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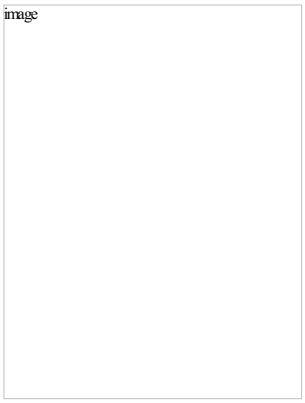

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Footwear interventions for foot pain, function, impairment and disability for people with foot and ankle arthritis: a literature review

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Abstract

Objective: To conduct a literature review on the effectiveness of footwear on foot pain, function, impairment and disability for people with foot and ankle arthritis.

Methods: A search of the electronic databases Scopus, Medline, CINAHL, SportDiscus and the Cochrane Library was undertaken in September 2017. The key inclusion criteria were studies reporting on findings of footwear interventions for people with arthritis with foot pain, function, impairment and/or disability. The Quality Index Tool was used to assess the methodological quality of studies included in the qualitative synthesis. The methodological variation of the included studies was assessed to determine the suitability of meta-analysis and the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system. Between and within group effect sizes were calculated using Cohen's *d*.

Results: 1440 studies were identified for screening with 11 studies included in the review. Mean (range) quality scores were 67% (39%-96%). The majority of studies investigated rheumatoid arthritis (n=7), but also included gout (n=2), and 1st metatarsophalangeal joint osteoarthritis (n=2). Meta-analysis and GRADE assessment were not deemed appropriated based on methodological variation. Footwear interventions included off-the-shelf footwear, therapeutic footwear and therapeutic footwear with foot orthoses. Key footwear characteristics included cushioning and a wide toe box for rheumatoid arthritis; cushioning, midsole stability and a rocker-sole for gout; and a rocker-sole for 1st metatarsophalangeal joint osteoarthritis. Between group effect sizes for outcomes ranged from 0.01-1.26. Footwear interventions were associated with reductions in foot pain, impairment and disability for people with rheumatoid arthritis. Between group differences were more likely to be observed in studies with shorter follow-up periods in people with rheumatoid arthritis (12 weeks). Footwear interventions improved foot pain, function and disability in people with gout and foot pain and function in 1st metatarsophalangeal joint osteoarthritis. Footwear interventions were associated with changes to plantar pressure in people with rheumatoid arthritis, gout and 1st metatarsophalangeal joint osteoarthritis and walking velocity in people with rheumatoid arthritis and gout.

Conclusion: Footwear interventions are associated with reductions in foot pain, impairment and disability in people with rheumatoid arthritis, improvements to foot pain, function and disability in people with gout and improvements to foot pain and function in people with 1st metatarsophalangeal joint osteoarthritis. Footwear interventions have been shown to reduce plantar pressure rheumatoid arthritis, gout and 1st metatarsophalangeal joint osteoarthritis and improve walking velocity in rheumatoid arthritis and gout.

Keywords:

Systematic review, Arthritis, Interventions, Foot, Pain

Introduction

Foot problems are commonly observed by people with foot and ankle arthritis [1, 2]. High levels of foot pain, impairment and disability are also reported in this population [3, 4]. Foot problems in people with arthritis are also associated with reduced function [5] and quality of life [6]. Reduced walking velocity and increased plantar pressure is also observed in people with arthritis [7]. The aim of pharmacological and non-pharmacological management of foot and ankle arthritis is pain reduction, maintenance of function, accommodation of existing deformity and prevention of further deformity. Footwear is routinely used as non-pharmacological intervention [8]. Footwear can include off-the-shelf footwear, therapeutic footwear and therapeutic footwear combined with a foot orthosis. People with arthritis affecting the foot and ankle often use footwear which may contribute to foot pain and associated disability [9] and describe difficulties in finding suitable footwear [10]. Current evidence suggests that footwear may offer benefits for people with foot and ankle arthritis [11-13]. While there are studies examining the effects of footwear, at this time it is difficult to appreciate the strength and consistency of experimental work providing support for the utilisation of footwear in arthritic conditions. Hence, the aim of this review is to evaluate the evidence for the clinical effectiveness of footwear interventions for foot pain, function, impairment and disability in people with arthritis.

Methodology

Identification of studies

The following electronic databases (CINAHL, MEDLINE, Scopus, SPORTDiscus and the Cochrane Library) were searched in September 2017, with no limitations were placed on the publication date. The search strategy comprised of the following keywords: arthritis, rheumatoid arthritis, gout, osteoarthritis, rheumatic disease, psoriatic arthritis, lupus erythematous, ankylosing spondylitis, systemic sclerosis, polymyalgia rheumatica *with* footwear, footwear intervention, foot orthoses, foot orthosis, foot orthotic, insole and shoe (supplementary material table 1). The term 'footwear interventions' encompasses the use of footwear, footwear with orthoses in the management of arthritic conditions.

Inclusion/exclusion criteria

Titles and abstracts were screened by a single reviewer (MF). Full-text articles were obtained from selected abstracts and compared against the following inclusion criteria by a single reviewer (MF). Studies were included if they met the following criteria: being a randomised controlled trial, prospective observational intervention trials or cross-sectional intervention trials; published in English; peer-reviewed publications; participants over the age of 18 years; studies reporting on findings of footwear interventions for people with arthritis with foot pain, function (including temporal-spatial, plantar pressure, kinematic and kinetic data), impairment and/or disability measured as a primary outcome. Studies were excluded if: investigated arthritis not affecting the foot or ankle; case study and case series design; studies reporting findings of interventions where footwear was not been standardised for participants (custom footwear); studies where footwear was used as a control condition for foot orthoses or adapted for three-dimensional marker placement for foot orthosis interventions. Off-the-shelf footwear was defined as commercially available walking and running shoes. Therapeutic footwear was defined as readymade, orthopaedic-style footwear. Citations of retrieved publications were examined to obtain further sources.

Data extraction

A standardised form was used to extract publication details (author(s) and year), study design, participant sample characteristics (age gender, participants entered into study), follow-up period, description of footwear intervention, control/comparator intervention and outcome measures used to assess foot pain, function, impairment and disability were recorded.

Assessment of methodological quality

Methodological quality was independently assessed by two authors (MF and MC) using the Quality Index Tool [14]. The Quality Index Tool comprises of 27 items allowing for the assessment of internal validity, external validity, power, analysis and reporting. Item 27 was adapted to be scored, 0 or 1 based on the reporting of a powered sample size calculation. Total raw scores were converted into a percentage. The tool displays high internal consistency, test-retest reliability and inter-rater reliability [14]. Kappa statistic was used to assess intra-tester agreement between reviewers. All disagreements in scoring were resolved following discussion, with a third reviewer (KR) consulted if consensus could not be reached. The methodological variation of the included studies was assessed to determine the suitability of meta-analysis and the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system [15]. Between and within group effect sizes were calculated for the included studies using Cohen's *d*, with effect sizes interpreted as negligible (<0.2), small (≥0.2), medium (≥0.5) and large (≥0.8) [16].

Results

Search results

Following the removal of duplicates, 1440 studies were screened with 1384 records excluded with 56 full-text records obtained (Figure 1). A further 45 records were excluded. Key reasons for the exclusion of studies included the use of custom footwear and the use of footwear as a control condition for 3D gait analysis. A total of 11 studies met the inclusion criteria for assessment. Of the included studies, seven investigated rheumatoid arthritis (RA) [17-19, 13, 20-22], two investigated gout [11, 23], and two investigated first metatarsophalangeal joint osteoarthritis (1MTP OA) [12, 24]. Five studies were randomised clinical trials [18, 19, 13, 21, 12], three studies were prospective observational intervention studies [11, 17, 22] and three studies were laboratory-based intervention studies [20, 23, 24].

Methodological quality of studies

The inter-rater agreement between reviewers showed good agreement (kappa statistic: 0.81). Quality index scores ranged from 39% - 96% (Table 1). Quality assessment of studies highlighted higher bias with respect to blinding of participants and assessors to treatment allocation, blinding of assessors to main outcomes, external validity, adjustment for confounding and reporting adverse events attributed to inventions.

Study characteristics

Study characteristics are displayed in Tables 2-4. A total of 382 participants with arthritis affecting the foot and ankle were reported, with 218 RA, 92 1MTP OA and 72 participants with gout. In the gout and RA studies, the majority of participants had well-established disease duration, but for 1MTP OA the majority had early disease duration. Follow-up period ranged between 8-24 weeks. Meta-analysis and GRADE assessment were not deemed appropriated based on the variation in disease type, interventions and tools used to measure primary outcomes. Negligible to large between group effect sizes were observed for foot pain, function impairment and disability.

Footwear interventions

Footwear interventions included off-the-shelf footwear [20, 11, 23, 12, 24], therapeutic footwear [18, 13, 17, 22, 20] and therapeutic footwear combined with foot orthoses [19, 21].

Off-the-shelf footwear

The use of off-the-shelf footwear was reported in people with RA [20], gout [23, 11] and 1MTP OA [12, 24]. In one study in people with RA, an athletic shoe was used with the footwear characteristic of this shoe being cushioning for forefoot pain [20]. For people with gout a range of walking shoes were used and divided into good footwear characteristics and poor footwear characteristics. Good footwear characteristics included a rocker-sole to facilitate a heel-to-toe gait, a dual-density midsole to provide motion control, heel and forefoot cushioning to improve shock attenuation and a zip to allow for ease of entry and exit of footwear [11, 23]. Poor footwear characteristics included a single density midsole, no cushioning, minimal heel counter stiffness and midsole stability [11, 23]. For people with 1MTP OA, a rocker-sole shoe was used, allowing smoother progression of the body's centre of mass over the stance foot, reducing the amount of 1MTP dorsiflexion required and loading at the forefoot joints [12, 24].

Therapeutic footwear

The use of therapeutic footwear was reported in five studies for people with RA [18, 13, 17, 22, 20]. Footwear characteristics included extra-depth in the forefoot region to accommodate for foot orthoses and forefoot deformity, soft leather upper and smooth lining to offer protection, laces, padded heel counter to improve fit at the heel and a long inside counter to improve rearfoot stability and arch support [18].

Therapeutic footwear combined with foot orthoses

The use of therapeutic footwear with a foot orthosis was reported in two studies for people with RA [19, 21]. Footwear characteristics included a wide and deep toe box was used to accommodate for the foot orthoses. Foot orthoses used in these studies included semi-rigid and soft devices, manufactured as both prefabricated and custom.

Foot pain

Rheumatoid arthritis

Three RCTs [21, 13, 19] and one prospective observational study [22] measured foot pain in people with rheumatoid arthritis. One RCT [13] compared traditional therapeutic footwear to a newer therapeutic footwear designed with patient and practitioner input. After 12 weeks, significant between group improvement was observed for the newer therapeutic footwear group compared to the traditional therapeutic footwear group (*d*= 0.92-1.26; large effect). Significant within group improvement in foot pain was observed in the newer therapeutic footwear group (*d*= 1.08-1.24; large effect), with no significant improvement in the traditional therapeutic footwear group (*d*= 0.18-0.19; negligible effect). Another RCT [19] compared three footwear conditions; extra-depth footwear only, extra-depth footwear with soft foot orthoses and extra-depth footwear with semi-rigid foot orthoses. At 12 weeks, significant between group reductions in MTP pain was reported in the extra-depth footwear with semi-rigid orthoses group compared to the footwear with soft orthoses group (*d*=0.45; medium effect) and footwear only group (*d*=0.78; medium effect). There was no significant

within group improvement observed in the footwear with soft orthoses and footwear only groups at 12 weeks. A further RCT [21] compared extra-depth footwear with semi-rigid foot orthoses compared to extra-depth footwear with soft orthoses. After 24 weeks, no significant difference was found between groups (*d*= 0.46; small effect), however, significant within group improvements in foot pain was observed in the footwear with semi-rigid orthoses group (*d*=0.56; medium effect) and the footwear with soft orthoses group (*d*=1.07; large effect). The prospective observational study [22] reported significant within group improvements in foot pain with high-top, rocker-sole footwear after 4 weeks (*d*=1.45; large effect), however, there was no comparator to this intervention.

Gout

One prospective observational study [11] measured foot pain in people with gout. One group with good footwear characteristics was compared to a group with poor footwear characteristics over an eight-week period. After eight weeks, significant within group improvement in foot pain was observed in the good footwear characteristics group only (*d*=0.75; medium effect). There was no significant improvement in foot pain in the poor footwear characteristics group (*d*=0.19; negligible effect).

1MTP OA

One RCT [12] measured foot pain in people with 1MTP OA. Rocker-sole footwear was compared to the participant's own footwear with foot orthoses. After 12 weeks, improvements in foot pain were observed in the rocker-sole footwear group (*d*=1.25; large effect) and own footwear with foot orthoses group (*d*=0.95; large effect), however, no significant differences were observed between groups at follow-up (*d*=0.01; negligible effect).

Patient-reported outcomes

Patient reported outcome measures assessing function, impairment and disability were reported for RA, gout and 1MTP OA.

Rheumatoid arthritis

One RCT [18] reported a significant within group improvement in function in the extra-depth footwear group with no improvement in the control group at eight weeks. The control group of this sample were subsequently provided with extra-depth footwear in a repeated-measures design with significant within group improvements in function at eight weeks (*d*=0.30; small effect). Another RCT [13] reported significant between group improvement in foot function, functional limitation and disability in the new design therapeutic footwear compared to traditional therapeutic footwear at 12 weeks (*d*=0.88-1.07; large effect). Significant within group improvement was seen in the new design therapeutic footwear (*d*=0.92-1.06; large effect) with non-significant within group improvement in the traditional therapeutic footwear group (*d*=0.04-0.33; negligible-small effect). One RCT [21] comparing therapeutic footwear with soft orthoses and therapeutic footwear with semi-rigid orthoses reported no significant between group differences in activity limitation and disability at 24 weeks (*d*=0.94; large effect). Non-significant within group improvements in activity limitation and disability was observed in the footwear with semi-rigid orthoses group (*d*=0.78; medium effect) and the footwear with soft orthoses group (*d*=1.31; large effect). One prospective observational study [17] reported a significant within group improvement in self-reported walking ability with heat-mouldable footwear (unable to calculate effect size). Another prospective observational study [22]

reported within group improvements in foot function, activity limitation and disability with rocker-sole footwear use at four weeks (*d*=1.03; large effect).

Gout

One prospective observational study [11] measured function, foot-related impairment and disability. Significant improvements in function (*d*=0.44; small effect) and foot-related disability (*d*=0.67; medium effect) were observed in the good footwear characteristics group, with no significant differences observed in the poor footwear characteristics group at eight weeks (*d*=0.14-0.17; negligible effect).

1MTP OA

One RCT [12] measured function. Improvements in foot function were observed in the rocker-sole footwear group (*d*=0.61; medium effect) and own footwear with foot orthoses group (*d*=0.58; medium effect), however, no significant differences were observed between groups at follow-up (*d*=0.04; negligible effect).

Plantar pressure and temporal-spatial parameters

Data for plantar pressure and temporal-spatial parameters was reported for three conditions; RA, gout and 1MTP OA.

Rheumatoid arthritis

One cross-sectional study [20] reported significant reductions in total foot, rearfoot and forefoot peak plantar pressure (PPP) in the running footwear (*d*=1.84, 1.07, 1.78; large effects) and orthopaedic footwear (*d*=0.86, 0.82, 0.84; large effects) groups compared to the control group. Significant reductions in total foot (*d*=1.72, 1.06; large effects) and forefoot pressure (*d*=1.74, 1.14; large effects) time integrals (PTI) in the running footwear and orthopaedic footwear groups compared to the control group. Significant reductions in rearfoot PTI was observed in the running footwear group compared to the control group (*d*=0.24; small effect). Significant reductions in PPP and PTI for total foot pressure (*d*=1.02, 0.87; large effects) and forefoot pressure (*d*=0.91, 0.84; large effects) in the running footwear group compared to the orthopaedic footwear group. One RCT [18] reported significant within group increases in walking velocity (*d*=0.31; small effect) and stride length (*d*=0.30; small effect) following the provision of extra-depth footwear compared to the participant's own shoes after eight weeks. Another RCT [19] reported no within group or between group improvements during overground walking, stair climbing or 50 foot walk time with extra-depth footwear only, extra-depth footwear with soft orthoses and extra-depth footwear with semi-rigid orthoses after 12 weeks (*d*=0-0.16; negligible effect).

Gout

One cross-sectional study [23] compared good footwear characteristics to poor footwear characteristics to the participant's own footwear. Significant reductions in PPP and PTI at the heel and 5MTP with increases in midfoot pressure was observed in the good footwear characteristics group compared to the poor footwear characteristics footwear group (*d*=0.02-0.70; negligible-medium effect). Significant within group reductions in PPP at 3MTP and 5MTP, reductions in PTI at 3MTP, 5MTP and heel with increases in midfoot PTI was observed in the good footwear characteristics group compared to their own footwear (*d*=0.03-1.11; negligible-large effect).

Significant within group increases in PPP at the heel and lesser toes, reductions at 3MTP and reductions in midfoot PTI was observed in the poor footwear characteristics group compared to their own footwear (*d*=0.02-0.44; negligible-small effect). Significant within group increases in walking velocity, step length and stride length in both the good and poor footwear characteristics groups compared to the participant's own footwear (*d*=0.16-0.53; negligible-medium effect), however, no between group differences were observed (*d*=0.29; small effect).

1MTP OA

One cross-sectional study [24] reported significant within group reductions in PPP were observed at 1MTP (*d*=0.31; small effect), 2-5MTP (*d*=0.91; large effect) and heel (*d*=0.90; large effect) in the rocker-sole footwear group compared to the participant's own footwear. Significant reductions in PPP at lesser toes (*d*=0.35; small effect), 2-5MTP (*d*=1.12; large effect) and midfoot (*d*=0.72; medium effect) was observed between the footwear intervention group compared to the own footwear with orthoses group. A significant reduction in stance phase percentage (*d*=0.51; medium effect) in the rocker-sole footwear group compared to the own footwear with orthoses group. Significant within-group reductions for cadence (*d*=0.25; small effect) and stance phase percentage (*d*=0.43; small effect) were observed in the rocker-sole footwear group compared to the participant's own footwear.

Discussion

The aim of this systematic review was to identify and evaluate the evidence for the clinical effectiveness of footwear interventions for foot pain, function, impairment and disability in people with arthritis. Despite the broad search strategy, the search only identified studies investigating RA, gout and 1MTP OA. The findings of the review support that footwear is associated with improvements to foot pain, function, impairment and disability in people with RA. There is evidence to suggest that footwear is associated with improvements to foot pain, function and disability in people with gout and improvements to foot pain and function in people with 1MTP OA. A greater body of evidence exists for RA compared to gout and OA, and there are no studies of footwear interventions for other forms of arthritis.

Within and between group effect sizes for foot pain indicate that footwear interventions are likely to result in improvements to foot pain in people with arthritis. However, for people with rheumatoid arthritis there was conflicting evidence between studies as to which type of intervention was preferable. Between group findings indicated the majority of studies in favour of therapeutic footwear with a semi-rigid insole compared to therapeutic footwear with a soft insole on foot pain, however, one study favoured therapeutic footwear with a soft insole compared to a semi-rigid insole.

There was considerable variation in the methodology with respect to the footwear interventions and measures used to assess both primary and secondary outcomes. Of the included studies, footwear interventions included footwear only and footwear with orthoses conditions. It is difficult to isolate the individual treatment effect of footwear and foot orthoses when prescribed individually or as co-interventions. It is also difficult to ascertain if the observed changes are related to 'the footwear' or specific characteristics of the footwear. There is currently no universally accepted standard for the measurement of foot pain and self-reported foot pain intensity is the most frequently used research tool to measure foot pain [25]. Instruments include visual analogue scales (VAS), numeric rating

scales and verbal category/Likert scale. The complexity of arthritic conditions may advocate the use of multiple tools to capture the spectrum of foot pain across a particular condition.

In the RCTs investigating RA, differences between groups was observed in studies with a shorter follow-up period (from 4 to 12 weeks) compared to studies with a longer follow-up period (24 weeks). The lack of a control group in the observational studies for people with RA was also a limitation. It is difficult to discuss the influence of follow-up periods for gout and 1MTP OA as there was only one longitudinal study for each condition. The description of footwear interventions ranged from the use of footwear assessment scales, listing desirable footwear characteristics or simply stating the type of footwear. There was also inconsistency in the observed changes to outcomes in the control groups in the RA population. Such variance in the description of footwear and findings makes it difficult to determine if changes to the outcomes are be attributed to 'footwear' or specific footwear characteristics.

Footwear was associated with reductions in plantar pressure in people with RA, gout and 1 MTP OA. The studies included which investigated plantar pressure all employed a cross-sectional design, so it is unclear whether these changes are maintained over time or are associated with improvements to patient reported outcomes. Footwear was also associated with changes to walking velocity and stance time. Significant reductions in walking velocity have been found in people with arthritis [7]. Reduced walking velocity and increased stance time are indicative of foot related-impairment and disability [26]. A limitation of these findings is that their relationship to other parameters such as in-shoe kinematics and kinetics is unknown.

When considering footwear for people with RA, key footwear characteristics associated with improvements to patient reported outcomes included extra-depth footwear and cushioning. Adequate toe box volume allows for the accommodation of forefoot deformity and foot orthoses. Foot pain associated with forefoot deformity [26] and increased forefoot plantar pressure have been reported people with RA [27]. Footwear with cushioned midsoles can significantly reduce forefoot plantar pressure in people with RA [20]. The mean disease duration in the included studies is indicative of participants with established RA. People with early onset RA may present with different footwear needs.

Footwear characteristics which may be associated with improvements to foot pain and disability include cushioning and support for people with gout [11]. These benefits may be related to changes in plantar pressure and temporal-spatial parameters [23]. Footwear with an absence of cushioning, minimal heel counter and midsole stability were not associated with improvements to foot pain in people with gout [11]. Footwear with poor cushioning and support is common in people with gout and is associated with higher levels of foot-related impairment and disability [9]. Difficulties finding footwear which fits appropriately, accommodates existing deformity and is suitable for activities of daily living has been identified by people with gout [28-30]. Further investigation into these domains may help to improve understanding regarding footwear habits of people with gout.

For people with 1MTP OA, the rocker-sole characteristic of the footwear was found to reduce loading at the 1MTP and subsequent improvement in patient reported outcomes. These reductions may be attributed to reductions in 1-5MTP plantar pressure, cadence and stance time percentage observed with the rocker-sole footwear compared to participant's own footwear [24]. Biomechanical changes have been reported with rocker-sole footwear in both asymptomatic and symptomatic populations, however, it is difficult to determine if these changes are associated with improved patient-reported outcomes [31].

This review is not without limitations. Pooling of data was not possible due to the methodological inconsistency between the included studies, thus recommendations regarding the most appropriate intervention cannot be made. The search strategy did not include unpublished literature including theses and conference proceedings. Differences in the reporting of footwear characteristics made it difficult to draw conclusions regarding the influence of specific design features on patient-reported outcomes and biomechanical variables. Not all types of footwear have been tested in clinical studies, and it is unclear whether findings can be generalised to other types of footwear which may deliver different biomechanical effects. As much of the data presented comes from cross-sectional studies, the long-term effects of footwear on gait parameters remains unclear.

Future work needs to explore the foot-related problems and footwear needs of people with other arthritic conditions. Improved understanding of these conditions may help to determine the role of footwear interventions in the management of these populations. The majority of the studies included in this review were for RA with only one RCT with a follow-up period beyond 12 weeks. Longitudinal prospective studies and randomised clinical trials may help to determine the clinical effectiveness of footwear. Further prospective studies may help to determine if changes to gait parameters associated with footwear are preserved and associated with improvements to patient reported outcomes.

Conclusion

Footwear interventions are associated with reductions in foot pain, impairment and disability in people with rheumatoid arthritis, improvements to foot pain, function and disability in people with gout and improvements to foot pain and function in people with 1st metatarsophalangeal joint osteoarthritis. Footwear interventions have been shown to reduce plantar pressure rheumatoid arthritis, gout and 1st metatarsophalangeal joint osteoarthritis and improve walking velocity in rheumatoid arthritis and gout.

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Conflict of interest statement

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Tables/figures

In-text figures and tables:

Figure 1: PRISMA flow diagram of search strategy

Table 1: Quality Index scoring of included studies

Table 2: Description of randomised clinical trials

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Table 4: Description of included lab-based intervention studies

Supplementary material:

Table 1: Search strategy

Figure 1

PRISMA flow diagram of search strategy

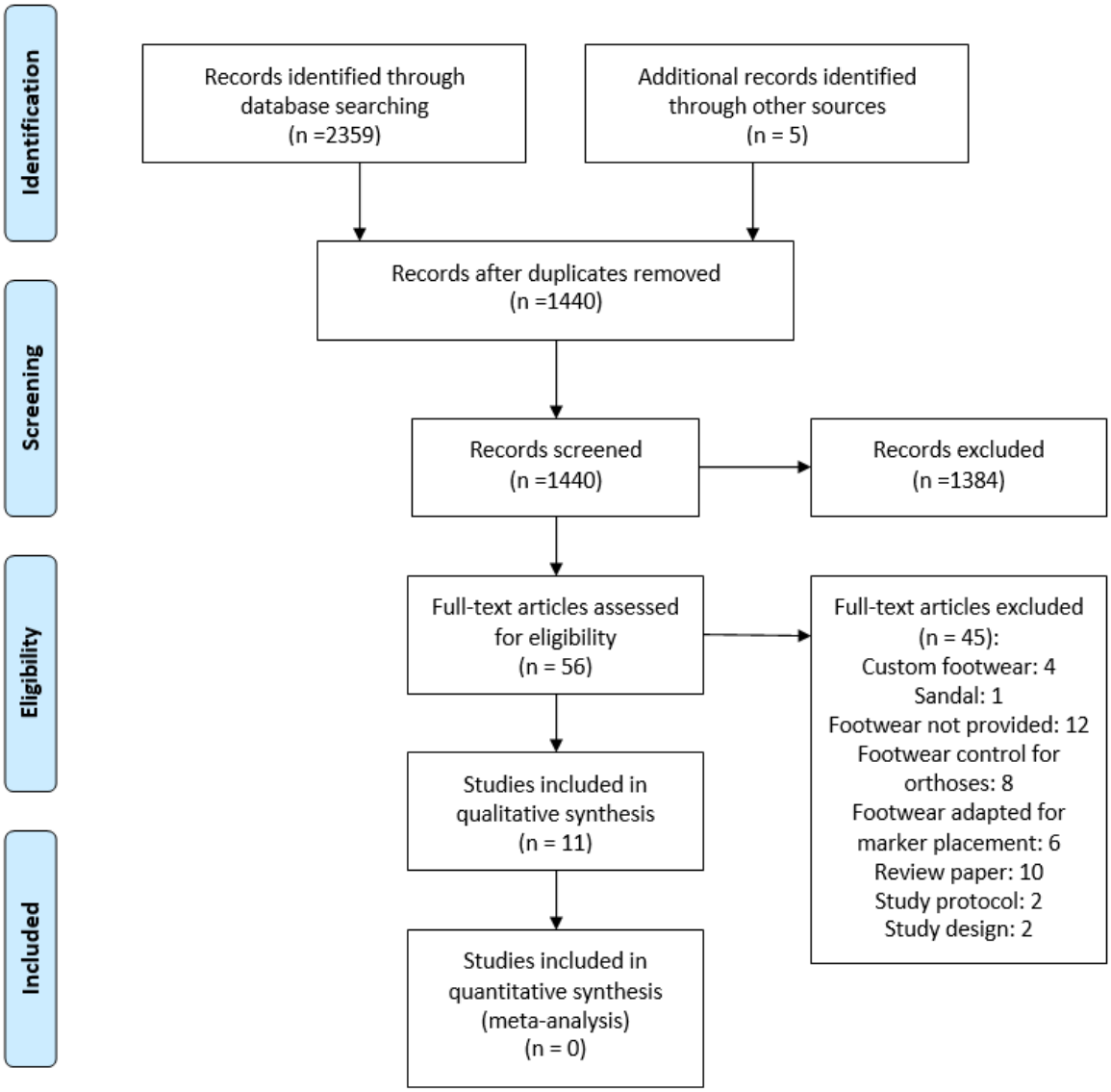

Table 1

Quality assessment scores of included studies

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
Moncur & Ward, 1990 [17]	1	1	1	1	0	1	0	1	1	0	0	0	0	0	0	1	0	0	1	0	1	0	0	0	0	1	0
Fransen & Edmonds, 1997 [18]	1	1	1	1	1	1	1	0	0	1	0	0	0	0	0	1	1	0	1	1	1	0	1	0	0	1	1
Chalmers et al. 2000 [19]	1	1	1	1	1	1	1	1	1	1	0	0	1	0	1	1	1	1	1	1	1	1	1	0	0	1	1
Williams et al. 2007 [13]	1	1	1	1	1	1	1	1	1	1	0	0	1	1	0	1	1	1	0	1	1	0	1	1	0	0	1
Hennessy et al. 2007 [20]	1	1	1	1	1	1	1	0	na	1	0	0	1	1	0	1	na	1	na	1	1	1	1	1	0	na	1
Cho et al. 2009 [21]	1	1	1	1	1	1	1	0	1	1	0	0	1	0	0	0	1	1	0	1	1	1	1	0	0	0	1
Rome et al. 2013 [11]	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1	1	1	1	1	0	1	1	1	1	1
Bagherzadeh Cham et al. 2014 [22]	1	1	1	1	1	1	1	0	1	1	0	0	0	0	0	1	1	1	0	1	0	0	0	0	0	1	0
Stewart et	1	1	1	1	1	1	1	0	na	1	0	1	1	1	0	1	na	1	na	1	1	0	1	1	1	na	0

al. 2014 [23]																										
Menz et al. 2016 [12]	1	1	1	1	2	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1
Menz et al. 2016 [24]	1	1	1	1	2	1	1	0	na	1	1	1	1	0	0	1	na	1	na	1	1	1	1	1	1	na	0

1 Study objectives clearly described? 2 Main outcome measures described in introduction and methods? 3 Patient characteristics clearly described? 4 Interventions clearly described? 5 Distribution of confounders described? 6 Main study findings clearly described? 7 Estimates of random variability in data for main outcomes described? 8 Adverse events reported? 9 Characteristics of patients lost to follow-up described? 10 Confidence intervals and/or actual *P* values reported? 11 Subjects asked to participate representative of entire population? 12 Subjects who agreed to participate representative of entire population? 13 Staff and facilities representative of treatment patients receive? 14 Blinding of patients to interventions?	15 Blinding of assessors measuring main outcomes? 16 Results based on data dredging made clear? 17 Adjustment for different lengths of follow-up? 18 Statistical tests for main outcomes appropriate? 19 Compliance with intervention reliable? 20 Main outcome measures accurate (valid and reliable)? 21 Cases and controls recruited from same population? 22 Cases and controls recruited over the same period of time? 23 Patients randomised to intervention groups? 24 Randomisation concealed from patients and assessors until after recruitment? 25 Adequate adjustment for confounding? 26 Losses of patients to follow-up take into account? 27 Power calculation?

Table 2

Characteristics of included randomised clinical trials

Author	**Nos (% Female)**	**Sample characteristics Mean (SD)**	**Follow-up (weeks)**	**Intervention**	**Control**	**Outcome measures**	**Findings**	**Quality score**
Franse n & Edmon ds, 1997	15 RA (80%) 15 Contr	Interventio n group Age: 59 (14) Disease	8	**Extra-depth footwear** (P.W. Minor & Son Inc.)	Own footwear	**Primary outcome** Not stated	**Between group measures** Not reported.	**54%**

[18]	ols (67%)	duration: 16 (10) Control group Age: 60 (9) Disease duration: 15 (12)		Long inside counter (rear stability and arch support), foam padded heel counter (leather lining), soft leather upper, extra depth (orthoses accommodation)		**Outcomes assessed** Lower limb walk pain, lower limb stair pain, lower limb NWB pain (VAS) Function (HAQ) Pain-free walk time (minutes) Temporal-spatial (normal and fast walking velocity, cadence, stride length)	**Within group measures** Significant reduction in lower limb walk pain (p=0.001), lower limb stair pain (p=0.001), HAQ scores (p=0.04) with a significant increase in pain-free walk time (p=0.001) for intervention group at follow-up. No significant differences found in the control group at follow-up. Significant improvement (p<0.05) in normal and fast walking velocity and stride length for intervention group at follow-up. No significant observed	

							in control group at follow-up.	
Chalmers et al. 2000 [19]	28 RA (75%)	Total sample Age: 60 (10) Disease duration: 15 (9)	12	**Extra-depth footwear** (P.W. Minor or Drew Co) Firm heel counter, heel height 1.5-2.0 cm, instep lacing, wide deep toe box, thick composite sole **Extra-depth footwear + soft orthoses** Firm heel counter, heel height 1.5-2.0 cm, instep lacing, wide deep toe box, thick composite sole Soft orthoses; 6mm Plastazote with medium		**Primary outcome** MTP pain (VAS) **Outcomes assessed** Lower extremity function (RB, TADL, 50ft walk time)	**Between group measures** Significant improvement in MTP pain scores (p=0.006) for footwear and semi-rigid orthoses group, compared to footwear and soft orthoses group and footwear alone. No significant differences in RB, TADL and 50ft walk time between groups.	**79%**

				density 6mm Plastazote metatarsal lifts **Extra-depth footwear + semi-rigid orthoses** Semi-rigid orthoses; NWB cast, 3mm Subortholen, RF and FF Nickleplast posting, FF 3mm PPT foam, full length leather top cover			**Within group measures** Significant improvement in MTP pain scores (p=0.0004) for footwear with semi-rigid orthoses at follow-up. No significant differences in MTP pain with footwear and Plastazote and footwear only groups at follow-up. No significant differences in RB, TADL, and 50ft walk time and joint count within groups.	
Williams et al. 2007 [13]	40 RA (73%) 40 Controls (53%)	Total sample Age: not reported Disease duration: 17 (10)	12	**New therapeutic footwear** Front of shoe, heel and sole unit, leather and lining, ease of don/doff,	**Traditional therapeutic footwear** Soft, flat 6mm Plastazote, 3mm Poron	**Primary outcomes** Foot pain, disability, activity limitation (FFI) Foot	**Between group measures** Significant improvement in FFI foot pain (p=0.02), disability (p=0.01), limitation	**71%**

				heel height, sole thickness Firm contoured insole	insole	pain, foot function, physical activity (FHSQ)	(p=0.02) and total scores (p=0.01) for intervention group compared to control group at follow-up. Significant improvement in FHSQ foot pain (p=0.00) and foot function (p=0.00) for intervention group compared to control group at follow-up.	
							Within group measures Significant improvement in FFI pain (p=0.00), disability (p=0.00), limitation p=0.00) and total scores (p=0.00) in intervention group at follow-up. Significant improvem	

							ent in FHSQ foot pain (p=0.00), foot function (p=0.00) and physical activity scores (p=0.02) for interventi on group at follow-up. No significant within group improvem ent in the control group at follow-up.	
Cho et al. 2009 [21]	22 RA (100%) 20 Contr ols (100%)	Interventio n group Age: 49 (12) Disease duration: 8 (6) Control group Age: 49 (12) Disease duration: 7 (7)	24	**Extra-depth shoes + custom orthoses** Wide toe box, cushioned heel, forefoot rocker Custom orthoses: medial arch support, medial heel post, metatarsal pad	**Extra-depth shoes + prefabrica ted insoles** Wide toe box, cushioned heel, forefoot rocker Prefabrica ted insole; 6mm Plastazote	**Primary outcom es** Foot pain (VAS) Foot pain, disabilit y, activity limitati on (FFI)	**Between group measures** No significant differences in foot pain and FFI total scores between interventi on and control group at follow-up. **Within group measures** Significant reduction in foot pain (P<0.05)	**61%**

							in intervention and control groups at follow-up.	
Menz et al. 2016 [12]	46 1MTPJOA (61%) 52 Controls (44%)	Intervention group Age: 57 (11) Median Disease duration: 2 Control group Age: 57(11) Median Disease duration: 3	12	**Rocker-sole footwear** (Masai Barefoot Technology (MBT) Mahuta/Matwa) Rounded sole, soft cushioned heel	**Own footwear + orthoses** (Vasyli Customs) Full length, cut out under 1st metatarsal, varus wedge (FPI >7)	**Primary outcome** Foot pain (FHSQ) **Outcomes assessed** Function (FHSQ) Foot pain, stiffness, difficulty, activity limitation, social issues (FFI-R SF) 1MTP walk pain, 1MTP rest pain, 1MTP stiffness (VAS)	**Between group measures** No significant differences in foot pain, function, stiffness, difficulty, activity limitation, social issues, MTP pain and MTP stiffness between groups at follow-up. **Within group measures** Not reported.	**96%**

NWB: non-weightbearing, VAS: Visual Analogue Scale, HAQ: Health Assessment Questionnaire, MTP: metatarsophalangeal joint, RB: Robinson Bashall Functional Assessment, TADL: Toronto Activities of Daily Living Measure, FFI: Foot Function Index, FHSQ: Foot Health Status Questionnaire, FFI-R SF: Foot Function Index - Revised (Short Form), SF: Short Form

Table 3

Characteristics of included prospective observational studies

Author	Nos (% Female)	Sample characteristics Mean (SD)	Follow-up (weeks)	Intervention	Control	Outcome measures	Findings	Quality score
Moncur & Ward 1990 [17]	25 RA (100%)	Age: 57 (not reported) Disease duration: not reported	12	**Heat-mouldable shoes** (Thermold, P. W. Minor Extra Depth Shoe Co) Extra depth, extra forefoot width, mouldable Plastomold lining, pillow top, leather upper, heat mouldable	No control	**Primary outcome** Not stated **Outcomes assessed** Walking ability (1-10 Likert scale)	**Between group measures** Not assessed. **Within group measures** Significant improvement in walking ability ($p<0.01$) at follow-up.	**39%**
Rome et al. 2013 [11]	36 Gout (8%)	Age: 57 (13) duration: 15 (11)	8	**Good footwear characteristics** (ASICS Cardio Zip) Leather upper, rubber sole, dual density midsole, rigid heel counter, moderate midfoot sole stability, heel and forefoot cushioning **Poor footwear**	Own footwear	**Primary outcome** Foot pain (VAS) **Outcomes assessed** Function (HAQ-II) General pain (VAS) Lower limb function (LLTQ) Impairment and disability (LFIS)	**Between group measures** Not assessed. **Within group measures** Significant improvement in foot pain ($p=0.002$), general pain ($p=0.001$), HAQ-II ($p=0.002$) and LFIS impairment subscale ($p=0.004$)	**86%**

				characteristics (Dunlop Asteroid) Synthetic upper, rubber sole, single density midsole, minimal heel counter stiffness, minimal midfoot sole stability, no cushioning (Dunlop Apollo) Synthetic upper, synthetic sole, single density midsole, minimal heel counter stiffness, minimal midfoot sole stability, no cushioning (Helix Viper) Synthetic upper, Phylon sole, single density midsole, moderate heel counter stiffness, minimal midfoot			observed in good footwear characteristics group at follow-up. No significant improvement in poor footwear characteristics group at follow-up.	

				sole stability, heel and forefoot cushioning				
Bagherzadeh Cham et al. 2014 [22]	18 RA (100%)	Age: 47 (8) Disease duration: 8 (7)	4	**Rocker-soled footwear** High-top, wide toe box, Velcro, heel-toe rocker	No control	**Primary outcome** Not stated **Outcomes assessed** Foot pain, disability, activity limitation (FFI)	**Between group measures** Not assessed. **Within group measures** Significant improvement in FFI pain (p=0.001), disability (p=0.044), activity limitation (p=0.04) and total (p=0.001) scores at follow-up.	**50%**
VAS: Visual Analogue Scale, HAQ: Health Assessment Questionnaire, LLTQ: Lower Limb Tasks Questionnaire, LFIS: Leeds Foot Impact Scale, FFI: Foot Function index								

Table 4

Characteristics of included lab-based intervention studies

Author	Nos (% Female)	Sample characteristics Mean (SD)	Interventions	Control	Outcome measures	Findings	Quality score
Hennessy et al. 2007 [20]	20 RA (80%)	Age: 60 (11) Disease duration: not reported	**Running shoe** (Brooks Glycerin 3, Texas Peak Pty Ltd.) Commercially available, 'premium' cushioned running shoe **Orthopaedic footwear** (P.W. Minor and Son) Extra-depth, cushioning	**Control** (Dunlop volley) Sock liner removed, thin flexible sole	**Primary outcome** Plantar pressure (PPP, PTI)	**Between group measures** PPP significantly reduced at forefoot, rearfoot and total foot in running shoe ($p<0.001$) and orthopaedic shoe ($p<0.001$) compared to control. PTI significantly reduced at forefoot ($p<0.001$), rearfoot ($p=0.008$) and total foot ($p<0.001$) with the running shoe compared to the control. PTI significantly reduced at forefoot ($p<0.001$) and total foot	**64%**

						(p<0.001) with the orthopaedic shoe compared to the control. **Within group measures** Not assessed.	
Stewart et al. 2014 [23]	21 Gout (5%) 15 Gout (13%)	**Good footwear group** Age: 57(13) Disease duration: 13 (8) **Poor footwear group** Age: 58 (14) Disease duration: 18 (13)	**Good footwear characteristics** (ASICS Cardio Zip) Leather upper, rubber sole, dual density midsole, rigid heel counter, moderate midfoot sole stability, heel and forefoot cushioning **Poor footwear characteristics** (Dunlop Asteroid) Synthetic upper, rubber sole, single density midsole,	**Between group** Good footwear characteristics and poor footwear characteristics **Within group** Participant's own footwear	**Primary outcome** Not stated **Outcomes assessed** Plantar pressure (PPP, PTI) Temporal-spatial (walking velocity, step length, stride length, cadence)	**Between group measures** Significant decrease in PPP at the medial heel (p=0.000) and 5MTP (p=0.000) in the good footwear group compared to the poor footwear group. Significant decrease in PTI at the heel (p=0.003),	**64%**

			minimal heel counter stiffness, minimal midfoot sole stability, no cushioning (Dunlop Apollo) Synthetic upper, synthetic sole, single density midsole, minimal heel counter stiffness, minimal midfoot sole stability, no cushioning (Helix Viper) Synthetic upper, Phylon sole, single density midsole, moderate heel counter stiffness, minimal midfoot sole stability, heel and forefoot cushioning			lateral heel (p=0.001) and 5MTP (p=0.005) and a significant increase in PTI at the midfoot (p=0.000) in the good footwear group compared to the poor footwear group. No significant differences in velocity, step length, stride length or cadence between groups.	
						Within group measures Significant reduction in PPP at 3MTP (p=0.003) and 5MTP (p=0.001). Decreased PTI at heel (p=0.000), 3MTP (p=0.000) and 5MTP (p=0.005) and	

						increased PTI at midfoot (p=0.000) with good footwear group compared to control. Significant reduction in PPP at 3MTP (p=0.004) and increased PPP at heel (p=0.000) and lesser digits (p=0.003). Decreased PTI at midfoot (p=0.003) in poor footwear group compared to control. Significant increase in velocity (p=0.000), step length (p=0.000) and stride length (p=0.000) in both interventi on groups compared to control.	

Menz et al. 2016 [24]	46 1MTPJ OA (61%) 52 Controls (44%)	**Rocker-sole group** Age: 57 (11) Median Disease duration: 3 **Control** Age: 57(11) Median Disease duration: 3	**Rocker-sole footwear** (MBT Mahuta/Matwa) Rounded sole, soft cushioned heel	**Between group** Participant's own footwear + orthoses **Within group** Participant's own footwear	**Primary outcome** Not stated **Outcomes assessed** Plantar pressure (PPP) Temporal spatial (walking velocity, stride length, cadence, stance phase %)	**Between group measures** Significant reduction in PPP at lesser toes (p=0.008), 2-5MTP (p<0.001) and midfoot (p=0.003) in the footwear intervention group compared to control group. Significant reduction (p=0.015) in stance phase percentage in footwear intervention group.	**71%**
						Within group measures Significant reduction in PPP at 1MTP (p=0.002), 2-5MTPs (p<0.001) and heel (p<0.001) in footwear intervention group. Significant reduction in cadence (p=0.015) and stance	

						phase percentage (p=0.021).	

Peak Plantar Pressure, PTI: Pressure Time Integral, MTP: metatarsophalangeal joint