

Cleland JA, Mintken PE, et al. Manual physical therapy and exercise versus supervised home exercise in the management of patients with inversion ankle sprain: a multicenter randomized clinical trial. J Orthop Sports Phys Ther. 2013;43(7):443-55.

Design: randomized clinical trial

Purpose of study: to compare the effectiveness of manual therapy and exercise (MTEX) to a home exercise program (HEP) in the management of individuals with acute inversion ankle sprains.

Population/sample size/setting:

- 74 patients (36 women, 38 men, mean age 35) treated for acute inversion ankle sprains at 4 physical therapy clinics in the United States including Denver, Boulder, and Aurora
- Eligibility criteria were age between 16 and 60 with current symptoms from a grade 1 or grade 2 inversion ankle sprain, with a pain score of 3/10 or more and ruling out a fracture using the Ottawa rules
- Exclusion criteria were tumor, fracture, rheumatoid arthritis, prolonged steroid use, severe vascular disease, and osteoporosis; other exclusions were prior surgery of the distal tibia, the fibula, ankle joint, or rearfoot region

Interventions:

- Patients were randomized to either MTEX (n=37) or to HEP (n=37)
- HEP group had 4 weekly sessions of 30 minute duration with a physical therapist for a total of 4 sessions in which the patient was first taught mobilization and strengthening exercises with resistive bands, body weight resistance exercises, one-leg standing activities, standing on a balance board, and weight-bearing functional activities
 - o These exercises were taught on the first session and the subsequent three sessions were used for instruction on exercise progression
- MTEX group had twice weekly sessions of 30 minute duration for a total of 8 sessions in which a physical therapist delivered manual interventions focused on the proximal tibiofibular joint, the distal tibiofibular joint, the talocrural joint, and the subtalar joint
 - o The MTEX group began the same exercises that the HEP group was taught, and also had instruction in two self-mobilization techniques to use at home
- All patients had advice on how to stay active and how to use ice, compression, and elevation of the ankle, and were instructed to continue with strengthening and balance activities at the end of therapy

Outcomes:

- Outcomes were measured at the end of treatment (4 weeks) and again at 6 months
- Primary outcome was the activities of daily living (ADL) subscale of the Foot and Ankle Ability Measure (FAAM)
 - o Secondary outcome included the FAAM sports subscale, the Lower Extremity Functional Scale (LEFS), and pain on the 0-10 point numeric pain rating scale (NPRS)
 - o The ADL subscale has 21 items which the patient rates for the degree of difficulty in performing; higher scores indicate higher levels of function
 - The minimal clinically important difference (MCID) is considered to be 8 percentage points for the ADL subscale and 9 points for the sports subscale
- Both groups had improvements over baseline at the 4 week and 6 month followups
 - o The average improvement of the FAAM ADL scores for the HEP group was 9.6% at 4 weeks and was 24.6% at 6 months; the improvements for the MTEX group were 21.3 and 30.3% respectively
- The overall analysis favored the MTEX group over the HEP group
 - o At 4 weeks, the difference on the FAAM ADL subscale between MTEX and HEP was 11.7 % with 95% confidence interval from 7.4 to 16.1%
 - o At 6 months, the difference between MTEX and HEP was 6.2% with 95% CI from 0.98 to 11.5%
 - o The secondary outcomes also generally favored MTEX over HEP
- No adverse events were reported in either group
- Recurrent ankle sprain was reported in 3 MTEX and 5 HEP patients, a statistically nonsignificant difference

Authors' conclusions:

- The MTEX group had greater improvement in pain and function over the HEP group at 4 weeks and at 6 months
- Although the difference between MTEX and HEP did not exceed the MCID at the 6 month followup, the MCID over baseline was exceeded at both 4 week and 6 month time points
- In the absence of a no treatment control group, it cannot be determined what percentage of the improvement was due to the natural history of ankle sprains and how much was a placebo response
- The MTEX group had twice the contact time with physical therapists as the HEP group, which in itself could have contributed to the difference between groups; the power of touch also could have been a contributing factor apart from the specific effects of the manual techniques employed

Comments:

- The description of the interventions and the overall conduct of the study are clear and reproducible, and the authors' discussion point out one source of the observed group difference which could be separate from the effect of manual techniques, namely, the additional time spent with the physical therapists
- In a condition like ankle sprain in which the expected clinical course is one of improvement over time, it is also expected that the difference between intervention groups will decrease over time, and the MCID between groups observed at 4 weeks should not be expected to be of equal magnitude at 6 months
- Few recurrent sprains occurred, and the observed differences between the 3 recurrences in the MTEX and the 5 in the HEP group is of uncertain significance

Assessment: Adequate for some evidence that a 4 week program of twice weekly manual physical therapy plus home exercise provides benefits in addition to the benefits of home exercise alone at the end of treatment, but that these differences decrease over a 6 month period as the natural history of ankle sprains begins to resolve