knee.