

**Vuorenmaa M, Ylinen, J, Piitulainen K, and et al. Efficacy of a 12-month, monitored home exercise programme compared with normal care commencing 2 months after total knee arthroplasty: a randomized controlled trial. J Rehabil Med 2014; 46:166–172.**

**Critique author:** Linda Metzger 5-22-15

**Design:** Randomized clinical trial

**Objective:** To evaluate the efficacy of a delayed, long-term 12-month home exercise program compared with normal care after primary total knee arthroplasty (TKA).

**Population /sample size/setting:**

- A total of 108 participants (66 females, mean age 69 years) recruited from a single hospital in Finland during TKA pre-op visits were randomized to a home-based exercise group (EG,  $n = 53$ ) or to a control group (CG,  $n = 55$ ).
- Study design was a randomized, assessor blinded, prospective controlled trial with a 12-month intervention and follow-up.
- Inclusion criteria included diagnosed knee OA, primary arthroplasty of the knee in question, and age over 18 years.
- Exclusion criteria included other surgery for the lower limbs planned to be performed within 12 months, dementia, fibromyalgia, other serious co-morbidities preventing active training, and difficulty visiting a physiotherapist due to a long travelling distance.

**Interventions/Methods:**

- The questionnaires and physical performance tests were undertaken 2 months after the TKA operation (baseline), at the time when the intervention started, and 12 months thereafter, i.e. 14 months after surgery. In addition the SF-36 and WOMAC questionnaires were completed at 6 months after baseline.
- All of the outcome measurements were obtained by two physiotherapists who were blinded to the treatment group assignment.
- All of the participants underwent cemented TKA.
- On the second day after the operations, all of the participants were allowed to perform full weight-bearing on the operated leg or as much as they could tolerate. On discharge from hospital after one week, the participants received a written exercise program, which included active and passive knee range of-motion exercises, knee flexor and extensor exercises, and hip abductor and extensor exercises in the standing position, using the weight of an extremity as resistance. Participants were instructed to perform these exercises 1–2 times per day, with 10–15 repetitions. The participants were also advised to be active, gradually increasing their walking distance over time.
- The participants randomized to the EG were given individual guidance at baseline (2 months post-operatively) and at 1 and 4 months thereafter by the same physiotherapist. At each visit, they received written information on the exercises and were instructed to keep a weekly exercise diary.

- At baseline (2 months post-operatively), the EG home exercise program was started and consisted of isometric strengthening exercises for the quadriceps and hamstrings muscles at multiple knee joint angles, performed in a sitting position. Repetitions were successively increased. At one-month (3 months post-operatively), the new exercise program included squats, hack squats with the back held against the wall, and step exercise with a 30 cm high gym bench. At the 4-month visit (6 months post-operatively), the progressions of all of the exercises were increased. Participants continued exercising 3 times per week.
- The CG did not receive any additional guidance after the baseline measurements, in accordance with normal care.
- Intention to treat (ITT) principles were followed for all analyses.
- The intended sample size was based on the primary outcome (WOMAC subscale for pain). Assuming a mean difference of 6 in change in WOMAC pain score between the groups at 12 months (SD 10), a sample size of 100 (50 in each group) was required to detect an effect size of 0.50 at alpha of 0.05 and power of 85%.

### **Main outcome measures/Results:**

- The primary outcome measurements were:
  - pain and functional disability, measured using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC);
- Secondary outcomes were;
  - health related quality of life (HRQoL), measured using the ShortForm-36 questionnaire (SF-36);
  - maximal walking speed;
  - isometric knee flexion muscle strength;
  - Timed Up and Go (TUG) test used to measure basic mobility
- The preoperative demographic and clinical characteristics of the groups displayed no differences between the groups, except that the duration of pain in the operated knee was longer in the CG.
- At baseline, outcome measurements did not differ between the groups.
- Within group analyses showed that in both groups, the mean changes in the WOMAC pain and function scores were statistically significant after 12 months. No significant differences between the groups for pain and function were found.
- Quality of life in both groups increased significantly, but no between group differences were found.
- Improvements in knee flexion strength and maximal walking speed were statistically significant different between the EG compared with the CG. The EG increased their knee flexion strength by 4.4 kg compared to 2.4 kg in the CG at the 12 month time point. The EG increased their walking speed by 0.32 meters/second compared to 0.17 meters/second in the CG at the 12 month time point. After adjustment for multiple comparisons, a statistically significant difference between the groups was found in maximal walking speed ( $p = 0.0064$ ).
- Both groups improved significantly in knee extension strength, TUG test time and the ROM of the operated knee, but no significant differences between the groups were found.

- During the first 6 months, 72% of the participants in the EG performed the home-based exercise sessions at least twice per week. From 6 to 12 months, the training diary data was not complete. At the 12-month questionnaire, 49% of the EG and 34% of the CG performed exercises at least once per week during the last month ( $p = 0.24$ ). The mean exercise frequency and time engaged in leisure-time physical activities was similar for both groups.
- In the EG, 5 participants discontinued the training due to pain during exercising. In addition, 5 discontinued training because they were satisfied with their painless knees and were no longer motivated to engage in training. All of these participants were included in the intention-to-treat analysis.

### **Authors' conclusions:**

- The long-term home exercise program in this study improved physical performance by increasing maximal walking speed and knee flexion strength significantly more in the EG compared with the CG.
- The results of this study show that a 12-month home-based exercise program starting 2 months after TKA, did not improve knee pain or decrease functional disability beyond the improvement achieved by usual care.
- Both groups showed marked improvements in self-reported pain, functional disability, and quality of life, but no differences were found between the groups. After the intervention, the WOMAC pain and functional disability scores decreased in both groups, but no between-group differences were observed, either at 6 or 12 months after baseline.
- Both groups in the study improved similarly in quality of life.
- The long-term home exercise program had a low cost and appeared to be well tolerated, as only 2 participants reported pain in the operated knee.
- According to the training diaries, during the first 6 months, 72% of the participants exercised at least twice per week, which is sufficient to increase strength. Over the second 6 months, training compliance declined, and the strength increase was consequently less than expected.
- Future trials should determine ways to increase exercise adherence.

### **Comments:**

- The primary outcome measures of pain and functional disability were clearly stated a priori.
- The strength of the study was the long training period (12 months), compared with many studies that use only 3–12 weeks. The study also had only a few drop-outs.
- The home-based exercise program had some positive effects on objectively measured physical performance which is related to function. Even though exercise compliance was sub-optimal, significant improvements in walking speed and knee flexion strength were observed.
- Despite the extended home exercise program not yielding greater improvements in WOMAC pain or quality of life, it did have some positive effects on physical performance. Faster maximal walking speed was found in the EG than in the CG. This

result was meaningful because walking is a basic human function, and limitations in walking increase the risk for disability and dependency.

- The home exercise program yielded greater knee flexion strength in the EG, compared with controls. Greater knee muscle strength and knee motion have been reported to have positive effects on balance and on the prevention of falling.
- A major limitation of the study was poor exercise compliance. According to the 12-month questionnaire responses, exercise compliance decreased considerably during the last month and probably during the last 6 months as well, since the training diaries were insufficiently completed during this period. This could introduce measurement error and underestimate the effect in the EG group.
- Implications from this study suggest that a home-based exercise program might require a larger number of booster contacts to promote better exercise adherence.
- Participants with pain might need effective therapies to abolish pain in order to increase their exercise compliance and to reduce drop-outs.
- The exercise program was suitable for use at home for most participants and was easy to implement in general practice.
- The study was adequately powered to detect significant differences.

#### **Assessment:**

- This adequate study provides some evidence that a long-term, 12-month home exercise program intervention is not more effective in reducing pain or improving function in patients after primary total knee arthroplasty than a control group receiving normal care, but is more effective in improving walking speed and knee flexion strength.