The efficacy of non-surgical and non-pharmacological treatment options in the management of adults with osteoarthritis of the foot and ankle. a systematic review

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Purpose: Osteoarthritis (OA) of the foot and ankle is associated with pain and reduced function. Research has historically been focused on the hip and knee, and there is less evidence and understanding of treatment options for patients with OA of the foot or ankle. Therefore, the purpose was to systematically review available evidence for the efficacy of non-surgical and non-pharmacological treatment options in adult patients with osteoarthritis of the foot or ankle.
Methods: Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Statement guidelines were followed and the protocol was registered with the International Prospective Register of Systematic reviews (PROSPERO registration number CRD42018106390). A comprehensive search of MEDLINE, CINAHL, AMED, PubMed, PsycInfo, SPORTDiscus, Central Register of Controlled Trials, Web of Knowledge/Science and the Cochrane databases from their inception to 9$_{th}$September 2019 was conducted (Figure 1). Studies were screened using predefined inclusion/exclusion criteria. a) adult human participants with a clinical or radiological diagnosis of the ankle or foot, b) non-pharmacological or non-surgical intervention and c) patient reported outcome measure for pain, function, quality of life or wellbeing. Studies were excluded if they evaluated rehabilitation in conjunction with surgical or pharmacological interventions. The studies were assessed for quality and risk of bias. Analysis was undertaken for the efficacy of the interventions described in the data. The search strategy was developed using the Population, Intervention, Comparison, Outcome and Study design (PICOS) framework and was adapted for each information source$_{13}$. Restrictions were placed for adult, and human only studies. Methodological quality was assessed by the modified Downs and Black tool and study quality was based on previous literature: excellent (26-28); good (20-25); fair (15-19) and poor (≤14) (Figure 2). A manual reference list search of included studies did not reveal additional studies.

Results: Of 408 identified studies, the abstracts of 271 unique studies were screened. 42 full text articles were assessed for eligibility. 9 satisfied the inclusion criteria for analysis in the review. These were 1 randomised trial, 1 randomised controlled trial (RCT) feasibility study, 1 quasi-randomised controlled trial, a pilot case-control study, 3 case series, 1 prospective comparative study and 1 retrospective cross sectional study. There were a total of 378 recruited participants of whom 363 had an OA diagnosis and 15 were healthy individuals with no history of OA. Four studies looked at first metatarsophalangeal (MTP) joint OA, 4 studies looked at midfoot OA which included the first metarso-cuneiform joint, second metatarso-cuneiform joint, the navicular-cuneiform joint and the talo-navicular joint, and one study reported results for pedal OA defined as pain in the ankle, heel and forefoot location 'all diagnosed radiographically as OA'. No studies reported data for left, right or bilateral feet symptoms separately, nor were results reported independently for male and female participants. The interventions assessed were custom made insoles, rocker sole footwear, shoe-stiffening inserts and carbon fibre footplates and physiotherapy interventions of joint mobilisations, manipulation, strengthening exercises, gait training, advice and education. In shoe orthotics or insoles had the largest number of studies and focused on midfoot and first metatarsophalangeal OA. Two studies focused on manual therapy and strength training for first metatarsophalangeal OA. No studies focused on treatments specifically for ankle OA. Meta-analyses for pain, function, quality of life or well-being outcomes were not possible due to the heterogeneity of the results.
Conclusions: There is tentative evidence that full length carbon fibre inserts are effective in the treatment of pain and improving physical function in subjects with midfoot OA. But, it is yet to be established if foot orthoses are a more effective treatment for this patient population than rocker-soled shoes. The use of orthoses in the treatment of foot pain and physical function for first MTP OA has minimal evidence and there is a small body of low-quality evidence for the use of specific manual therapy techniques, strengthening exercises and gait training in this same population. There is a paucity of evidence to sufficiently address this review's objectives in terms of quality of life and wellbeing outcomes and there remains no evidence to investigate the efficacy of non-pharmacological and non-surgical management of patients with ankle OA.

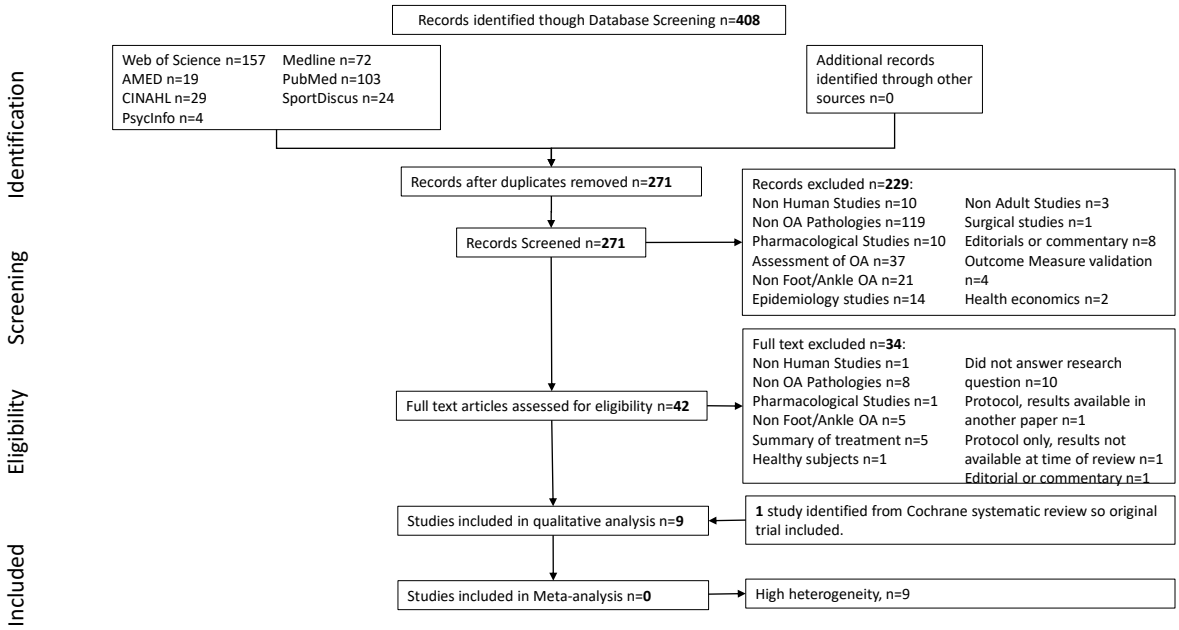

Figure 1. PRISMA 2009 flow diagram for the selection process

Modified Downs and Black.	Brantingham 2015[22]	Halstead 2016[23]	Ibuki 2010[24]	Jerilyn 2016[25]	Menz 2016[26]	Rao 2009[27]	Shamus 2004[28]	Thompson 1992[21]	Yi 2018[29]	Studies scoring full marks (%)
Reporting										
1. *Is the hypothesis/aim/objective of the study clearly described?*	1	1	1	1	1	1	1	1	1	**100**
2. *Are the main outcomes to be measured clearly described in the Introduction or Methods section?*	1	1	1	1	1	1	1	1	1	**100**
3. *Are the characteristics of the patients included in the study clearly described?*	0	1	1	1	1	1	1	1	1	**89**
4. *Are the interventions of interest clearly described?*	1	1	1	1	1	1	1	0	1	**89**
5. *Are the distributions of principal confounders in each group of subjects to be compared clearly described?*	0	2	0	2	2	0	0	1	2	**44**
6. *Are the main findings of the study clearly described?*	1	1	1	1	1	1	1	0	1	**89**
7. *Does the study provide estimates of the random variability in the data for the main outcomes?*	0	1	1	1	1	1	1	0	1	**78**
8. *Have all important adverse events that may be a consequence of the intervention been reported?*	1	1	0	1	1	0	0	0	0	**44**
9. *Have the characteristics of patients lost to follow-up been described?*	1	1	1	1	1	1	1	1	1	**100**
10. *Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?*	0	0	0	1	1	1	0	0	1	**44**
External Validity										
11. *Were the subjects asked to participate in the study representative of the entire population from which they were recruited?*	0	0	0	0	0	0	0	0	0	**0**
12. *Were those subjects who were prepared to participate representative of the entire population from which they were recruited?*	0	0	0	1	0	0	0	0	0	**11**

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13. *Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?*	0	1	0	0	0	0	0	1	1	**33**
Internal Validity – Bias										
14. *Was an attempt made to blind study subjects to the intervention they have received?*	0	1	0	0	0	0	0	0	0	**11**
15. *Was an attempt made to blind those measuring the main outcomes of the intervention?*	0	1	0	0	1	0	0	0	0	**22**
16. *If any of the results of the study were based on "data dredging", was this made clear?*	1	1	1	1	1	1	1	1	1	**100**
17. *In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?*	1	1	1	1	1	1	1	0	1	**89**
18. *Were the statistical tests used to assess the main outcomes appropriate?*	1	1	1	1	1	1	1	0	1	**89**
19. *Was compliance with the intervention/s reliable?*	1	1	0	0	1	0	1	1	1	**67**
20. *Were the main outcome measures used accurate (valid and reliable)?*	1	1	0	1	1	1	1	0	1	**78**
Internal Validity – Confounding										
21. *Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?*	0	1	1	0	1	1	1	1	0	**67**
22. *Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?*	0	0	0	0	1	0	0	0	0	**11**
23. *Were study subjects randomised to intervention groups?*	0	1	0	0	1	0	0	0	0	**22**
24. *Was the randomised intervention assignment concealed from both patients and health care staff until recruitment as complete and irrevocable?*	0	1	0	0	0	0	0	0	0	**11**
25. *Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?*	0	0	0	1	0	0	0	0	1	**22**
26. *Were losses of patients to follow-up taken into account?*	1	1	1	1	1	1	1	1	1	**100**
Power – Modified[17,18,19]										
27. *Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?* Sample sizes have been calculated to detect a difference of x% and y%.	0	0	1	0	1	0	1	0	0	**33**
Total score: /28	**12**	**22**	**13**	**18**	**22**	**14**	**15**	**10**	**18**	

Green Shading = Full Score, Amber shading = Partial Score, Red shading = No score or unable to determine

Figure 2. Results from quality Assessment of all included papers