**Hennig T, Hæhre L, Hornburg VT, and et al. Effect of home-based hand exercises in women with hand osteoarthritis: a randomised controlled trial. Ann Rheum Dis 2015; 74: 1501–1508.**

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**Design:** Randomized controlled trial

**Objective:** To compare the effectiveness of home-based hand exercises plus hand osteoarthritis (HOA) information (exercise group) with HOA information only (control group) in improving functionality in women with HOA.

**Population /sample size/setting:**

* A total of 80 female patients (mean age 60.8 years) were recruited from the outpatient clinic at Martina Hansens Hospital in Bærum, Norway between February 2011 and December 2012.
* The 80 patients were randomly assigned to one of 2 groups: exercise group (n = 40) home-based hand exercises plus hand osteoarthritis (HOA) information or control group (n = 40) HOA information only.
* Inclusion criteria included female gender, HOA diagnosed by rheumatologists or orthopaedic surgeons according to the American College of Rheumatology criteria, age between 18 and 80 years, stable medication over the past 3 months, a minimum of 3 self-reported HOA-related activity limitations identified by patients in the Patient-Specific Functional Scale (PSFS), and ability to communicate in Norwegian.
* Exclusion criteria included hand surgery within the past 6 months, steroid injections within the past 2 weeks, impaired hand function due to trauma or diseases other than HOA, and cognitive or mental impairment.

**Methods/Interventions/Outcome Measures:**

* Study design was a randomized, controlled, single-blind study. A statistician not involved in the study made a computer generated randomization list with a block size of 10. Concealed, opaque envelopes were used to allocate patients to the exercise or control group. The envelopes were opened by the patient after baseline assessments and information about HOA were completed. Patients and the 2 occupational therapists (OTs) delivering the interventions were aware of the treatment assigned. To achieve observer blinding, patients were asked not to inform the outcomes assessor about their group allocation at the 3-month assessments.
* Baseline demographic data was collected regarding patient age, symptoms and disease duration, comorbidity, hand dominance and use of medication. All finger joints in both hands were examined by one of the OTs for the presence of pain on pressure, and for bony enlargements.
* All patients completed (baseline) testing and 3 month assessments for all the primary and secondary outcome measures. The primary outcome was change in activity performance measured after 3 months by the Patient-Specific Functional Scale (PSFS). Patients identified up to 5 activity limitations caused by their HOA and rated their performance of each activity on an 11-point scale (0–10, 0=unable to perform activity).
* Secondary outcome measures included measures of hand function, disease severity, symptoms, and number of responders to treatment. Fatigue, pain, stiffness and patient global assessment of disease activity were recorded on a numeric rating scale from 0 to 10, 0=no activity or symptoms. Maximum grip strength was measured in Newtons by the Grippit electronic instrument, and the grip size instrument was used to assess thumb web space. Joint mobility was recorded in all fingers and the thumb. The Functional Index for HOA (FIHOA) was used as a patient-reported outcome of activity performance.
* All participants received a leaflet and advice containing information about hand osteoarthritis (HOA) and ergonomic principles from the 2 OTs. Advice was given, suggesting rather than stopping certain activities, adjusting the way they are performed. Some suggestions for alternative working methods included using both hands, transferring weight from smaller to larger joints, using lighter equipment, using alternative hand grips, and balancing activity and rest.
* Participants in the exercise group also received a home-based hand exercise program from the OTs aimed at maximizing the stable and pain-free functional range of motion and flexibility of the finger joints, increasing grip strength, maintaining joint stability, and preventing or delaying development of fixed deformities. A rubber ball was used to provide resistance in the grip strengthening exercise, and rubber bands were used to provide resistance to the thumb exercise. Participants were instructed to perform 3 exercise sessions a week, with each exercise to be performed with 10 repetitions at the beginning and increasing if possible, to 15 repetitions for the rest of the 3-month exercise period. Adverse events, adherence to exercise, and pain after exercise were recorded by participants in a diary. In addition, exercise group participants received 8 follow-up calls from the occupational therapist during the 3-month study period to answer questions and discuss adherence and adjustment to the exercise program.
* Sample size power calculations were conducted and found that a sample size of 25 patients for each group was required to detect a difference of 2.2 points between groups with a significance level of 0.05 and a power of 80% with the expectation of a 20% loss to follow-up after 3 months. The minimal clinically important difference (MCID) in PSFS was estimated as 2.2 points. Due to uncertainties, 40 participants were included in each group.
* Intention-to-treat analysis was conducted and analysis of covariance was used to estimate treatment effects between the 2 groups.

**Results:**

* Of the 80 women randomized, 71 (89%) completed the 3-month follow-up assessment. Three patients in the exercise group and 6 patients in the control did not complete the study.
* Patients in the two groups did not differ in baseline characteristics with the exception that a significantly larger number of participants in the exercise group had nodal HOA.
* The participants in the exercise group reported a median number of exercise sessions of 37. Mean pain after exercises at the start of the study was 5.6 which decreased to 4.2 at the end of 3 months, yielding a mean difference in pain between weeks 1 and 13 of 1.4.
* After 3 months, there was a significant adjusted mean difference between groups in the PSFS total score of 1.4 points (95% CI 0.6 to 2.2) in favor of the exercise group. The effect size was 1.0. Thirteen participants in the exercise group reached a clinically relevant positive change of 2.2 (the MCID) in the PSFS total score compared to 2 participants in the control group. No participants in the exercise group reported a clinically relevant negative change compared to 2 participants in the control group.
* For the secondary outcomes, significant differences between the two groups in favor of the exercise group were found in joint pain, grip strength, thumb web space, fatigue, and in the functional index for HOA activity performance score.
* Significant improvements of within-group differences were found at the 3 month follow-up in the exercise group for joint pain, stiffness, functional index HOA scores, grip strength, and pain and thumb web space. Measurements of ROM remained stable.
* There were no significant improvements found in any of the outcome measures at the 3-month follow-up in the control group. Instead, there was a general trend towards deterioration, with a significant increase in flexion deficit in the right hand and a significant worsening of the functional index HOA score.
* The only adverse event reported was that one patient withdrew from the trial after 9 weeks owing to high and sustained pain.

**Authors’ conclusions:**

* The results of this study demonstrated that hand exercises significantly improved activity performance, fatigue and joint pain, grip strength, and thumb web space in women with HOA. The control group did not demonstrate any significant improvements in any of the outcome measures, but rather a trend towards deterioration with a significant increase in flexion deficit in the right hand.
* In summary, an evidence-based, low-cost hand-exercise program was well tolerated and significantly improved activity performance, grip strength, fatigue and pain in women with HOA.
* These findings are in line with The European League Against Rheumatism (EULAR) recommendations that patients with HOA should receive an exercise regimen that includes both ROM and strengthening exercises, as ROM exercises seem to be important in helping to maintain joint mobility and thumb web space, while strengthening exercises maintain joint stability and increase grip strength.
* Thirteen participants in the exercise group reached a clinically relevant positive change of 2.2 (the MCID) in the PSFS total score compared to 2 participants in the control group. The intervention was delivered in a short time at low cost. This cheap and effective program should therefore be considered for inclusion in the standard care for people with HOA.
* There was a considerable increase in grip strength in the exercise group in this study, which might be one factor explaining the significant effect on activity.
* The results from this study show that even if participants reported considerable pain after exercising, this pain decreased significantly during the study period, and general joint pain improved. The high adherence to the program also indicates that the exercise program was safe and well tolerated.
* The PSFS was selected as the primary outcome, because it is not only a measure of function, but includes a broadened concept of function that includes measures of the activities most relevant to patients.

**Comments:**

* The difference between groups in the primary outcome of activity performance was 1.4 points in the PSFS, not quite meeting the original MCID of 2.2 points in the PSFS total score. However, the confidence intervals did include the MCID (95% CI 0.6 to 2.2). This difference did meet the more recent post-study MCID estimate of 1.2 points. Together with the significant effects on pain and activity as measured by the functional index HOA, and the large effect size of 1.0, these results show that hand exercises do lead to clinically important functional improvements.
* The selection and monitoring of exercises in the program was done according to recent research and recommendations. The distinct and positive effectiveness of the program may be attributed to the combination of not only the evidence-based exercise program, but the close phone follow-up and monitoring during the study period. The control group did not receive the additional phone call follow-ups and monitoring during the study period, and this extra attention received by the exercise group could definitely contribute to the positive effectiveness of this group’s well-monitored exercise program, as well as to co-intervention bias. It is not known if either the exercise program or the follow-up monitoring or both contributed to the improvement in the exercise group.
* Strengths of the study were the inclusion of an accurate power calculation and sample size determination. The study had sufficient power to detect clinically relevant differences produced by hand exercising.
* One strength of the study included the analysis of covariance which adjusted for baseline imbalances. Additional strengths include the follow-up monitoring in the exercise group, adherence diaries to monitor exercise compliance, primary outcome clearly designated, trial registration, and blinding of outcome assessors.
* Since the OTs delivering the interventions could not be blinded, there is potential for performance bias to be present.
* One limitation of the study is that the sample is not representative of all patients with HOA. The results of this study can only be extrapolated to women with HOA.
* Future studies on exercise and HOA should include men and examine the long-term effectiveness of an exercise program for HOA.

**Assessment*:***

This adequate study provides some evidence that home-based hand exercises with phone call follow-up and monitoring plus hand osteoarthritis (HOA) information is more effective than only giving HOA information in improving hand functionality in women with HOA.