

JOSHUA A. CLELAND, PT, PhD<sup>1</sup> • PAUL MINTKEN, DPT<sup>2,3</sup> • AMY MCDEVITT, DPT<sup>2</sup> • MELANIE BIENIEK, DPT<sup>4</sup>  
KRISTIN CARPENTER, DPT<sup>5</sup> • KATHERINE KULP, DPT<sup>6</sup> • JULIE M. WHITMAN, PT, DSc<sup>7</sup>

# Manual Physical Therapy and Exercise Versus Supervised Home Exercise in the Management of Patients With Inversion Ankle Sprain: A Multicenter Randomized Clinical Trial

● **STUDY DESIGN:** Randomized clinical trial.

● **OBJECTIVE:** To compare the effectiveness of manual therapy and exercise (MTEX) to a home exercise program (HEP) in the management of individuals with an inversion ankle sprain.

● **BACKGROUND:** An in-clinic exercise program has been found to yield similar outcomes as an HEP for individuals with an inversion ankle sprain. However, no studies have compared an MTEX approach to an HEP.

● **METHODS:** Patients with an inversion ankle sprain completed the Foot and Ankle Ability Measure (FAAM) activities of daily living subscale, the FAAM sports subscale, the Lower Extremity Functional Scale, and the numeric pain rating scale. Patients were randomly assigned to either an MTEX or an HEP treatment group. Outcomes were collected at baseline, 4 weeks, and 6 months. The primary aim (effects of treatment on pain and disability) was examined with a mixed-model analysis of variance. The hypothesis of interest was the 2-way interaction (group by time).

● **RESULTS:** Seventy-four patients (mean  $\pm$  SD age, 35.1  $\pm$  11.0 years; 48.6% female) were randomized into the MTEX group ( $n = 37$ ) or the HEP group ( $n = 37$ ). The overall group-by-time interaction for the mixed-model analysis of variance was statistically significant for the FAAM activities of daily living subscale ( $P < .001$ ), FAAM sports subscale ( $P < .001$ ), Lower Extremity Functional Scale ( $P < .001$ ), and pain ( $P \leq .001$ ). Improvements in all functional outcome measures and pain were significantly greater at both the 4-week and 6-month follow-up periods in favor of the MTEX group.

● **CONCLUSION:** The results suggest that an MTEX approach is superior to an HEP in the treatment of inversion ankle sprains. Registered at [clinicaltrials.gov](http://clinicaltrials.gov) (NCT00797368).

● **LEVEL OF EVIDENCE:** Therapy, level 1b-. *J Orthop Sports Phys Ther* 2013;43(7):443-455. Epub 29 April 2013. doi:10.2519/jospt.2013.4792

● **KEY WORDS:** manipulation, mobilization



Inversion ankle sprains are common among physically active people, with an annual incidence of 7 ankle sprain injuries per 1000 people.<sup>1,10,23,42,49,55,63</sup>

These injuries often occur as a result of landing on a plantar flexed and inverted foot.<sup>33</sup> The foot twists medially in relation to the externally rotated tibia, often causing injury to the lateral ligaments of the ankle.<sup>1</sup> This injury can occur during sports, running on uneven surfaces, and landing on an unbalanced foot after jumping.<sup>33</sup> Most patients who have sustained

<sup>1</sup>Department of Physical Therapy, Franklin Pierce University, Concord, NH; Rehabilitation Services, Concord Hospital, Concord, NH; Manual Physical Therapy Fellowship Program, Regis University, Denver, CO. <sup>2</sup>Physical Therapy Program, School of Medicine, University of Colorado-Denver, Aurora, CO. <sup>3</sup>Wardenburg Health Center, University of Colorado-Boulder, Boulder, CO. <sup>4</sup>Rehabilitation Services, Concord Hospital, Epsom, NH. <sup>5</sup>Waldron's Peak Physical Therapy, Boulder, CO. <sup>6</sup>Children's Hospital Colorado, Aurora, CO; Functional Physical Therapy, Denver, CO. <sup>7</sup>Orthopedic Manual Physical Therapy Program and Musculoskeletal Management Program, Evidence in Motion, Louisville, KY. This study was approved by the following Institutional Review Boards: Concord Hospital, Concord, NH; the Colorado Multiple Institutional Review Board, Aurora, CO; and the University of Colorado-Boulder, Boulder, CO. The American Academy of Orthopaedic Manual Physical Therapists Orthopaedic Physical Therapy Products Grant provided funding for this project. This organization played no role in the design, conduct, or reporting of the study or in the decision to submit the manuscript for publication. The authors certify that they have no affiliations with or financial involvement in any organization or entity with a direct financial interest in the subject matter or materials discussed in the article. Address correspondence to Dr Joshua A. Cleland, Department of Physical Therapy, Franklin Pierce University, 5 Chenell Drive, Concord, NH 03301. E-mail: [joshcleland@comcast.net](mailto:joshcleland@comcast.net) ● Copyright ©2013 *Journal of Orthopaedic & Sports Physical Therapy*®

an inversion ankle sprain respond well to conservative management; however, some individuals continue to experience pain and persistent disability at long-term follow-up.<sup>18,28</sup> In a general population of patients with an inversion ankle sprain presenting to primary care, Braun<sup>9</sup> found that 72% reported persistent symptoms at the 6-month follow-up. Additionally, it has been estimated that the reinjury rate following an inversion ankle sprain may be as high as 80%, suggesting the need to identify the most effective management strategies for this condition.<sup>56</sup>

It has been suggested that patients with recurrent inversion ankle sprains frequently demonstrate dysfunction at the proximal tibiofibular,<sup>3,31</sup> distal tibiofibular,<sup>34</sup> talocrural,<sup>17</sup> or subtalar joint.<sup>30</sup> In addition, individuals with a history of an inversion ankle sprain may exhibit deficits in strength of the ankle inverters and increased sway with single-leg stance tested on a stable (eyes closed) or unstable surface.<sup>32</sup> Addressing impairments of the foot and ankle region in patients with inversion ankle sprains may lead to improved pain and function. It has been demonstrated that following an inversion ankle sprain, manual therapy techniques (both thrust and nonthrust mobilization/manipulation) may be beneficial in restoring or improving ankle dorsiflexion,<sup>3,13,15,29,51,59</sup> posterior talar glide,<sup>59</sup> stride speed and step length,<sup>29</sup> distribution of forces through the foot,<sup>41</sup> and pain.<sup>14</sup> Only a few clinical trials have investigated the impact of manual therapy on improving function in a population of patients with inversion ankle sprain.<sup>3,14,51</sup> Among them, Pellow and Brantingham<sup>51</sup> demonstrated that 8 sessions of thrust manipulation resulted in greater improvements in function, as measured with a functional evaluation scoring scale, at a 1-month follow-up compared to placebo ultrasound. In a recent systematic review, Brantingham et al<sup>8</sup> concluded that limited evidence exists for manual therapy plus exercise to improve outcomes in the short term in this population. However, we were unable to identify studies report-

ing long-term outcomes.

In a recent study,<sup>62</sup> a clinical prediction rule was developed to identify patients who had sustained an inversion ankle sprain and were likely to benefit from manual therapy and exercise (MTEX) directed at the distal lower extremity. Consecutive patients with inversion ankle sprain underwent a standardized examination, followed by an intervention consisting of manual therapy, which included both thrust and nonthrust manipulation and general mobility exercises. In that study, 64 of 85 patients (75%) met the threshold for successful outcome.<sup>62</sup> It has been suggested that with a high pretreatment probability of success (75%) and a low chance of harm, therapists should consider utilizing the respective treatment approach, and a clinical prediction rule is not needed to guide clinical decision making.<sup>27</sup>

In the previously published clinical prediction rule derivation study,<sup>62</sup> only gentle ankle mobility exercises were used. Although evidence supports the use of general range-of-motion exercises in patients with an inversion ankle sprain,<sup>18,19,22,40</sup> a more comprehensive exercise program that includes strengthening and proprioceptive retraining may further enhance the treatment effect.<sup>61</sup> The authors of a recent systematic review<sup>52</sup> reported a significant improvement in functional outcomes and reductions in the subjective report of instability following proprioceptive training in patients with ankle ligament injury. Other systematic reviews have concluded that there is moderate evidence that neuromuscular training results in improved function and decreased reinjury rates in patients with inversion ankle sprains.<sup>7,20</sup> In a randomized clinical trial utilizing a progressive exercise regimen, Bassett and Prapavessis<sup>2</sup> concluded that a supervised home-based exercise program resulted in outcomes similar to those of 8 sessions of in-clinic management. However, the authors did not incorporate any form of manual therapy into their in-clinic management approach, which consisted

solely of exercise. Hence, data are insufficient to determine if a combined MTEX program is superior to a home exercise program (HEP) in the management of inversion ankle sprains both in the short and long term. The purpose of this multicenter randomized clinical trial was to investigate the effects of MTEX compared to an HEP for the management of patients with inversion ankle sprain.

## METHODS

**O**VER A 30-MONTH PERIOD (JANUARY 2010-June 2012), consecutive patients with inversion ankle sprain presenting at any of 4 physical therapy clinics (Rehabilitation Services, Concord Hospital, Concord, NH; Wardenburg Health Center, University of Colorado-Boulder, Boulder, CO; Anschutz Medical Campus, University of Colorado-Denver, Aurora, CO; and Waldron's Peak Physical Therapy, Boulder, CO) were screened for eligibility criteria to participate in this multicenter clinical trial. To be eligible to participate, patients had to present with current symptoms (the number of days since injury was not restricted) associated with a grade 1 or grade 2 inversion ankle sprain, as defined by the West Point Ankle Sprain Grading System,<sup>28,33</sup> to be between the ages of 16 and 60 years, to have a numeric pain rating scale (NPRS) score greater than 3/10 in the last week, and to have a negative result from the Ottawa ankle rules.<sup>57</sup> Patients were excluded if they exhibited contraindications to manual therapy, as noted in the patient's medical screening questionnaire (eg, tumor, fracture, rheumatoid arthritis, osteoporosis, prolonged history of steroid use, or severe vascular disease). Other exclusions included prior surgery to the distal tibia, fibula, ankle joint, or rearfoot region (proximal to the base of the metatarsals); fracture; other absolute contraindications to manual therapy; insufficient English-language skills to complete all questionnaires; or inability to comply with the treatment and follow-up schedule. The study was approved by

the Institutional Review Boards of the following institutions: Concord Hospital, Concord, NH; the Colorado Multiple Institutional Review Board, Aurora, CO; and the University of Colorado-Boulder, Boulder, CO. All patients provided informed consent prior to their enrollment in the study. This trial was registered at [clinicaltrials.gov](http://clinicaltrials.gov) (NCT00797368).

### Therapists

Seven physical therapists (mean  $\pm$  SD age, 42.7  $\pm$  15.4 years) participated in the recruitment, examination, and treatment of the patients in this study. All participating therapists were provided with a detailed manual of standard operations and procedures that outlined all the study procedures, and were trained in the study procedures by 1 of the investigators (J.A.C. and P.M.) who were orthopaedic clinical specialists and fellows of the American Academy of Orthopaedic Manual Physical Therapists. The training session included instruction in the administrative aspects of the study (informed consent, subject recruitment, etc) and specific training in the performance of the examination and treatment procedures, including the manual physical therapy techniques and the exercise program. The purpose of the training was to ensure that the examination and treatment procedures were performed in a standardized fashion across the 4 data-collection sites. Participating therapists had a mean  $\pm$  SD of 17  $\pm$  15 years (range, 1-40 years) of clinical experience in the outpatient orthopaedic physical therapy setting. Of the 7 physical therapists, 4 (57%) were orthopaedic certified specialists and 3 (43%) were fellows of the American Academy of Orthopaedic Manual Physical Therapists. It was not possible to blind the treating therapists to the patients' treatment group assignment due to the nature of the interventions provided.

### Outcome Measures

After signing informed consent forms, all patients provided a history, underwent a physical examination, and com-

pleted a number of self-report measures at baseline. The historical items included questions pertaining to the onset of symptoms, the distribution of symptoms, aggravating and easing postures, mechanism of injury, prior treatments, and prior history of ankle pain. The physical examination consisted of items routinely used in the physical therapy examination of the lower extremity and included observation of posture, range-of-motion and joint mobility assessment, and the performance of provocation tests. The physical examination items were used to further determine if any contraindications to manual therapy were present and to determine the rigor with which manual therapy techniques would be delivered.

The primary outcome measure was the Foot and Ankle Ability Measure (FAAM) activities of daily living (ADL) subscale.<sup>45</sup> Secondary outcome measures included the FAAM sports subscale,<sup>45</sup> the Lower Extremity Functional Scale (LEFS),<sup>6</sup> and the NPRS.<sup>38</sup> Patients completed all outcome measures at baseline and at 4-week and 6-month follow-up periods. The FAAM<sup>45</sup> is a region-specific, self-report questionnaire with 2 subscales. The ADL subscale consists of 21 questions, each with a Likert response scale ranging from 4 (no difficulty) to 0 (unable to do the activity). Individuals can also mark "N/A" in response to any of the activities listed. Items marked N/A are not scored. The scores for all items are added together. The number of questions with a response is multiplied by 4 to get the highest potential score. If all questions are answered, the highest possible score is 84; if 1 question is not answered, the highest possible score is 80; if 2 questions are not answered, the highest possible score is 76, etc. The total score for the items is divided by the highest possible score and multiplied by 100 to obtain a percentage. Higher scores indicate higher levels of function.<sup>45</sup> The sports subscale is scored separately (highest possible number of points is 28) using the same method as that described for the ADL subscale. Both the FAAM ADL and

FAAM sports subscales have been shown to exhibit excellent test-retest reliability and validity when compared to the Medical Outcomes Study 36-Item Short Form Health Survey physical functioning subscale in individuals with leg, ankle, and foot disorders.<sup>45</sup> The minimal clinically important difference (MCID) for the FAAM ADL subscale is 8 percentage points (0%-100% scale) and for the sports subscale is 9 percentage points (0%-100% scale).<sup>45</sup>

The LEFS consists of 20 questions, and the highest possible score is 80.<sup>6</sup> Higher scores indicate greater levels of function. The LEFS has been shown to have excellent validity, test-retest reliability, and responsiveness to change in patients with lower extremity disorders,<sup>6,44,60</sup> and to have an MCID of 9 points.<sup>6</sup>

An 11-point NPRS was used to measure pain intensity. The scale is anchored on the left by 0 as "no pain" and on the right by 10 as "worst imaginable pain." The NPRS has been shown to be reliable and valid.<sup>21,36-39,53</sup> Patients rated their current level of pain and their worst and least amount of pain in the previous 24 hours. The average of the 3 ratings was used to represent the patient's level of pain. The NPRS has been shown to be reliable and valid in patients with low back pain<sup>11</sup> and neck pain.<sup>12</sup> However, this has yet to be examined in a population with inversion ankle sprains. The MCID for the NPRS has been reported to be 2 points.<sup>24</sup>

In addition to the aforementioned self-report measures, patients also completed a 15-point global rating of change (GRC) scale at the 4-week and 6-month follow-up periods. The GRC scale, originally described by Jaeschke et al,<sup>35</sup> was completed by each patient to rate their own perception of improved ankle function. The scale ranges from -7 ("a very great deal worse") to 0 ("about the same") to +7 ("a very great deal better"). Intermittent descriptors of worsening or improving are assigned values from -1 to -6 and +1 to +6, respectively. At the 6-month follow-up, patients were also asked if they

experienced a recurrence of their inversion ankle sprain since the time of their enrollment in the study. In an attempt to ascertain adherence to their HEP, patients were also asked, “What percentage of the time did you complete your home exercise program?”

## Randomization

Once the baseline assessment was completed, patients were randomly assigned to receive either MTEX or an HEP. Concealed allocation to treatment group was performed by an individual not involved in subject recruitment, using a computer-generated randomized table of numbers created for each participating site prior to the beginning of the study. The group assignment was recorded on an index card. This card was folded in half such that the label with the patient’s group assignment was on the inside of the fold. The folded index card was then placed inside the envelope, and the envelope was sealed. A second therapist, blinded to the baseline examination findings, opened the envelope and proceeded with treatment according to the group assignment. All patients received treatment on the day of the collection of baseline measurements and enrollment in the study.

## Interventions

Patients in the HEP group were seen by a physical therapist for 4 sessions (1 per week) focusing on progression of the exercise regimen. Patients in the MTEX group were treated by a physical therapist twice weekly for 4 weeks, for a total of 8 therapy sessions. Each treatment session lasted 30 minutes for both treatment groups. Both groups received advice to stay active, as well as education on ice, compression, and elevation. Due to the nature of the interventions, it was not possible to blind the patients to group assignment.

**HEP Group** Patients attended physical therapy for 4 sessions for instruction and progression of exercise. The first instruction occurred on the day of enrollment in the trial and was based on the status of

the patient and clinical decision making of the therapist. Patients returned to the clinic once a week for the next 3 weeks for instruction on exercise progression. On the first day of treatment, the patient began mobilizing and strengthening exercises based on patient status and tolerance, as described by Bassett and Prapavessis,<sup>2</sup> which included the following: mobilizing exercises for the foot and ankle, gentle strengthening exercises, resistive-band exercises, body-weight resistance exercises, 1-leg standing activities, standing on balance board, and weight-bearing functional activities. Specific details regarding exercises and indicators for progression are provided in **APPENDIX A**.

The exercise progression was based on feedback from the patient and the clinical decision making of the therapist. Patients in this group were asked to perform the above exercise regimen at home once daily for the duration of the study. Patients were also instructed to continue normal activities that do not increase symptoms, and to avoid activities that aggravate symptoms. At each visit with a physical therapist, patients were asked if they had experienced any adverse events from the exercise program. At the fourth and final visit (week 4), patients were instructed to continue with strengthening and balance activities.

**MTEX Group** At each session, the physical therapist delivered manual physical therapy interventions that were originally used in a prospective cohort study by Whitman et al.<sup>62</sup> The following descriptions of the manipulations are consistent with the model proposed by Mintken et al<sup>48</sup>:

- Proximal tibiofibular joint: high-velocity, end-range anterior force to the head of the fibula on the tibia through end-range flexion and external rotation of the knee in a supine position.
- Distal tibiofibular joint: low-velocity, mid- to end-range anterior-to-posterior oscillatory force to the distal fibula and/or tibia in a supine position, with slight ankle plantar flexion.
- Talocrural and subtalar joints: high-

velocity, end-range longitudinal traction force to the dorsum of the foot on the lower leg in a supine position, with ankle dorsiflexion and eversion. Low-velocity, mid- to end-range anterior-to-posterior oscillatory force to the talus on the distal tibiofibular joint in a supine position, with varying amounts of ankle dorsiflexion. Low-velocity, mid- to end-range medial-to-lateral oscillatory force to the medial side of the talus (or calcaneus) on the lower leg in a left sidelying position. Low-velocity, end-range anterior-to-posterior sustained glide to the talus in a weight-bearing position, with active ankle dorsiflexion and knee flexion in an on/off fashion.

These techniques are described in detail in **APPENDIX B**. The goal of the low-velocity manual physical therapy interventions was for the clinician to perform grades III to IV, as described by Maitland et al,<sup>43</sup> for five 30-second bouts. However, the therapist was allowed to modify the grade of manual therapy (I-IV) to maximize patient comfort with the technique.

On the first day of treatment, the patients began the exact same mobilizing and strengthening exercises, as described by Bassett and Prapavessis,<sup>2</sup> that the HEP group received (**APPENDIX A**). The exercise progression was based on feedback from the patient and the clinical decision making of the therapist. Patients in this group were asked to perform the above exercise regimen at home once daily for the duration of the study. Patients in this group were also instructed to perform 2 self-mobilization techniques at home (ankle eversion self-mobilization and weight-bearing dorsiflexion self-mobilization), as described by Whitman et al.<sup>62</sup> Patients were also instructed to do all activities that did not increase symptoms and to avoid activities that aggravated symptoms. At each therapy session with a physical therapist, patients were asked if they had experienced any adverse events from the exercise program or manual physical therapy interventions. Upon discharge from therapy, all patients were



instructed to continue with strengthening and balance activities.

### Follow-up

At the final physical therapy session (4-week follow-up) and at the 6-month follow-up, patients in both groups completed the FAAM ADL, FAAM sports, LEFS, NPRS, and GRC. Self-report questionnaires were administered at the 4-week follow-up by an individual who was blind to group assignment, and were mailed to the subjects at the 6-month follow-up.

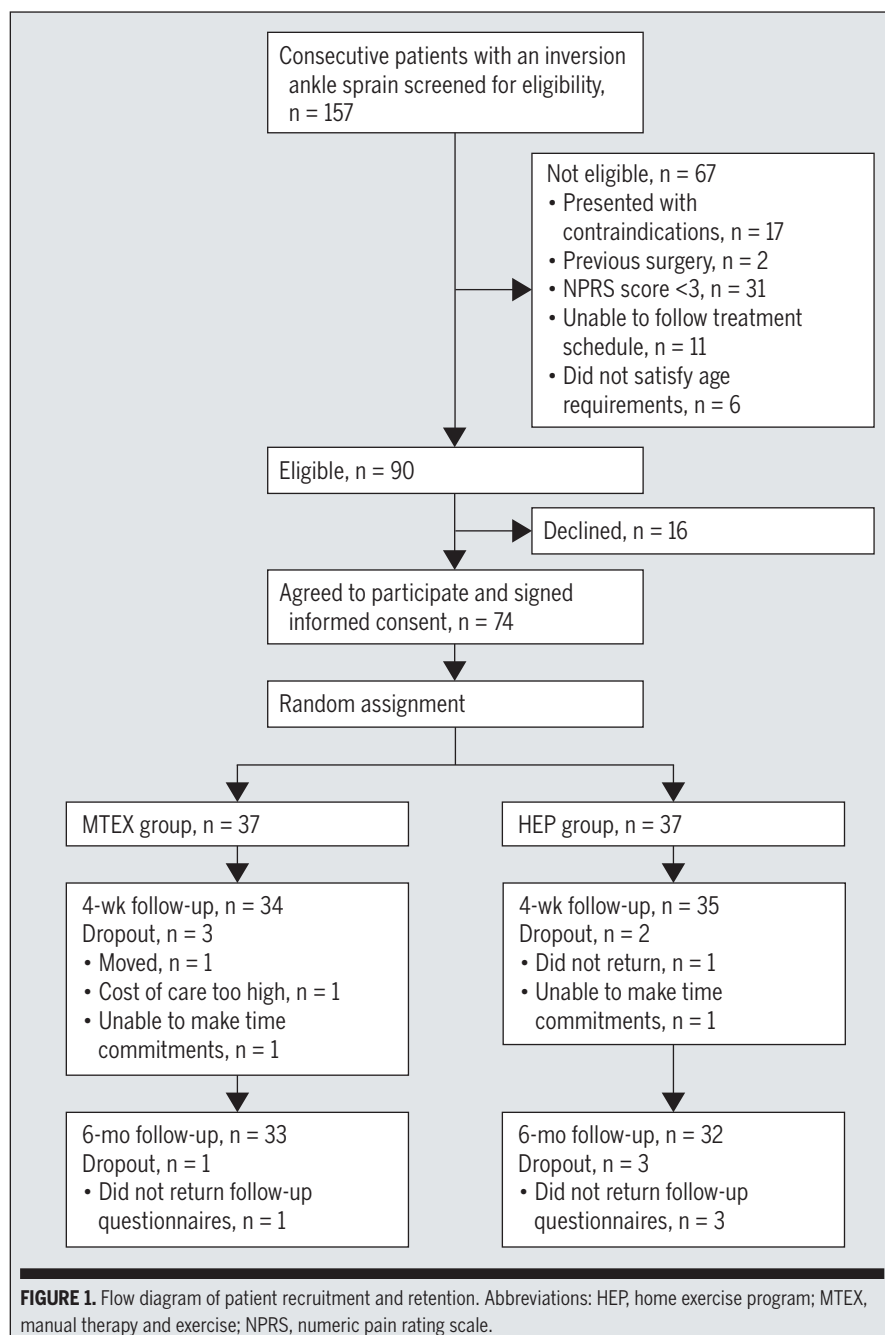
### Sample Size

The calculations were based on detecting an 8% difference in the FAAM ADL at the 4-week follow-up, assuming a standard deviation of 11%, a 2-tailed test, and an alpha level equal to .05 and 80% power. This generated a sample size of 32 patients per group. Allowing for a conservative dropout rate of approximately 15%, we recruited 74 patients into the study.

### Data Analysis

Descriptive statistics, including measures of central tendency and dispersion, were calculated for baseline demographic data. Frequency distributions were estimated for categorical data. Baseline demographic data were compared between treatment groups using independent *t* tests for continuous data and chi-square tests of independence for categorical data to assess the adequacy of the randomization. Patients were also categorized according to their stages of injury as follows: acute, less than 6 weeks' duration; subacute, 6 to 12 weeks' duration; chronic, greater than 12 weeks' duration.

The primary aim, the effects of treatment on disability and pain, was examined with a 2-by-3 mixed-model analysis of variance (ANOVA), with treatment group (MTEX versus HEP) as the between-subject factor and time (baseline, 4-week follow-up, 6-month follow-up) as the within-subject factor. Separate ANOVAs were performed with the FAAM ADL, FAAM sports, LEFS, and NPRS as



**FIGURE 1.** Flow diagram of patient recruitment and retention. Abbreviations: HEP, home exercise program; MTEX, manual therapy and exercise; NPRS, numeric pain rating scale.

the dependent variable. For each ANOVA, the hypothesis of interest was the 2-way group-by-time interaction. To determine if missing data points associated with dropouts were missing at random or missing for systematic reasons, we performed the Little missing completely at random test.<sup>54</sup> Intention-to-treat analysis was performed by using expectation

maximization, whereby missing data are computed using regression equations.<sup>54</sup> Planned pairwise comparisons were performed examining the difference between baseline and follow-up periods, using the Bonferroni equality at an alpha level of .05. A Mann-Whitney *U* test was used to determine a difference in the GRC between groups at the 4-week and 6-month

follow-up periods. An independent *t* test was used to determine if a difference existed between groups for adherence to the exercise regimen, and a chi-square analysis was used to examine the number of recurrences between groups. The alpha level for all analyses was a priori established at .05 using a 2-tailed test. Data analyses were performed using the SPSS Version 20.0 statistical software package (SPSS Inc, Chicago, IL).

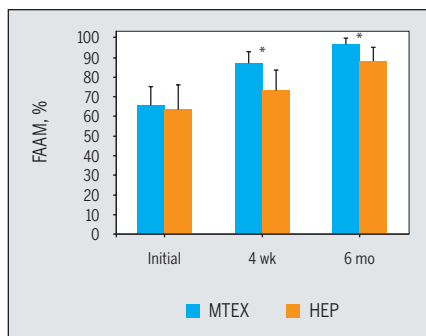
## RESULTS

**O**NE HUNDRED FIFTY-SEVEN patients with inversion ankle sprain were screened for eligibility to participate in this clinical trial. Seventy-four patients (mean ± SD age, 35.1 ± 11.0 years; 48.6% female) met the eligibility criteria, agreed to participate, and signed informed consent. Of these 74 patients, 37 were randomized to the HEP group and 37 were randomized to the MTEX group. **FIGURE 1** shows a flow diagram of patient recruitment and retention for this trial. All baseline demographics were similar between groups ( $P > .05$ ) (**TABLE 1**). Of the 74 patients enrolled, 69 (93.2%) completed the 4-week follow-up and 65 (87.8%) completed the 6-month follow-up (**FIGURE 1**). The percentages of dropouts at 4 weeks and at 6 months were not statistically different between treatment groups.

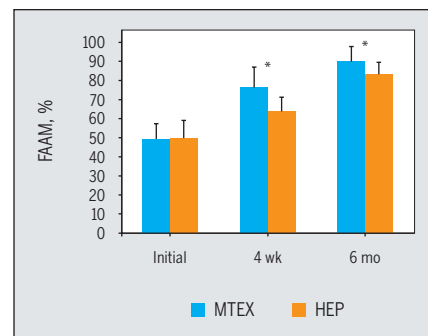
The overall group-by-time interaction for the mixed-model ANOVA was statistically significant for the FAAM ADL ( $P \leq .001$ ), FAAM sports ( $P < .001$ ), LEFS ( $P \leq .001$ ), and pain ( $P \leq .001$ ). Between-group differences revealed that the MTEX group experienced statistically significantly greater improvement in the FAAM ADL and FAAM sports subscales at both the 4-week (FAAM ADL mean difference, 11.7; 95% confidence interval [CI]: 7.4, 16.1; FAAM sports mean difference, 13.3; 95% CI: 8.0, 18.6, respectively) and 6-month (FAAM ADL mean difference, 6.2; 95% CI: 0.98, 11.5; FAAM sports mean difference, 7.2; 95% CI: 2.6, 11.8) follow-up periods. Similarly, sig-

Variable	HEP (n = 37)*	MTEX (n = 37)*	P Value
Age, y	33.2 ± 9.8	37.1 ± 11.8	.12 <sup>†</sup>
Gender (female), n (%)	19 (51)	17 (46)	.81 <sup>‡</sup>
Duration of symptoms, d	59.9 ± 31.3	72.1 ± 67.7	.32 <sup>†</sup>
Acute (<6 wk), n	11	12	
Subacute (6-12 wk), n	22	17	.37 <sup>†</sup>
Chronic (>12 wk), n	4	8	
NPRS (0-10) <sup>§</sup>	3.9 ± 0.9	3.9 ± 0.7	.99 <sup>†</sup>
LEFS (0-80)	53.8 ± 7.2	51.1 ± 8.7	.16 <sup>†</sup>
FAAM ADL (0%-100%)	63.5 ± 12.5	65.8 ± 9.7	.39 <sup>†</sup>
FAAM sports (0%-100%)	49.9 ± 9.4	49.3 ± 8.0	.76 <sup>†</sup>
Taking medications at the start of the study, n (%)	7 (18.9)	5 (13.5)	.75 <sup>†</sup>

*Abbreviations: ADL, activities of daily living; FAAM, Foot and Ankle Ability Measure; HEP, home exercise program; LEFS, Lower Extremity Functional Scale; MTEX, manual therapy and exercise; NPRS, numeric pain rating scale.*  
<sup>\*</sup>Values are mean ± SD unless otherwise indicated.  
<sup>†</sup>Independent-samples *t* tests.  
<sup>‡</sup>Chi-square tests.  
<sup>§</sup>Lower score is better. In all other scales, higher score is better.



**FIGURE 2.** Mean ± SD FAAM activities of daily living subscale scores at each assessment point. The scale ranges from 0% to 100%, with higher scores indicating better function. \*Significant difference between groups ( $P < .05$ ). Abbreviations: FAAM, Foot and Ankle Ability Measure; HEP, home exercise program; MTEX, manual therapy and exercise.

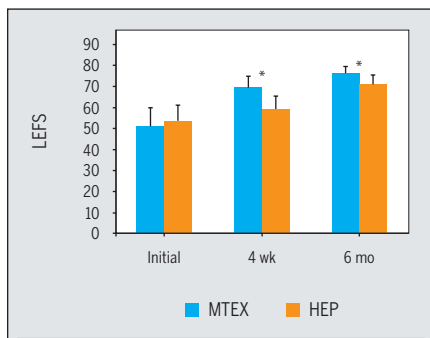


**FIGURE 3.** Mean ± SD FAAM sports subscale scores at each assessment point. The scale ranges from 0% to 100%, with higher scores indicating better function. \*Significant difference between groups ( $P < .05$ ). Abbreviations: FAAM, Foot and Ankle Ability Measure; HEP, home exercise program; MTEX, manual therapy and exercise.

nificant between-group differences for improvement existed for the LEFS at 4 weeks (mean difference, 12.8; 95% CI: 9.1, 16.5) and at 6 months (mean difference, 8.1; 95% CI: 4.1, 12.1), both favoring the MTEX group. **FIGURES 2** through **4** show the scores at each time frame for the FAAM ADL, FAAM sports, and LEFS, respectively.

There was also a significant difference

in favor of greater improvements in pain for the MTEX group at both the 4-week (mean difference, -1.2; 95% CI: -1.5, -0.90) and 6-month (mean difference, -0.47; 95% CI: -0.90, -0.05) follow-up periods (**TABLE 2**). **FIGURE 5** shows the scores at each time frame for the NPRS. The Mann-Whitney *U* test revealed a significant difference in favor of the MTEX group for the GRC at both the 4-week



**FIGURE 4.** Mean  $\pm$  SD LEFS scores at each assessment point. The scale ranges from 0 to 80, with higher scores indicating better function. \*Significant difference between groups ( $P < .05$ ). Abbreviations: LEFS, Lower Extremity Functional Scale; HEP, home exercise program; MTEX, manual therapy and exercise.

(MTEX group mean, 4.1; median, 4.0; mode, 4.0; and HEP group mean, 3.0; median, 3.0; mode, 3.0;  $P < .001$ ) and 6-month (MTEX group mean, 6.3; median, 6.0; mode, 7.0; and HEP group mean, 4.4; median, 4.6; mode, 5.0;  $P < .001$ ) follow-up periods.

No adverse events were reported for either group during the study period. There was no statistically significant difference in the recurrence of ankle sprain rate ( $P = .48$ ) between the MTEX (3/33, 9.1%) and HEP (5/32, 15.6%) groups. Furthermore, there was no statistically significant difference ( $P = .56$ ) for the percentage of patients who reported completing their home exercises between the MTEX group (mean, 69.3% completion rate) and the HEP group (mean, 65.5% completion rate).

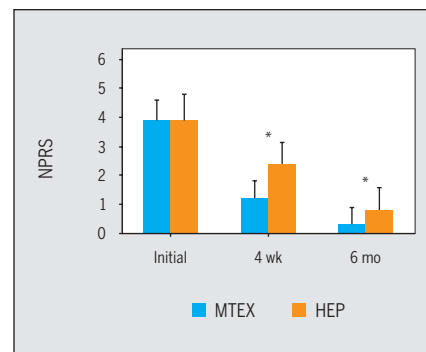
## DISCUSSION

**T**HE RESULTS OF THE CURRENT STUDY demonstrate that both groups experienced improvements in pain and function during the study period. However, the patients in the MTEX group exhibited significantly greater improvements in pain and function at both 4 weeks and 6 months as compared to those in the HEP group. Although point estimates of between-group effect sizes for treatment benefit suggest clinically meaningful benefits of MTEX over an HEP, widths of the

TABLE 2		CHANGES IN PAIN AND FUNCTION FOR THE 2 INTERVENTIONS	
Variable*	Home Exercise Program <sup>†</sup>	Manual Therapy and Exercise <sup>†</sup>	Between-Group Differences <sup>‡</sup>
FAAM ADL (0%-100%)			
Baseline to 4 wk	9.6 (6.5, 12.6)	21.3 (18.2, 24.5)	11.7 (7.4, 16.1) <sup>§</sup>
Baseline to 6 mo	24.6 (20.5, 28.7)	30.8 (27.4, 34.2)	6.2 (0.98, 11.5) <sup>  </sup>
FAAM sports (0%-100%)			
Baseline to 4 wk	13.8 (10.9, 16.8)	27.1 (22.7, 31.6)	13.3 (8.0, 18.6) <sup>§</sup>
Baseline to 6 mo	33.5 (30.7, 36.3)	40.7 (37.0, 44.4)	7.2 (2.6, 11.8) <sup>¶</sup>
LEFS (0-80)			
Baseline to 4 wk	5.6 (3.1, 8.1)	18.4 (15.5, 21.2)	12.8 (9.1, 16.5) <sup>§</sup>
Baseline to 6 mo	17.3 (14.5, 20.0)	25.3 (22.3, 28.3)	8.1 (4.1, 12.1) <sup>§</sup>
NPRS (0-10)			
Baseline to 4 wk	-1.5 (-1.8, -1.3)	-2.7 (-2.9, -2.5)	-1.2 (-1.5, -0.90) <sup>§</sup>
Baseline to 6 mo	-3.1 (-3.5, -2.8)	-3.6 (-3.9, -3.4)	-0.47 (-0.90, -0.05) <sup>#</sup>

*Abbreviations: ADL, activities of daily living; FAAM, Foot and Ankle Ability Measure; LEFS, Lower Extremity Functional Scale; NPRS, numeric pain rating scale.*  
<sup>\*</sup>Higher scores on the functional scales indicate improvement, and lower scores on the pain scale indicate less pain.  
<sup>†</sup>Values are within-group mean (95% confidence interval) differences over time.  
<sup>‡</sup>Values are mean (95% confidence interval) differences in within-group changes between groups at each time occasion.  
<sup>§</sup> $P < .001$ .  
<sup>||</sup> $P = .02$ .  
<sup>¶</sup> $P = .002$ .  
<sup>#</sup> $P = .03$ .

CI around these estimates (with the exception of the LEFS at 4 weeks) fail to provide completely convincing evidence for a clinically meaningful advantage (greater than MCID) for MTEX in the target population. Though the between-group differences did not surpass the MCIDs at 6 months, we believe that clinicians should consider using a multimodal approach incorporating manual physical therapy interventions and exercise for the management of patients with inversion ankle sprain, based on the fact that the within-group average improvements (as well as the lower bound of their 95% CIs) for the patients in the MTEX group exceeded the MCIDs at both the 4-week and 6-month follow-ups. Furthermore, although the difference between groups for recurrence rates was not statistically significant, the HEP group experienced almost double the rate of recurrence compared to the MTEX group (15.6% versus 9.1%), which may be clinically relevant.



**FIGURE 5.** Mean  $\pm$  SD NPRS scores at each assessment point. The scale ranges from 0 to 10, with lower scores indicating less pain. \*Significant difference between groups ( $P < .05$ ). Abbreviations: HEP, home exercise program; MTEX, manual therapy and exercise; NPRS, numeric pain rating scale.

The findings from the current study differ from those reported by Bassett and Prapavessis,<sup>2</sup> who compared a mean of 7.6 sessions of supervised in-clinic exercise with a physical therapist to 4.6 sessions of supervised HEP progression. In contrast to our results, showing superior

results with an MTEX approach over an HEP, the results in the Bassett and Prapavessis<sup>2</sup> trial revealed no statistically significant difference between the groups at the completion of treatment. It is possible that the inclusion of manual physical therapy interventions in the treatment approach in our trial was the primary reason for the different findings between studies. However, Bassett and Prapavessis<sup>2</sup> also included strategies to enhance adherence to the HEP, which included educational materials, a treatment booklet, and cognitive-behavioral interventions. These strategies were not used in the current study and could have led to greater improvements in the HEP group in their study. Bassett and Prapavessis<sup>2</sup> reported adherence to the HEP using a 1-to-5 scale (1 is no, 5 is all), whereas we asked the patients to report their percentage of adherence. Therefore, direct comparisons regarding exercise adherence between studies cannot be made. Although it is expected that increased adherence to home exercise would result in better clinical outcomes, very few studies have examined this potential association.<sup>46</sup> Future studies should examine whether exercise adherence contributes to better outcomes.

The results of the current study further support the conclusions of a systematic review by Brantingham et al<sup>8</sup> that MTEX is effective in the short term for reducing pain and improving function in patients with an inversion ankle sprain. This is in contrast to the findings of Beazell and colleagues.<sup>3</sup> They examined the benefits of a joint manipulation applied to either the proximal or distal tibiofibular joint versus no treatment in patients with chronic ankle instability, and their results revealed that all 3 groups showed similar improvement in dorsiflexion range of motion and function. Perhaps the difference between the current study and that of Beazell et al<sup>3</sup> is the fact that their population had chronic symptoms and received only 1 intervention technique. However, our sample included 12 patients in the chronic stage (greater than 12 weeks)

who exhibited improvements within our trial, suggesting that the current study's MTEX approach might be beneficial for individuals with ankle inversion sprain, regardless of the time since injury. Similarly, the authors of a recent study<sup>14</sup> that examined the impact of a 30-second bout of grade III anterior/posterior talocrural joint mobilization in patients with acute inversion ankle sprains reported no better improvements in dorsiflexion or function at a 24-hour follow-up as compared to a control group. As only 1 manual therapy technique was used for a single session, this suggests that multiple treatment sessions utilizing a variety of manual therapy techniques may be necessary to significantly improve function, or that a combination of manual therapy and exercises may increase the potential to maximize patient outcomes.

The exact mechanism by which manual therapy achieves its effects is unknown, but there are possible explanations worth considering. It has been reported that patients with an inversion ankle sprain often exhibit impairments at joints that contribute to ankle mobility, including the proximal tibiofibular, distal tibiofibular,<sup>34</sup> talocrural,<sup>17</sup> and subtalar joints.<sup>30</sup> Perhaps manual therapy is helpful in restoring motion at these joints, leading to improved foot and ankle mechanics, less pain, and improved function. It is also possible that the effects of manual therapy are neurophysiological in nature.<sup>4,5</sup> For example, it has been demonstrated that the soleus and peroneal muscles exhibit arthrogenous muscle inhibition in patients with ankle instability.<sup>47,50</sup> The authors of these studies have suggested that this might be the result of altered mechanoreceptors following the ankle sprain, leading to a disrupted neural feedback system to the dynamic stabilizers of the ankle. Interestingly, Grindstaff et al<sup>31</sup> demonstrated that patients with chronic ankle instability who were treated with manipulation to the distal tibiofibular joint exhibited increased soleus activation. Perhaps manual therapy interventions stimulate mechanorecep-

tors and thereby assist the improvement of neural feedback, which may aid in dynamic stability and maximize the benefits of therapeutic exercise. Additionally, it is plausible that manual therapy interventions could result in a reduction of inflammatory cytokines,<sup>58</sup> an increase in beta endorphins,<sup>16</sup> and hypoalgesia.<sup>25,26</sup> These hypotheses require further scientific investigation.

There are a number of limitations to the current study that should be considered. First, the study did not include a comparison group that received either no treatment (control) or a placebo intervention. Therefore, we cannot determine what percentage of the improvements made by the patients enrolled in the current trial was a result of the interventions they received, placebo, or simply the natural history of the disorder. Additionally, the physical therapists spent twice as much time with the patients in the MTEX group as they did with those in the HEP group. This in itself could have contributed to the differences between groups. It should also be recognized that the therapists had no physical contact with the patients in the HEP group and that the power of touch might also have contributed to the differences in outcomes between groups. Smoking was not captured as a baseline variable, hence it is not known if this contributed to a poorer prognosis for some individuals. Future studies should include a comparison group receiving no intervention and, potentially, a placebo group, and should ensure that equal time is spent with individuals in each treatment group.

## CONCLUSION

**I**N THIS RANDOMIZED CLINICAL TRIAL, A management approach incorporating MTEX for individuals with inversion ankle sprain resulted in greater improvements in pain and function in both the short and long term as compared to the use of an HEP. Although both groups exhibited improvement, the MTEX group experienced greater changes over time



that were not only statistically significant but also surpassed the MCID of the various outcome measures at the 4-week follow-up. ●

## KEY POINTS

**FINDINGS:** In this randomized clinical trial, a management approach incorporating MTEX for individuals with inversion ankle sprain resulted in greater improvements in pain and function in both the short and long term as compared to the use of an HEP.

**IMPLICATIONS:** Incorporating both manual therapy and exercise into a multimodal treatment program for the management of patients with inversion ankle sprain should be considered.

**CAUTION:** Attention bias might have been partially or fully responsible for the differences between groups.

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## APPENDIX A


### GUIDELINES FOR EXERCISE PROGRESSION

Physical Therapy	Progression
<p><b>Education:</b> refrain from activity detrimental to recovery, elevate the ankle and apply ice, use elastic compression to assist with edema control.</p> <p><b>Mobility:</b> active range of motion and mobilizing exercises for the foot and ankle: plantar flexion, dorsiflexion, inversion, and eversion. Target: 3 sets of 15 repetitions.</p> <p><b>Strength:</b> gentle strengthening exercises initially consisting of isometrics: pushing foot against the wall for inversion, eversion, and plantar flexion, using the other foot for resistance of dorsiflexion (5-second holds for 5 repetitions in all directions), and scrunching a towel under the sole of the foot for intrinsic muscles.</p>	<p>As swelling and bruising decrease, reduce the time spent elevating the ankle and decrease frequency of ice application.</p> <p>Progress to greater range of movement, adding holds at the end range and increasing the duration of holds.</p>
<p><b>Body-weight resistance:</b> heel raises and mini-squats in bilateral standing.</p>	<p>Strengthening exercises progress to isotonic exercises using elastic band for resistance. Three sets of 15 repetitions to be performed in all directions, with the goal of achieving muscle fatigue at the end of 3 sets. Increase range of movement, duration of holds at the end range, and strength level of the elastic band over time. Progress strength of elastic band when 3 sets of 15 repetitions are completed in the full range.</p>
<p><b>Stretching:</b> calf and heel cord stretches, starting in long sitting, using a towel to manually provide the stretch; 3 stretches of 30 seconds' duration.</p>	<p>Progress to heel raises and mini-squats standing on the injured limb. Increase time spent in the weight-bearing position.</p>
<p><b>Balance:</b> 1-legged standing on the injured limb, with arms abducted and eyes open; 3 sets of 30 seconds' duration.</p>	<p>Progress to standing stretches for gastrocnemius and soleus; 3 stretches of 30 seconds' duration.</p>
<p><b>Dynamic balance:</b> standing on balance/wobble board (or pillow) with eyes open; 3 sets of 60 seconds' duration.</p>	<p>Progress from arms abducted to arms across chest when able to stand without losing balance, 3 × 30 seconds. Progress eyes open to eyes closed when able to stand without losing balance, 3 × 30 seconds with eyes open, arms across chest.</p>
<p><b>Functional weight-bearing activities:</b> walking, running, skipping, and hopping, according to patient's activities and participation.</p>	<p>Options for progression: eyes open to eyes closed, decrease the standing base, throwing and catching a ball, and standing on the injured limb only.</p> <p>Progress from walking to running/hopping when strength, range of motion, and balance exercises have been progressed fully as above.</p>





Adapted from Bassett SF, Prapavessis H. Home-based physical therapy intervention with adherence-enhancing strategies versus clinic-based management for patients with ankle sprains. *Phys Ther.* 2007;87:1132-1143, with permission of the American Physical Therapy Association. This material is copyrighted, and any further reproduction or distribution requires written permission from APTA.

## APPENDIX B

### DESCRIPTION OF THRUST/NONTHRUST MANIPULATION TECHNIQUES


Technique	Description of Technique	Illustration*
<p>Rearfoot: distraction high-velocity manual physical therapy intervention</p>	<p>The therapist grasped the dorsum of the patient's foot with interlaced fingers. Firm pressure with both thumbs was applied in the middle of the plantar surface of the forefoot. The therapist engaged the restrictive barrier by passively dorsiflexing the ankle and applying a long-axis distraction. The therapist pronated and dorsiflexed the foot to fine tune the barrier. The therapist applied a high-velocity, low-amplitude force in a caudal direction.</p>	

## APPENDIX B

Technique	Description of Technique	Illustration*
Talocrural joint: anterior-to-posterior low-velocity manual physical therapy intervention	The therapist used the left hand to firmly stabilize the lower leg at the malleoli. The therapist grasped the anterior, medial, and lateral talus with the right hand. The therapist applied a low-velocity, anterior-to-posterior oscillatory force to the talus. Tip: the therapist used the thigh to help stabilize the foot and to progressively increase the amount of ankle dorsiflexion. The therapist may need to adjust the amount of supination/pronation to optimize the technique.	
Weight-bearing talocrural joint: anterior-to-posterior low-velocity manual physical therapy intervention	The therapist supported the arch of the foot and applied a stabilizing force (anterior-to-posterior-directed force) over the anterior talus. A belt (padded) was placed over the patient's distal posterior tibia and fibula and around the therapist's buttock region. The patient was guided into dorsiflexion of the involved ankle while, simultaneously, the therapist applied a posterior-to-anterior-directed force to the distal leg by leaning backward/pulling on the belt. As the patient dorsiflexes more, the therapist should squat down while leaning back to keep a direct posterior-to-anterior force at the talocrural joint (therefore following the plane of the joint).	
Lateral glides and eversion: low-velocity manual intervention	<p><i>Talocrural joint lateral glide:</i> the therapist grasped the malleoli just proximal to the talocrural joint with the left index finger/thumb and used the forearm to stabilize the patient's left leg against the table. The therapist placed the right thenar eminence on the talus just distal to the malleoli and grasped the rearfoot. The therapist used his body to impart a low-velocity oscillatory force to the talus through the right arm and thenar eminence.</p> <p><i>Subtalar joint lateral glide:</i> the therapist shifted the left hand/forearm distally and grasped the talus with the left index finger/thumb. The therapist placed his right thenar eminence on the patient's medial aspect of the calcaneus and grasped the rearfoot. The therapist used his body to impart a low-velocity oscillatory force to the calcaneus through the right arm and thenar eminence.</p>	
Proximal tibiofibular joint: high-velocity manual intervention	The therapist placed his second MCP in the popliteal fossa, then pulled the soft tissue laterally until the MCP was firmly stabilized behind the patient's fibular head. The therapist used the left hand to grasp the foot and ankle. The therapist externally rotated the leg and flexed the knee to the restrictive barrier. Once the restrictive barrier was met, the therapist applied a high-velocity, low-amplitude force through the tibia (directing the patient's heel toward his ipsilateral buttock).	



## APPENDIX B

Technique	Description of Technique	Illustration*
Distal tibiofibular joint: low-velocity manual intervention	The therapist grasped and stabilized the distal tibia with 1 hand. The therapist placed the thenar eminence over the lateral malleolus and used his body to impart a low-velocity, oscillatory, anterior-to-posterior force to the fibula on the tibia.	

Abbreviation: MCP, metacarpophalangeal joint.  
 \*Images reproduced with kind permission of Evidence in Motion (<http://www.evidenceinmotion.com/>).

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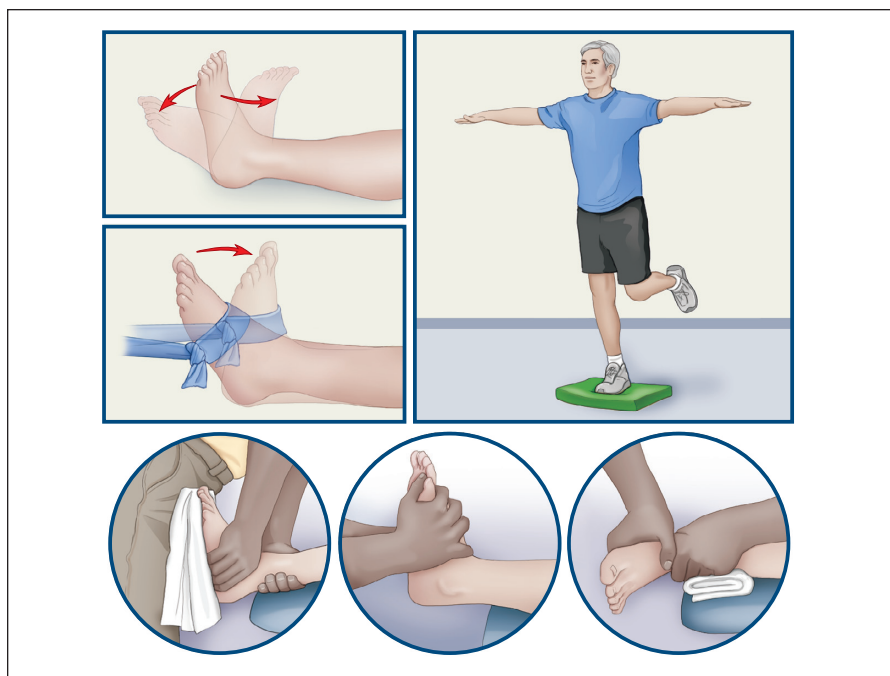
# Ankle Sprains

## *Combination of Manual Therapy and Supervised Exercise Leads to Better Recovery*

*J Orthop Sports Phys Ther* 2013;43(7):456. doi:10.2519/jospt.2013.0504

**A**nkle sprains often occur when running, walking on uneven ground, or jumping. Sprains are more common in sports activities. Usually, people are told to rest, elevate the foot, apply ice, and use an elastic wrap to reduce swelling. This treatment is typically followed by exercises that can be performed at home. Although the pain and swelling usually improve quickly, more than 70% of people who sprain their ankles continue to have problems with them. In fact, up to 80%

will sprain their ankles again. This suggests that it is important to better care for ankle sprains. One option is manual therapy, where the therapist moves the ankle and surrounding joints to help restore normal joint movement. A research report published in the July 2013 issue of *JOSPT* examines and compares the outcomes of a home exercise program with a more involved treatment program that includes manual therapy and supervised exercises.



**MANUAL THERAPY AND SUPERVISED EXERCISES.** The drawings above show examples of the exercises and manual therapy techniques used in this study. The physical therapist tailored each program to the individual to match the patient's injury and optimize recovery.

For this and more topics, visit *JOSPT* Perspectives for Patients online at [www.jospt.org](http://www.jospt.org).

This *JOSPT* Perspectives for Patients is based on an article by JA Cleland et al titled "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):443-455. doi:10.2519/jospt.2013.4792.

This Perspectives article was written by a team of *JOSPT*'s editorial board and staff, with Deydre S. Teyhen, PT, PhD, Editor, and Jeanne Robertson, Illustrator.

### NEW INSIGHTS

In this study, researchers treated 74 patients. Half of these patients received a typical home exercise program. The other patients received a combined manual therapy and supervised exercise program. The patients who received the manual therapy and supervised exercise program experienced about a 70% reduction in pain at 4 weeks and more than a 92% reduction in pain at 6 months. By contrast, patients who received the home exercise program only had a 39% reduction in pain at 4 weeks and an 80% reduction at 6 months. For those in the manual therapy and supervised exercise program, the ability to perform daily activities improved from 66% at the initial exam to 87% at 4 weeks and 97% at 6 months (100% is full function). Meanwhile, those doing just the home exercise program only saw improved function to 73% at 4 weeks and 88% at 6 months. The researchers concluded that the combination of manual therapy and a supervised exercise program was superior to a home exercise program alone in the treatment of ankle sprains, because the combined program provided better pain relief and improved function.

### PRACTICAL ADVICE

Patients who have sprained their ankles may benefit from a physical therapy program that includes manual therapy and a supervised exercise program. Potential benefits are less pain and improved ability to perform daily activities and return to sport. Your physical therapist can perform a thorough evaluation to help determine if you are a good candidate for this treatment as part of a program designed to help get you back to full activity after an ankle sprain. For more information on the treatment of ankle sprains, contact your physical therapist specializing in musculoskeletal disorders.



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