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ABSTRACT

Introduction: Soft tissue injuries of the leg, ankle, or foot are common and often treated by exercise. The purpose of this study was to determine the effectiveness of exercise for the management of soft tissue injuries of the leg, ankle, or foot.

Methods: A systematic review of the literature was conducted. We searched five databases from 1990 to 2015. Relevant articles were critically appraised using Scottish Intercollegiate Guidelines Network (SIGN) criteria. The evidence from studies with low risk of bias was synthesized using the best-evidence synthesis methodology.

Results: We screened 7946 articles. We critically appraised ten randomized trials and six had a low risk of bias. The evidence suggests that for recent lateral ankle sprain: 1) rehabilitation exercises initiated immediately post-injury are as effective as a similar program initiated one week post-injury; and 2) supervised progressive exercise plus education/advice and home exercise lead to similar outcomes as education/advice and home exercise. Eccentric exercises may be more effective than an AirHeel brace but less effective than acupuncture for Achilles tendinopathy of more than two months duration. Finally, for plantar heel pain, static stretching of the calf muscles and sham ultrasound lead to similar outcomes, while static plantar fascia stretching may provide short-term benefits compared to shockwave therapy.

Conclusions: We found little evidence to support the use of early or supervised exercise interventions for lateral ankle sprains. Eccentric exercises may provide short-term benefits over a brace for persistent Achilles tendinopathy and plantar fascia stretching may provide short-term benefits for plantar heel pain.
Key words: systematic review, exercise, ankle sprain, plantar fasciitis, Achilles tendinopathy
INTRODUCTION

Soft tissue injuries of the leg, ankle, and foot are common in the general population. In Ontario, 17.4% of all workers’ compensation claims are related to leg, ankle, or foot injuries [1]. In Saskatchewan, 27.5% of adults report lower extremity injuries following a traffic collision [2]. Common diagnoses for soft tissue injuries of the leg, ankle, and foot include ankle sprains, Achilles tendinopathy, and plantar fasciitis [3-8].

An estimated 23,000 lateral ankle sprains occur daily in the United States and 600,000 ankle injuries are reported annually in the Netherlands [3, 4]. Lateral ankle sprains account for 15-25% of all sports related injuries [5, 6]. The incidence of mid-portion Achilles tendinopathy is 1.85 per 1,000 Dutch patients visiting a general practitioner [7]. Achilles tendinopathy is more common in men between 35 and 45 years of age [9-12]. The lifetime incidence of plantar fasciitis is 10% and approximately two million Americans seek treatment annually [8].

Leg, ankle, and foot soft tissue injuries place a considerable burden on the healthcare system and society. In the United States, 1.6 million physician visits and 8,000 hospitalizations annually result from ankle sprains [13]. In the Netherlands, the mean total direct and indirect healthcare costs of one ankle sprain are estimated to be €360 [14]. In the United States, more than 11,000 cases of chronic tendon injury result in missed workdays each year (U.S. Department of Labor) [15]. Treatment of plantar fasciitis is estimated to cost third party payers between $192 and $376 million US
dollars (USD) annually in the United States [16]. Despite this burden, the optimal clinical management and rehabilitation of soft tissue injuries of the leg, ankle and foot has yet to be established.

A common treatment for ankle sprains is exercise [17, 18]. Previous systematic reviews found that supervised exercise plus usual care leads to faster recovery and return to sport following acute ankle sprains than usual care alone [19-21]. Three systematic reviews suggest that exercise therapy, including balance or neuromuscular training, is effective for preventing recurrent ankle sprains [6, 22, 23]. However, these reviews have important limitations. They included high risk of bias studies, namely selection bias due to attrition and confounding due to small sample sizes [6, 22, 23].

Exercise is also used to manage Achilles tendinopathy [24]. Recent systematic reviews report that there is insufficient evidence to support the effectiveness of eccentric exercises for Achilles tendinopathy [9-12]. However, these reviews included high risk of bias studies in their synthesis potentially influencing their conclusions [9-12]. There is a need for an up-to-date systematic review of adequate methodological quality examining the effectiveness of exercise for soft tissue injuries of the leg, ankle, and foot.

The purpose of this systematic review was to evaluate the effectiveness of exercise therapy compared to other interventions, placebo/sham interventions, or no intervention for the management of patients with leg, ankle, and foot soft tissue injuries, including grade I and II sprain and strain injuries.
METHODS

Registration

This review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on April 27, 2013 (CRD4201300XXXX).

Eligibility Criteria

Population:

Our review targeted studies of adults and children with leg, ankle, and foot soft tissue injuries including grade I-II sprain and strain injuries (Table 1) [18, 25]. We included studies of patients with grade III ankle sprains only when results were stratified by injury grade or equal numbers of grade III injuries were included in each group. We excluded studies solely on grade III sprains/strains, amputations, joint dislocations/subluxations, fractures, malignancy, infections, and osteoarthritis.

Interventions:

Exercise is defined as specific movements performed as routine practice or physical training to train or develop the body to promote good physical health and restore normal function of the joints and surrounding soft tissues [26]. These exercises include, but are
not limited to, range of motion, postural stability, proprioceptive training, strength training, and neuromuscular training. Supervised and unsupervised exercises were included. We excluded studies that included exercise as one component of a multimodal program of care and the specific effectiveness of exercise could not be determined. For example, a trial comparing a multimodal program that includes stretching exercises, structured patient education, and manual therapy to strengthening exercises plus acupuncture could not comment on the effectiveness of stretching or strengthening exercises. Exercise combined with patient education/instruction on exercises was not considered a multimodal intervention.

**Comparison groups:**

We included studies that compared exercise to other forms of exercise, other interventions, waiting list, or no intervention.

**Outcomes:**

Eligible studies had to include one of the following: 1) self-rated recovery; 2) functional outcomes (e.g., return to activities, work, or school); 3) clinical outcomes (e.g., pain intensity, disability, quality of life, psychological status); 4) administrative outcomes (e.g., time on disability benefits); or 5) adverse events.

**Study characteristics**

Eligible studies met the following inclusion criteria: 1) English language; 2) published between January 1, 1990 and February 4, 2015; 3) randomized controlled trials (RCTs),
cohort studies, or case-control studies; and 4) an inception cohort of at least 30 subjects per treatment arm with the specified condition for RCTs or 100 subjects per exposed group with the specified condition for cohort or case-control studies. A sample size of 30 per treatment arm is considered the minimum needed for non-normal distributions to approximate the normal distribution [27]. The assumption that data are normally distributed is required to ascertain a difference in sample means between treatment arms. We excluded: 1) letters, editorials, commentaries, unpublished manuscripts, dissertations, government reports, books and book chapters, conference proceedings, meeting abstracts, lectures and addresses, consensus development statements, guideline statements; 2) pilot studies, cross-sectional studies, case reports/series, qualitative studies, clinical practice guidelines, systematic reviews (with or without meta-analyses), narrative reviews, biomechanical studies, laboratory studies, studies not reporting on methodology; or 3) cadaveric or animal studies.

Information Sources

We developed our search strategy with a health sciences librarian (Appendix I). A second librarian reviewed the search strategy for completeness and accuracy using the Peer Review of Electronic Search Strategies (PRESS) Checklist [28, 29]. We searched MEDLINE, EMBASE, CINAHL, PsycINFO and Cochrane Central Register of Controlled Trials from January 1, 1990 to February 4, 2015.
We developed the search strategy in MEDLINE and adapted it to the other bibliographic databases. The search terms included subject headings (e.g., MeSH in MEDLINE) specific to each database and free text words relevant to exercise, ankle, leg, and foot injury, sprains, and strains (Appendix I).

Study Selection

We used a two-phase screening process to select eligible studies. Random pairs of independent reviewers screened citation titles and abstracts in phase one screening to determine the study eligibility. Phase one screening resulted in studies being classified as relevant, possibly relevant, or irrelevant. The same paired reviewers independently reviewed the manuscripts of possibly relevant studies in phase two to determine eligibility. Reviewers met to resolve disagreements and reach consensus on the eligibility of studies. We consulted a third reviewer if consensus could not be reached.

Assessment of Risk of Bias

Random pairs of independent reviewers critically appraised the internal validity of eligible studies using the Scottish Intercollegiate Guidelines Network (SIGN) criteria (Table 2A) [30]. This checklist was developed by SIGN to guide the development of evidence-based clinical practice guidelines for the National Health Service in Scotland. It has been used internationally in more than 140 clinical practice guidelines [31]. During critical appraisal, we assessed for the presence of selection bias, information bias, and
confounding, and any impact these may have on the internal validity of the study. We did not use a rating scale cut-off or quantitative score to judge the quality of the study [32]. Rather, the SIGN criteria assisted reviewers in making an informed overall judgment on the internal validity of studies. This methodology has been previously described [33-41]. We focused on the presence or absence of important methodological issues. Studies were considered to have high risk of bias if the internal validity was markedly compromised due to biases and methodological flaws. Paired reviewers met to resolve disagreements and reach consensus on study admissibility. We involved a third reviewer if consensus could not be reached.

We critically appraised the following methodological aspects of a study: 1) clarity of the research question; 2) randomization method; 3) concealment of treatment allocation; 4) blinding of treatment and outcomes; 5) similarity of baseline characteristics between/among treatment arms; 6) co-intervention contamination; 7) validity and reliability of outcome measures; 8) follow-up rates; 9) analysis according to intention-to-treat principles; and 10) comparability of results across study sites (where applicable). We contacted authors when additional information was needed to complete critical appraisal. Studies with adequate internal validity had low risk of bias and were included in our evidence synthesis [42].

Data Extraction and Synthesis of Results
One author extracted data from scientifically admissible studies into a database used to build evidence tables (Table 3). A second reviewer independently checked the extracted data. Meta-analysis was not performed due to heterogeneity of scientifically admissible studies with respect to patient populations, interventions, comparators, and outcomes. We performed a qualitative synthesis of findings from scientifically admissible studies to develop evidence statements according to principles of best evidence synthesis. We used standardized measures (minimal clinically important difference [MCID]) to determine the clinical significance of results in each trial for common outcome measures, including between-group 2/10 difference on the Numeric Rating Scale (NRS), 10/100 mm or 10% difference on the Visual Analogue Scale (VAS), 12/100 on the Victorian Institute of Sports Assessment – Achilles (VISA-A) Questionnaire, and a difference of 9/80 scale points on the Lower Extremity Functional Scale (LEFS) [43-48]. We stratified our results by type of disorder.

**Statistical Analyses**

We computed the inter-rater agreement for article screening using the kappa coefficient and 95% confidence intervals (CI). The percentage agreement for critical appraisal of articles was also calculated for admissible/inadmissible results. Where available, we used data provided in admissible articles to compute the difference in mean change between groups and its 95% CI to quantify the effectiveness of interventions. We based the computation of the 95% CI for the difference in mean change on the assumption that pre- and post-intervention outcomes were highly correlated ($r=0.8$) [49, 50].
Reporting

The systematic review was organized and reported based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [51].

RESULTS

Study Selection

We screened 7,946 articles for eligibility (Figure 1). Ten articles were eligible for critical appraisal; six articles were admissible and included in our synthesis [52-57]. Thirty studies were deemed irrelevant in phase two screening due to: 1) ineligible study design (13/30); 2) ineligible intervention (9/30); 3) sample size < 30 (4/30); 4) ineligible study population (3/30); and 5) ineligible outcome measures (1/30). The inter-rater agreement for the article screening was $k=0.89$ (95% CI 0.79, 0.99). The percentage agreement for classifying studies into scientifically admissible and inadmissible studies (evidence) was 80% (8/10). Consensus was reached through discussion for the two studies where reviewers disagreed [55, 56].

Study Characteristics

All six admissible studies were RCTs (Table 3). Two assessed the effectiveness of exercise interventions for adults with recent lateral ankle sprains [52, 56]. Two assessed the effectiveness of stretching interventions for adults with acute [55] and sub-acute [54] plantar fasciitis. Two RCTs investigated the effectiveness of eccentric training for adults
with chronic [53] and variable duration [57] Achilles tendinopathy. We did not find any admissible studies examining the effectiveness of exercise in children with leg, ankle, or foot soft tissue injuries.

Risk of Bias Assessment

All low risk of bias studies had clear research questions, appropriate randomization procedures, and valid and reliable outcome measures (Table 2A). Most studies used blinding procedures where applicable (5/6) [52, 54-57], reported adequate similarity in baseline characteristics (5/6) [52-55, 57], and conducted an intention-to-treat analysis (4/6) [52, 54-56]. The low risk of bias studies had limitations: 1) insufficient detail about allocation concealment method (2/5) [6, 55]; 2) insufficient detail or differences in co-intervention across treatment arms (5/5) [52-56]; and 3) insufficient detail regarding the number of sites or whether results were comparable between sites (4/6) [52, 53, 55, 57]. The follow-up rate was 100% in one study [54] and greater than 75% in four studies [52, 55-57]. In the trial by Petersen et al., the follow-up rate was above 80% at twelve weeks, but was 60% at one year for the brace group (versus 81% in the exercise group) [53]. Therefore, we only report results from the twelve week follow-up for this study.

The four high risk of bias studies had important methodological limitations (Table 2B): 1) poor or unknown randomization methods (4/4) [58-61]; 2) poor or unknown allocation concealment methods (3/4) [58, 60, 61]; 3) inadequate or no blinding (3/4) [59-61]; 4) clinically important differences in baseline characteristics between treatment arms (3/4)
A summary of the evidence highlights several important points:

5) co-interventions not measured or reported (4/4) [58-61]; 6) high attrition or differential attrition between treatment arms (2/4) [58, 60]; and 7) no mention of an intention-to-treat analysis (4/4) [58-61].

### Summary of Evidence

#### 1. Recent Lateral Ankle Sprains

1.1 Accelerated exercise program versus standard exercise program

Evidence from one RCT suggests that an accelerated exercise program leads to similar outcomes as a standard exercise program initiated one week post-injury for patients with recent grade I-II lateral ankle sprains (Table 3) [52]. The accelerated exercise program included flexibility, strengthening, and proprioceptive exercises and basic advice (ice and compression twice daily) during the first week post-injury. The standard group was not provided with exercises during the first week, but received the same basic advice as the accelerated exercise program during the first week. Both groups then received exercises pragmatically prescribed by a physiotherapist from week one to four (five 30-minute sessions per week; one session physiotherapist supervised, four at home). There were statistically significant but not clinically important differences in function favoring the accelerated exercise within the first two weeks post-intervention.
There were no statistically significant differences in any other outcomes at any follow-up.

1.2 Supervised Exercise Program

Evidence from one RCT suggests that adding progressive exercises to education and advice provides no additional benefits compared to education and advice alone in managing recent grade I-III lateral ankle sprains (Table 3) [56]. The exercise group received a three-month progressive supervised exercise program with a physiotherapist (balance exercises, walking, running, and jumping progressions). Both groups received identical education and advice which included information on early ankle mobilization, advice for early home exercise, and early weight bearing. Participants receiving supervised exercise were more likely to report treatment satisfaction at three months compared to the comparison group [odds ratio=4.69, 95% CI 1.41, 15.5]. However, no statistically significant differences in subjective recovery, range of motion, re-sprain rate, reported or tested instability between groups were found immediately and 12 months post-intervention.

2. Mid-portion Achilles Tendinopathy

2.1 Eccentric Training
Evidence from one RCT suggests that eccentric exercise training may be more effective than an AirHeel brace in the short-term for managing persistent mid-portion Achilles tendinopathy (>3 months) (Table 3) [53]. Petersen et al. randomized participants with mid-portion Achilles tendinopathy lasting more than three months to: 1) eccentric exercise training (straight leg and knee bent eccentric exercises for the gastrocnemius, soleus, and Achilles tendon three times/day for 12 weeks; 2) wearing an AirHeel daytime brace for 12 weeks; or 3) a combination of eccentric exercises and the AirHeel brace. The sample size of the combination group did not meet our inclusion criteria (n=28 participants); therefore, these results are not reported. There were statistically significant differences in pain during daily activities and gait immediately post-intervention favouring the exercise group (difference in percent improvement for VAS during daily activities: 25%; during gait: 21%; confidence intervals not reported and could not be calculated). There was a statistically significant difference favouring the exercise group in general health status immediately post-intervention [difference in mean change for SF-36 general health favouring exercise: 11.2, (95% CI 6.32, 16.08)]; however, the MCID for this subscale is unknown. There were no statistically significant differences in the other subscales of health-related quality of life, pain during sporting activities, or foot and ankle function between the two groups at follow-up. It is important to note that the improvement from baseline to follow-up within each group was small and not clinically significant. Although between group differences slightly favoured the exercise group, none of the groups had substantial improvement from baseline to follow-up.
However, evidence from another RCT suggests that eccentric exercises are less effective than acupuncture in reducing severity of symptoms in the short-term for managing Achilles tendinopathy of variable duration [57]. Zhang et al. randomized participants to: 1) eccentric exercises of the gastrocnemius and soleus muscles with the option of progressing with weights (frequency and duration of exercises not reported); or 2) needle acupuncture inserted around Achilles tendon (three sessions per week over eight weeks) [57]. Both groups received written and verbal reassurance about usual course of symptoms and were allowed to use non-steroidal anti-inflammatory drugs if necessary. There were clinically and statistically significant differences in severity of symptoms favouring acupuncture immediately post-intervention and at eight weeks [difference in mean change in VISA-A of -19.50 (95%CI -22.26, -16.74) immediately post-intervention, -15.80 (95% CI -18.60, -13.00) at eight weeks]). There were statistically significant but not clinically important differences in severity of symptoms favouring acupuncture at 16 weeks. There were statistically significant between group differences in pain reduction favouring acupuncture immediately post-intervention, but not at eight or 16 weeks (clinical importance could not be determined as data was shown in median and interquartile ranges). There were no statistically significant between-group differences in other outcomes at any follow-up point.

3. Plantar Heel Pain

3.1 Stretching
Evidence from one RCT suggests that static triceps surae stretching leads to similar outcomes as sham ultrasound when treating subacute plantar heel pain (>4 weeks) (Table 3) [54]. Participants in the stretching group were advised to perform a static stretch on a wooden wedge for a minimum of five minutes per day (in one minute intervals) over a two-week period. Both exercise and control groups received three minutes of sham ultrasound to the painful heel. There were no clinically or statistically significant differences between groups at follow-up for any outcome measures.

However, a second RCT suggests that static plantar fascia stretching may offer short-term benefits over radial shockwave therapy for managing acute plantar fasciopathy (<6 weeks) (Table 3) [55]. Participants randomized to the stretching group were instructed to perform a static plantar fascia stretch with specific exercises (three times a day for eight weeks). Participants allocated to the shockwave therapy group received three sessions of radial shockwave therapy (over a three week period) to the area of maximal tenderness. Immediately and four months post-intervention, there were statistically significant differences in foot function and patient relevant outcome measures favoring the stretching group. There were no statistically significant differences between groups in foot function or patient relevant outcome measures (pain, function, treatment satisfaction) at 15 months post-intervention. The clinical significance of these outcomes is unclear as their MCID has not been determined.

**Adverse Events**
Four admissible RCTs reported on adverse events [52-55]. No serious adverse events were reported. In the trial by Rompe et al., 48/48 (100%) of the shockwave therapy group reported transient skin reddening [55]. Furthermore, 4/48 (8%) of the shockwave therapy group and 8/54 (15%) of the stretching group reported pain with treatment. In the trial by Petersen et al., participants dropped out of the study due to severe pain during exercises or discomfort due to poor fitting of the brace (exact numbers not reported but total dropout rate was 14%) [53]. In the trial by Radford et al., some participants in the stretching group experienced increased pain (4%), calf pain (4%), new lower limb pain (2%), or discontinued due to an adverse event (2%; not specified) [54].

DISCUSSION

Summary of Evidence

Our systematic review aimed to investigate the effectiveness of exercise for the management of individuals with leg, ankle, or foot soft tissue injuries. For recent lateral ankle sprains, evidence from two low risk of bias RCTs suggests that: 1) an accelerated exercise program provided immediately after treatment leads to outcomes similar to an exercise program provided one week after injury (one RCT) [52]; and 2) combined supervised progressive exercise with education and advice leads to similar outcomes as education and advice (includes a home exercise program) alone (one RCT) [56]. For persistent mid-portion Achilles tendinopathy, evidence from one low risk of bias RCT
suggests that exercise may be more effective than AirHeel brace in the short-term [53]. For variable duration Achilles tendinopathy, evidence from one low risk of bias RCT suggests that exercise may be less effective than acupuncture in the short-term [57]. Finally, evidence from two low risk of bias RCTs suggests that for plantar heel pain: 1) static triceps surae stretching leads to similar outcomes as sham ultrasound (one RCT) [54]; and 2) static plantar fascia stretching may lead to short-term benefits over shockwave therapy (one RCT) [55]. We found no evidence on exercise for the treatment of other leg, ankle, or foot soft tissue injuries or for these conditions in children.

Comparison of Results to Other Systematic Reviews

Our results differ from those of other systematic reviews investigating exercise for the management of ankle sprains. O’Driscoll et al. reported limited to moderate evidence favoring neuromuscular training for ankle sprains [23]. Van Os et al. reported preliminary evidence supporting the effectiveness of exercise for ankle sprains [21]. Petersen et al. found inconsistent evidence for exercises for the management of ankle sprains [6]. Finally, Seah et al. and van Rijn et al. reported that supervised rehabilitation with usual care can provide some benefit for acute lateral ankle sprains [19, 20]. These reviews used studies with high risk of bias to develop their conclusions. Including studies with high risk of bias may have biased results and influenced their conclusions [32].
Our results also differ from previous systematic reviews on Achilles tendinopathy. Kingma et al. could not draw conclusions on the effectiveness of eccentric exercises for Achilles tendinopathy [12]. Magnussen et al. reported that eccentric exercises are effective for the treatment of midportion Achilles tendinopathy [10]. Rowe et al. reported that evidence was strong for eccentric exercises for Achilles tendinopathy [9]. However, these conclusions were based on studies with small sample sizes that are likely underpowered and are susceptible to residual confounding. We also identified one low risk of bias RCT [57] that was not captured by the previous systematic reviews, as their literature searches are out-of-date. We have reviewed the most up-to-date literature to inform the management of Achilles tendinopathy.

One previous systematic review investigated the effectiveness of exercise for plantar heel pain, but it is withdrawn from the Cochrane database due to being substantially out-of-date (no longer accessible) [62]. Our review serves as the most up-to-date systematic review on the effectiveness of exercise for plantar heel pain. Other studies have examined exercise for the management of plantar fasciitis [63, 64]. Although these were not included in our review because of their smaller sample sizes, an examination of these studies indicate that they lacked statistical precision to measure differences. This highlights the need to design larger trials.

Clinical implications

For acute ankle sprains, patients and clinicians may want to equally consider starting an exercise program immediately after injury onset or waiting one week to initiate an
exercise program. The roles of patient preference and tolerance should be guiding principles during the decision-making of when to initiate exercises. Similarly, the option to add supervised exercises to education and advice (which includes a home exercise program) may be considered, but clinicians and patients should understand that adding a supervised exercise program will not provide additional benefits. For Achilles tendinopathy persisting for at least two months, patient preference may also need to be considered as eccentric exercises were more beneficial than an AirHeel brace but less effective than acupuncture. Finally, we found preliminary evidence that static plantar fascia stretching may benefit patients with plantar fasciitis, but static stretching of the calf muscles is unlikely to benefit patients with plantar heel pain.

Strengths and Limitations

There are strengths to our review. First, we used a rigorous and sensitive search of five databases that was reviewed by a second librarian to minimize errors. Second, we explicitly defined our inclusion and exclusion criteria to identify relevant citations and only considered studies with adequate sample sizes. We also only considered studies with a clearly defined inception cohort of individuals with leg, ankle, or foot injuries. Third, two independent reviewers conducted screening and critical appraisal to minimize error and bias. Fourth, we used the SIGN criteria to standardize the critical appraisal process, which is a well-accepted and validated set of criteria for critical appraisal. Reviewers were trained in these critical appraisal methods prior to starting our
systematic review. Lastly, our conclusions were based on the best evidence synthesis method to minimize the risk of bias with using low quality studies.

Our review also has limitations. First, the search strategy was restricted to studies published in the English language, and relevant studies may have been excluded. However, previous reviews studying the impact of restriction to the English language did not find that it led to bias within reported results [65-69]. Second, critical appraisal requires scientific judgment, which can vary among reviewers. This bias was minimized with standardized critical appraisal tools and using a consensus process between reviewers to reach decisions regarding scientific admissibility. Third, our search may not have retrieved all relevant citations, despite efforts to create a sensitive search strategy. Fourth, we searched the literature from 1990 onwards, and clinically relevant studies published prior to this date would be excluded. Finally, the inclusion criterion of \( n \geq 30 \) per treatment arm may exclude studies that had adequate power to detect a statistically significant difference [70].

CONCLUSIONS

Our systematic review clarifies the role of exercise for managing leg, ankle, and foot soft tissue injuries based on low risk of bias RCTs. For recent lateral ankle sprains, similar outcomes are offered between an accelerated exercise program and exercises given one week post-injury. Furthermore, supervised exercise provides no additional benefit when added to education and advice (including home exercises) compared to education
and advice alone. For mid-portion Achilles tendinopathy of greater than two months duration, exercise may be more effective than a daytime AirHeel brace in the short term, but less effective than acupuncture. For plantar heel pain, triceps surae stretching is no more effective than sham ultrasound, while plantar fascia stretching may provide short-term benefits over shockwave therapy. More studies of adequate methodological quality are needed to study exercise for other leg, ankle, and foot soft tissue injuries.
References


43. Carroll LJ, Jones DC, Ozegovic D, et al. How well are you recovering? The association between a simple question about recovery and patient reports of pain


Appendix I: MEDLINE Search Strategy on Exercise for Leg, Ankle, and Foot Injuries

1. exp Leg Injuries/
2. exp Foot/
3. exp Toes/in [Injuries]
4. Ankle Injuries/
5. Ankle Joint/
6. Ankle/
7. Lateral Ligament, Ankle/in [Injuries]
8. Fasciitis, Plantar/
9. (ankle* and (sprain* or strain* or injur* or pain*)).ab,ti.
10. ((talofibular or calcaneofibular or calcaneotibial or tibio*) and (sprain* or strain* or injur*)).ab,ti.
11. (deltoid and ankle*).ab,ti.
12. (fibularis and strain*).ab,ti.
13. ((peroneal or peroneus) and strain*).ab,ti.
14. (tibialis and strain* and (anterior or posterior)).ab,ti.
15. achilles.ab,ti.
16. gastrocnemius.ab,ti.
17. impingement.ab,ti.
18. (foot and (injur* or pain* or sprain* or strain*)).ab,ti.
19. (leg* and (injur* or pain* or sprain* or strain*)).ab,ti.
20. (toe* and (injur* or pain* or turf or sprain* or strain*)).ab,ti.
22. soleus.ab,ti.
23. talocrural.ab,ti.
24. "tarsal*".ab,ti.
25. tendinosis.ab,ti.
26. tendinopathy.ab,ti.
27. plantar fasciitis.ab,ti.
28. tibialis.ab,ti.
29. or/1-28
30. exp Exercise/
31. exp Exercise Movement Techniques/
32. exp Physical Fitness/
33. exp Physical Therapy Modalities/
34. exp Biofeedback, Psychology/
35. exp Combined Modality Therapy/
36. exp Motor Activity/
37. exp Muscle Strength/
38. Physical Endurance/
39. Physical Exertion/
40. Relaxation Therapy/
41. Behavior Therapy/
42. (alexander and (technique or method)).ab,ti.
43. dynamic muscle training.ab,ti.
44. "dynamic multimodal treatment protocol".ab,ti.
45. "dynamic resisted strengthening exercise".ab,ti.
46. (exercis* and (strengthening or home or fitness or neck or mobilization or mobilisation or mobility or supervis* or MedX)).ab,ti.
47. (exercis* and (eye-neck coordination or low load or low-load or low-tech or Mackenzie or proprioceptive or strength* or aerobic or therapy)).ab,ti.
48. (exercis* and (stretch-shortening or stretch shortening or postural)).ab,ti.
49. (training and (fitness or endurance or physical or postural or program* or strength* or supervis* or plyometric)).ab,ti.
50. (rehabilitat* and (eye-head coupling or program* or training)).ab,ti.
51. Feldenkrais.ab,ti.
52. "behavio* graded activity program".ab,ti.
53. (stretch* and (active or ballistic or dynamic or isometric or static)).ab,ti.
54. "early active mobili**.ab,ti.
55. physical conditioning.ab,ti.
56. (physiotherap* and (program* or regimen*)).ab,ti.
57. (physical therap* and (program* or regimen*)).ab,ti.
58. pilates.ab,ti.
59. kinesthesia.ab,ti.
60. Proprioceptive Neuromuscular Facilitation.ab,ti.
61. (scapul* and (repositioning or positioning or rehabilitat* or strength* or mobilis* or mobiliz*)).ab,ti.
62. (Qigong or Qi Gong or Ch'i Kung).ab,ti.
63. (Tai-jí or Tai Chi or Tai Ji Quan or Tai Ji or Taiji or Taijiquan or T'ai Chi or Tai Chi Chuan).ab,ti.
64. or/30-63
65. exp Randomized Controlled Trials as Topic/
66. exp Controlled Clinical Trials as Topic/
67. exp case-control studies/
68. exp Cohort Studies/
69. Double-Blind Method/
70. Single-Blind Method/
71. Placebos/
72. randomized controlled trial.pt.
73. controlled clinical trial.pt.
74. (meta analys* or meta-analys* or metaanalys*).ab,ti.
75. (cohort adj4 (study or studies or analys*)).ab,ti.
76. (random* adj4 (control* or clinical or allocat*)).ab,ti.
77. (case adj control*).ab,ti.
78. ((double or single) adj3 blind*).ab,ti.
79. "placebo*".ab,ti.
80. or/65-79
81. 29 and 64 and 80
82. limit 81 to (english language and humans and yr="1990 -Current")
Table 1. Definition of Grades for Sprain and Strains [25]

<table>
<thead>
<tr>
<th>Injury Type</th>
<th>Classification Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sprains</td>
<td>A sprain involves the stretch and/or tear of a ligament that occurs when a ligament and/or joint is placed under excessive load. Sprain severity is graded according to the extent of ligamentous damage that occurs [25].</td>
</tr>
<tr>
<td></td>
<td>I. Grade I occur when ligamentous fibres are stretched but remain structurally intact.</td>
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<td></td>
<td>II. Grade II occur when ligamentous fibres become partially torn, physical stress reveals increased laxity with a definite endpoint.</td>
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<tr>
<td></td>
<td>III. Grade III* occur when a ligament is completely torn, leading to gross instability.</td>
</tr>
<tr>
<td>Strains</td>
<td>A strain involves injury to a muscle and/or tendon that occurs with the muscle is placed under forcible stretch, either passively or during muscle contraction [25]. Strain severity is graded according to the severity of muscle fibre damage [61].</td>
</tr>
<tr>
<td></td>
<td>I. Grade I occur when less than 5% of the muscle/tendon fibres are disrupted, with fascia remaining intact</td>
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<td></td>
<td>II. Grade II occur when the muscle/tendon fibre discontinuity involves a moderate number of muscle fibres</td>
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<tr>
<td></td>
<td>III. Grade III* occur when there is a complete discontinuity in the muscle fibres</td>
</tr>
</tbody>
</table>

*Grade III sprains and strains were excluded from this systematic review
Table 2A: Risk of Bias for Accepted Randomized Controlled Trials based on SIGN Criteria

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Research Question</th>
<th>Randomization</th>
<th>Concealment</th>
<th>Blinding</th>
<th>Similarity at baseline</th>
<th>Differences between arms</th>
<th>Outcome measurement</th>
<th>Percent drop-out*</th>
<th>Intention to treat</th>
<th>Multiple sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleakley et al., 2010 [52]</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>CS</td>
<td>Y</td>
<td>16 weeks: Standard group: 9.8% Exercise group: 22%</td>
<td>Y</td>
<td>CS</td>
<td></td>
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<tr>
<td>Petersen et al., 2007 [53]</td>
<td>Y</td>
<td>Y</td>
<td>CS</td>
<td>CS</td>
<td>CS</td>
<td>Y</td>
<td>6 weeks: Eccentric training: 13.5% AirHeel brace: 11.4% 12 weeks: Eccentric training: 13.5% AirHeel brace: 11.4% 1 year: Eccentric training: 18.9% AirHeel brace: 40%</td>
<td>N</td>
<td>CS</td>
<td></td>
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<tr>
<td>Radford et al., 2007 [54]</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>CS</td>
<td>Y</td>
<td>No drop outs</td>
<td>Y</td>
<td>NA</td>
<td></td>
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<tr>
<td>Rompe et al., 2010 [55]</td>
<td>Y</td>
<td>Y</td>
<td>CS</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>2 months: Planter fascia specific stretching: 7.4% Shockwave therapy: 4.2% 4 months: Planter fascia specific stretching: 11.1% Shockwave therapy: 6.2% 15 months: Planter fascia specific stretching: 22.2% Shockwave therapy: 16.7%</td>
<td>Y</td>
<td>CS</td>
<td></td>
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<tr>
<td>Study</td>
<td>8 weeks</td>
<td>12 months</td>
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<tr>
<td>Van Rijn et al., 2007</td>
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<td>Y Y Y Y</td>
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<tr>
<td></td>
<td>Supervised exercise: 20.4%</td>
<td>Conventional therapy: 22.6%</td>
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<tr>
<td>Zhang et al., 2013</td>
<td>Y Y Y</td>
<td>Y Y Y Y</td>
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<td></td>
<td>Acupuncture: 0%</td>
<td>Exercise: 3.2%</td>
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<td></td>
<td>16 weeks:</td>
<td>Acupuncture: 3.2%</td>
<td>Exercise: 3.2%</td>
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<td></td>
<td>24 weeks:</td>
<td>Acupuncture: 3.2%</td>
<td>Exercise: 9.7%</td>
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</tbody>
</table>

*Includes withdrawals and lost to follow-up; Acronyms: SIGN: Scottish Intercollegiate Guidelines Network; Y: yes; N: no; CS: can’t say.*
Table 2B: Risk of Bias for Randomized Controlled Trials With High Risk of Bias based on SIGN Criteria

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Research Question</th>
<th>Randomization</th>
<th>Concealment</th>
<th>Blinding</th>
<th>Similarity at baseline</th>
<th>Differences between arms</th>
<th>Outcome measurement</th>
<th>Percent drop-out*</th>
<th>Intention to treat</th>
<th>Multiple sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>DiGiovanni et al., 2003 [58]</td>
<td>Y</td>
<td>CS</td>
<td>CS</td>
<td>Y</td>
<td>N</td>
<td>CS</td>
<td>CS</td>
<td>8 weeks: Achilles tendon stretching: 28% Plantar fascia stretching: 10% CS</td>
<td>CS</td>
<td></td>
</tr>
<tr>
<td>Knobloch et al., 2008 [59]</td>
<td>Y</td>
<td>CS</td>
<td>Y</td>
<td>CS</td>
<td>CS</td>
<td>CS</td>
<td>CS</td>
<td>Immediately post-intervention: Exercise+brace = 25% Exercise: 17%</td>
<td>CS</td>
<td>NA</td>
</tr>
<tr>
<td>Porter et al., 2002 [60]</td>
<td>Y</td>
<td>CS</td>
<td>CS</td>
<td>CS</td>
<td>N</td>
<td>CS</td>
<td>CS</td>
<td>1 month: Sustained: 11% Intermittent: 18% 2 months: Sustained: 21% Intermittent: 28% 3 months: Sustained:26% Intermittent: 33% 4 months: Sustained: 14/54= 26% Intermittent: 14/40= 35%</td>
<td>CS</td>
<td>NA</td>
</tr>
<tr>
<td>Wester et al., 1996 [61]</td>
<td>Y</td>
<td>CS</td>
<td>CS</td>
<td>N</td>
<td>CS</td>
<td>CS</td>
<td>N</td>
<td>13 patients (not reported by group)</td>
<td>CS</td>
<td>CS</td>
</tr>
</tbody>
</table>

*Includes withdrawals and lost to follow-up; Acronyms: SIGN: Scottish Intercollegiate Guidelines Network; Y: yes; N: no; CS: can't say.
### Table 3: Evidence Table for Accepted Randomized Controlled Trials on Exercise for Leg, Ankle, and Foot Soft Tissue Injuries

<table>
<thead>
<tr>
<th>Author(s), Year</th>
<th>Subjects and Setting; Number (n) Enrolled</th>
<th>Interventions; Number (n) of Subjects</th>
<th>Comparisons; Number (n) of Subjects</th>
<th>Follow-up</th>
<th>Outcomes</th>
<th>Key Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleakley et al., 2010 [52]</td>
<td>Patients aged 16 to 65 years attending an accident and emergency department in Ireland with grade I or II ankle sprains of &lt; 7 days duration (n=101)</td>
<td>Accelerated Exercise: Baseline to week 1: Therapeutic exercises adapted from a standard protocol (mobility, static strengthening, functional movement, and stretches). Received written instruction and DVD. Advice of ice and compression identical to standard group. Weeks 1-4: Same as standard. (n=50)</td>
<td>Standard: Baseline to week 1: No exercise intervention. Advice for application of ice and compression (two 10 minute applications of ice and compression interspersed with 10 minutes of rest and repeated 2 times daily). Weeks 1-4: Ankle rehabilitation exercise consisting of muscular strengthening, neuromuscular training, and functional exercise. (30 minute/week; one session supervised with a physiotherapist; and 4 times at home). (n=51)</td>
<td>Immediately post-intervention, 2, 3, 4, and 16 weeks</td>
<td>Primary outcome: Subjective ankle function (LEFS) (0-80)</td>
<td>Difference in mean change (Exercise-Standard) Immediately post-intervention: LEFS (0-80): 5.4 (95% CI 1.07, 9.73) Pain on activity (0-100): 8.1 (95% CI 2.20, 14.0) Week 2: LEFS (0-80): 6.4 (95% CI 1.73, 11.07) Week 3: LEFS (0-80): 2.0 (95% CI -2.80, 6.80) Week 4: LEFS (0-80): 2.6 (95% CI -2.56, 7.76) Week 16: LEFS not measured at 16 weeks. No statistically significant difference between groups for any other secondary outcomes. Adverse Events During first four weeks of follow-up, no incidences of skin burns or nerve palsies recorded and no reinjuries reported.</td>
</tr>
<tr>
<td>Petersen et al., 2007 [53]</td>
<td>Patients with chronic midportion Achilles tendinopathy of &gt;3 months duration confirmed with ultrasonography and limiting desired activity level (n=100)</td>
<td>Eccentric training: Patients instructed to perform exercises 3x/day for 12 weeks, (3 sets of 15 repetitions with straight leg and knee bent and progressing load at individual tolerance) (n=37)</td>
<td>AirHeel brace: Brace to be worn during the daytime (n=35) Combination: Patients instructed to perform both eccentric training regimen with corresponding use of the AirHeel brace (n=28)</td>
<td>Immediately after intervention, and 52 weeks*</td>
<td>Primary outcomes: Pain during activities of daily living (ADL), during gait, during sports activity (VAS 0-10 reported as % change), AOFAS hindfoot scale (0-100),</td>
<td>AOFAS: No statistically significant difference s between groups at all follow-ups. Immediately post-intervention: VAS (ADL): Difference in % improvement (Exercise – Brace): 25%³ VAS (Gait): Difference in % improvement (Exercise – Brace): 21%³ VAS(Sport): No statistically significant difference</td>
</tr>
<tr>
<td>Author(s), Year</td>
<td>Subjects and Setting; Number (n) Enrolled</td>
<td>Interventions; Number (n) of Subjects</td>
<td>Comparisons; Number (n) of Subjects</td>
<td>Follow-up</td>
<td>Outcomes</td>
<td>Key Findings</td>
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<tr>
<td>Radford et al., 2007 [54]</td>
<td>Patients with clinical diagnosis of planter heel pain (&gt; 4 weeks) aged 18 years or older, and presenting to a university podiatry clinic in Australia (n=92)</td>
<td>Stretching: Participants advised to stretch at least 5 minutes per day (acceptable in 1 minute blocks or greater) on a wooden stretching wedge for 14 days, and received three minutes of sham ultrasound (n=46)</td>
<td>Sham Ultrasound: Participants received three minutes of sham ultrasound at painful heel (n=46)</td>
<td>Immediately post-intervention</td>
<td>SF-36 (0-100). Adverse events</td>
<td>Difference in mean change (Exercise-Brace) SF-36 General health: 11.2 (95% CI 6.32, 16.08) Vitality: 3.5 (95%CI -1.32, 8.32) No statistically significant differences for Physical functioning, Physical role, Bodily pain, Vitality, Social functioning, Emotional role and Mental health. Adverse Events Severe pain during exercises or discomfort due to poor fitting of the brace.</td>
</tr>
<tr>
<td>Rompe et al., 2010 [55]</td>
<td>Participants aged 18 years or older with acute plantar fasciopathy (&lt;6 weeks duration) with NRS ≥ 6 points during first morning steps, and presenting to three outpatient clinics in Germany (n=102)</td>
<td>Stretching: Instruction on plantar fascia-specific stretching to be performed three times daily for an 8 week period (n=54)</td>
<td>Radial shock-wave therapy: 3 sessions of radial shock-wave therapy at weekly intervals targeted circumferentially at area of maximum tenderness (n=48)</td>
<td>Immediately after intervention, 4, and 15 months</td>
<td>Primary outcomes: PS-FFI (0-10), SROM Adverse events</td>
<td>Immediately post-intervention: Difference in mean change (Stretching-Sham) Primary outcomes: 'First-step’ pain (VAS 0-100), FHSQ (0-100) Secondary outcomes: Weight-bearing ankle dorsiflexion (degrees), FPI-6 (12-12) Adverse events: No serious adverse events; Stretching: 2% participant discontinued due to an adverse events (not specified), 4.3% increased pain, 4.3% calf pain, 2.2% new pain in lower limb.</td>
</tr>
<tr>
<td>Author(s), Year</td>
<td>Subjects and Setting; Number (n) Enrolled</td>
<td>Interventions; Number (n) of Subjects</td>
<td>Comparisons; Number (n) of Subjects</td>
<td>Follow-up</td>
<td>Outcomes</td>
<td>Key Findings</td>
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<tr>
<td>Van Rijn et al., 2007 [56]</td>
<td>Adults aged 18 to 60 years with an acute lateral ankle sprain (&lt;1 week duration) consulting general practices or emergency department in the Netherlands (n=102)</td>
<td>Supervised exercise: Individual progressive training programme supervised by a physiotherapist (balance exercises, walking, running and jumping (maximum of nine half-hour sessions within a 3 month period) Education and advice:</td>
<td>Conventional: Education and advice: Same as supervised exercise group (n=49)</td>
<td>Immediately post-intervention, 12 months</td>
<td>Primary outcomes: Subjective recovery (0-10), occurrence of re-sprains (%) Secondary outcomes: Patients appreciation of treatment, reported</td>
<td>Immediately post-intervention: Difference in mean change (Exercise-Conventional) Subjective recovery (0-10): 0.33 (95% CI -0.60, 1.27) OR for re-sprain: 0.80 (95% CI 0.31, 2.03) OR for full treatment appreciation: 4.69 (95% CI 1.41, 15.5) favoring exercise group. No statistically significant difference between groups for ROM, reported instability, or tested instability.</td>
</tr>
<tr>
<td>Author(s), Year</td>
<td>Subjects and Setting; Number (n) Enrolled</td>
<td>Interventions; Number (n) of Subjects</td>
<td>Comparisons; Number (n) of Subjects</td>
<td>Follow-up</td>
<td>Outcomes</td>
<td>Key Findings</td>
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<tr>
<td>Zhang et al., 2013 [57]</td>
<td>Adults aged 18 to 70 years with chronic (≥2 months) Achilles tendinopathy (with pain during and after physical activity, tenderness on palpation, morning stiffness, swelling, painful and thickened tendon in relation to activity and palpation, approximately 2 to 7 cm proximal to insertion of calcaneus) (n=64)</td>
<td>Eccentric exercises: Instructed to perform eccentric exercises of the calf muscles on small step (with knee straight and flexed), 15 repetitions. If pain decreased, they could progress exercises by adding 5 kg weight. Patients were allowed to use NSAIDs if necessary or discuss option of surgical treatment with doctor if pain reduction was insufficient. (n=32)</td>
<td>Acupuncture (3 sessions per week for 8 weeks): Four needles inserted around Achilles tendon for 30 minutes. Patients were allowed to use NSAIDs if necessary or discuss option of surgical treatment with doctor if pain reduction was insufficient. (n=32)</td>
<td>Immediately post-intervention, 8 and 16 weeks post-intervention</td>
<td>Primary outcomes: Pain after activity (VAS 10 cm), pain at rest (VAS 10 cm), function (VISA-A out of 100) Secondary outcomes: treatment satisfaction (satisfied vs unsatisfied), use of painkillers, working status (partial or complete sick leave)</td>
<td>Difference in mean change (Exercise – Acupuncture): VISA-A (100 points): -19.50 (95% CI -22.26, -16.74) 8 weeks: Difference in mean change (Exercise – Acupuncture): VISA-A (100 points): -15.80 (95% CI -18.60, -13.00) 16 weeks: Difference in mean change (Exercise – Acupuncture): VISA-A (100 points): -11.80 (95% CI -14.84, -8.76) Statistically significant differences were reported favouring acupuncture immediately post-intervention (mean differences could not be calculated as data was presented in median and interquartile ranges). No statistically significant between group differences in treatment satisfaction, use of pain killers, or sick leave.</td>
</tr>
</tbody>
</table>

*Recalculated data from study: mean difference between within-group mean changes adjusted to baseline mean values and 95% confidence interval [49, 50] Acronym: AOFAS: American Orthopaedic Foot and Ankle Society; CI: Confidence Interval; FAAM: Foot and Ankle Ability Measure; FHSQ: Foot Health Status Questionnaire; FPI-6: Foot Posture Index; GBC: Global Rating of Change; LEFS: Lower Extremity Functional Scale; NPRS: Numeric Pain Rating Scale; NSAID: non-steroidal anti-inflammatory drugs; OR: Odds Ratio; PS-FFI: pain subscale of Foot Function Index; ROM: range of motion; SF-36: Short Form-36; SROM: patient-relevant outcome measures questionnaire; VAS: Visual Analogue Scale; VISA-A: Victorian Institute of Sports Assessment-Achilles

1 Not considered relevant due to sample size under 30 patients in this treatment arm

2 Results at 52 weeks not included in our synthesis due to differential attrition bias
3 Statistically significant at p < 0.05
Citations identified through database search: (n=11,187)

Duplicates removed (n=3,241)

Citations screened using titles and abstracts (n=7,946)

Ineligible citations (n=7,906)

Citations screened for eligibility using full-text (n=40)

Full-text articles excluded: 30

Primary reasons for exclusion:
- Ineligible design = 13
- Ineligible intervention = 9
- Small sample size = 4
- Ineligible population = 3
- Ineligible outcome measures = 1

Studies eligible for critically appraisal (n=10)

Studies with a high risk of bias (n=4)

Studies with a low risk of bias included in qualitative synthesis (n=6)
Highlights

- Exercising immediately or within one week of a lateral ankle sprain leads to similar outcomes.
- Supervised progressive exercise provides no added benefits to education and home exercise.
- Exercise may be more effective than AirHeel brace in the short-term but less effective than acupuncture for Achilles tendinopathy of more than two months duration.
- Plantar fascia stretching may provide short-term benefits to patients with plantar heel pain.
Disclosure of Potential Conflicts of Interest

Author disclosure forms have been completed by Pierre Côté, Robert Brison, and Silvano Mior (see attached). All other authors have no potential conflicts of interest to disclose.