The effects of footwear on foot pain and disability in people with gout

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Abstract

Background: The prevalence of gout is increasing worldwide, with New Zealand having some of the highest reported rates of gout in the world. Gout frequently targets the articular and soft tissue structures of the foot and ankle. People with gout experience high levels of foot pain, impairment and disability. Footwear is of concern for people with gout, who frequently wear poor footwear that is associated with impairment and disability. Footwear has been found to offer short-term benefits to people with gout but there is limited evidence on the long-term impact. The thesis aimed to investigate: the effectiveness of footwear interventions for people with foot and ankle arthritis, the footwear experiences of people with gout, the long-term effects of footwear on foot pain and disability in people with gout and the effects of worn and new footwear on plantar pressure in people with gout.

Methods: A literature review was undertaken to evaluate the effectiveness of footwear interventions for people with foot and ankle arthritis. A qualitative descriptive study explored the footwear experiences of 11 people with gout, analysed using thematic analysis. A single-blind randomised controlled trial of 94 people with gout investigated the effectiveness of a footwear intervention on foot pain over six months. Participants were randomised to receive either podiatric care or podiatric care and commercially available athletic footwear with good footwear characteristics. The primary outcome was self-reported foot pain. Secondary outcomes were overall pain, foot impairment/disability, footwear comfort, fit, ease and weight. A cross-sectional study of 40 people with gout tested the effects of wear by comparing the plantar pressures worn and new footwear. Footwear wear was assessed at the upper, midsole and outsole.

Results: The literature review found that footwear is associated with improvements to foot pain, function and disability in people with arthritis. Four central themes were

derived from the qualitative study; (i) comfort as a priority, (ii) knowing what to buy, (iii) knowing what to wear and (iv) challenges of different environments. In the randomised controlled trial, no differences in foot pain scores were observed between groups. Improvements between groups in overall pain scores ($p < 0.01$) and foot impairment/disability scores ($p = 0.04$) favouring the footwear intervention were observed at two months, but not at four or six months. Improvements between groups in footwear fit ($p = 0.03$), ease ($p = 0.01$) and weight ($p = 0.03$) favouring the footwear intervention were observed over six months. Similar improvements were observed for footwear comfort over four months. In the cross-sectional study, the worn shoes displayed higher midsole hardness ($p < 0.0001$), normal upper ($p < 0.0001$), midsole ($p = 0.05$) and outsole ($p < 0.0001$) wear patterns. No differences in peak plantar pressures were found. However, lower pressure time integrals were observed at the 1MTP ($p < 0.0001$), 2MTP ($p < 0.0001$) and hallux ($p = 0.003$) with the worn shoes.

Conclusions: The review identified that footwear offers short-term benefits for people with arthritis and highlighted the need for long-term studies. People with gout experience problems finding comfortable footwear that is acceptable, attainable and usable across different environments. The footwear intervention did not significantly improve foot pain in people without high baseline levels of foot pain. Short-term improvements in overall pain and foot impairment/disability, and more durable improvements in footwear comfort and fit were observed with the footwear intervention. The changes to the footwear characteristics after six months may impact foot function, as observed by alterations in forefoot loading patterns between worn and new footwear. The thesis emphasises the importance of footwear comfort for people with gout.

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Dissemination

Published work

Frecklington, M, Dalbeth, N, McNair, P, Gow, P, Williams, A, Carroll, M, Rome, K. Footwear interventions for foot pain, function, impairment and disability for people with foot and ankle arthritis: a literature review. Semin Arthritis Rheum. 2018;47;814-24.

Frecklington, M, Williams, A, Dalbeth, N, McNair, P, Gow, P, Rome, K. The footwear experiences of people with gout: a quantitative study. J Foot Ankle Res. 2019;12;38.

Frecklington, M, Dalbeth, N, McNair, P, Morpeth, T, Vandal, AC, Gow, P, Rome, K. Effects of a footwear intervention on foot pain and disability in people with gout: a randomised controlled trial. Arthritis Res Ther. 2019;21;104.

Conference presentations

Frecklington, M, Williams, A, Dalbeth, N, McNair, P, Gow, P, Rome, K. May 2019. The footwear experiences of people with gout: a quantitative study (poster presentation) at Australian Podiatry Conference 2019

Frecklington, M, Dalbeth, N, McNair, P, Morpeth, T, Vandal, AC, Gow, P, Rome, K. Effects of a footwear intervention on foot pain and disability in people with gout: a randomised controlled trial (poster presentation) at Australian Podiatry Conference 2019

Frecklington, M, Dalbeth, N, McNair, P, Vandal, AC, Gow, P, Rome, K. Effects of worn and new footwear on plantar pressure in people with gout (poster presentation) at Australian Podiatry Conference 2019

Attestation of Authorship

‘I Michael John Frecklington hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgements), nor material which to a substantial extent has been submitted for the award of any other degree or diploma of a university or other institution of higher learning’

Mike Frecklington 24/01/2018

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Chapter 1: Introduction to gout

1.1 Introduction

This chapter provides an overview of gout in New Zealand before reviewing the pathophysiology, epidemiology, clinical staging and diagnosis of gout. Foot and ankle involvement in gout is then discussed with relation to patient-reported outcomes and functional changes. The chapter concludes with the current evidence surrounding the pharmacological management of gout and the non-pharmacological interventions specific to the foot and ankle. The terminology used throughout this thesis complies with the Gout, Hyperuricemia and Crystal-Associated Disease Network (G-CAN) consensus statement (1).

1.2 Gout in the context of Aotearoa/New Zealand

Gout is an inflammatory arthropathy characterised by elevated levels of serum urate (hyperuricaemia) leading to recurrent episodes of acute arthritis and the deposition of tophus into articular and soft tissue structures (2). The incidence and prevalence of gout is increasing in New Zealand (3, 4). New Zealand has some of the highest reported rates for gout in the world, with recent data indicating a national prevalence of 5.35% for those over the age of 20 (5). People with gout in New Zealand also have a higher prevalence of diabetes, chronic kidney disease and cardiovascular disease compared to those without the disease (6).

Gout is also more common in Māori and Pacific Island groups in New Zealand, who compared to other ethnicities, have 2–3 times the prevalence of gout (5). Māori also have an earlier disease onset, higher levels of serum urate, more frequent gout flares, greater polyarticular joint involvement and number of tophus present (4). Increased disease severity is also observed in Pacific Island populations (7). The increased

prevalence and greater severity of disease observed in Māori and Pacific Island populations may have a genetic underpinning, whereby urate is not excreted as efficiently as other ethnic groups (8). In addition to the increased disease burden, inequities exist for Māori and Pacific Island people who compared to other ethnic groups are less likely to receive appropriate care (5), have three times the treatment costs (7) and experience five times the number of hospital admissions (9). Qualitative studies from New Zealand describe the negative impact of gout on employment, whanau (family), sporting activities and social activities (10, 11).

1.3 Pathophysiology

1.3.1 Hyperuricaemia

Hyperuricaemia is commonly defined as a serum urate concentration of >0.41 mmol/L (12). When serum urate concentrations exceed this level, monosodium urate (MSU) crystals can form under normal physiological conditions (12). Urate is an end-product of purine metabolism, with high levels observed in humans due to an absence of the uricase enzyme responsible for urate degradation (13). Hyperuricaemia results from overproduction of urate from hepatic metabolism (14), or renal and extra-renal under excretion of urate (15). For people with gout, under excretion of urate is the main cause of hyperuricaemia (15). Renal excretion accounts for two-thirds of urate excretion, with the remaining third accounted for by the gut (16). The kidney is the major regulator of urate, through the balance of urate reabsorption and secretion (16), however in people with gout, approximately 90% of urate is reabsorbed in the renal proximal tubules (17).

1.3.2 Acute gout

Persistent hyperuricaemia may lead to the formation and deposition of MSU crystals within articular and soft tissue structures (2). Reasons for this are not well understood, although local factors contributing to crystal formation include lower temperatures, pH levels between 7–9, increased sodium ion concentration and the presence of connective tissue proteins (18). Some individuals with hyperuricaemia and evidence of MSU deposition can remain asymptomatic (19). For others, the interaction between MSU crystals and neighbouring tissues may stimulate an inflammatory response, observed clinically as an acute gout flare (20) (**Figure 1.1**). Clinical features of gout flares include intense pain, tenderness, swelling, heat and functional limitation (2), with symptoms reaching their peak within 24 hours of onset (21). Flares can be triggered by trauma, alcohol, surgery, illness or alterations to serum urate concentration following pharmacological intervention (22).

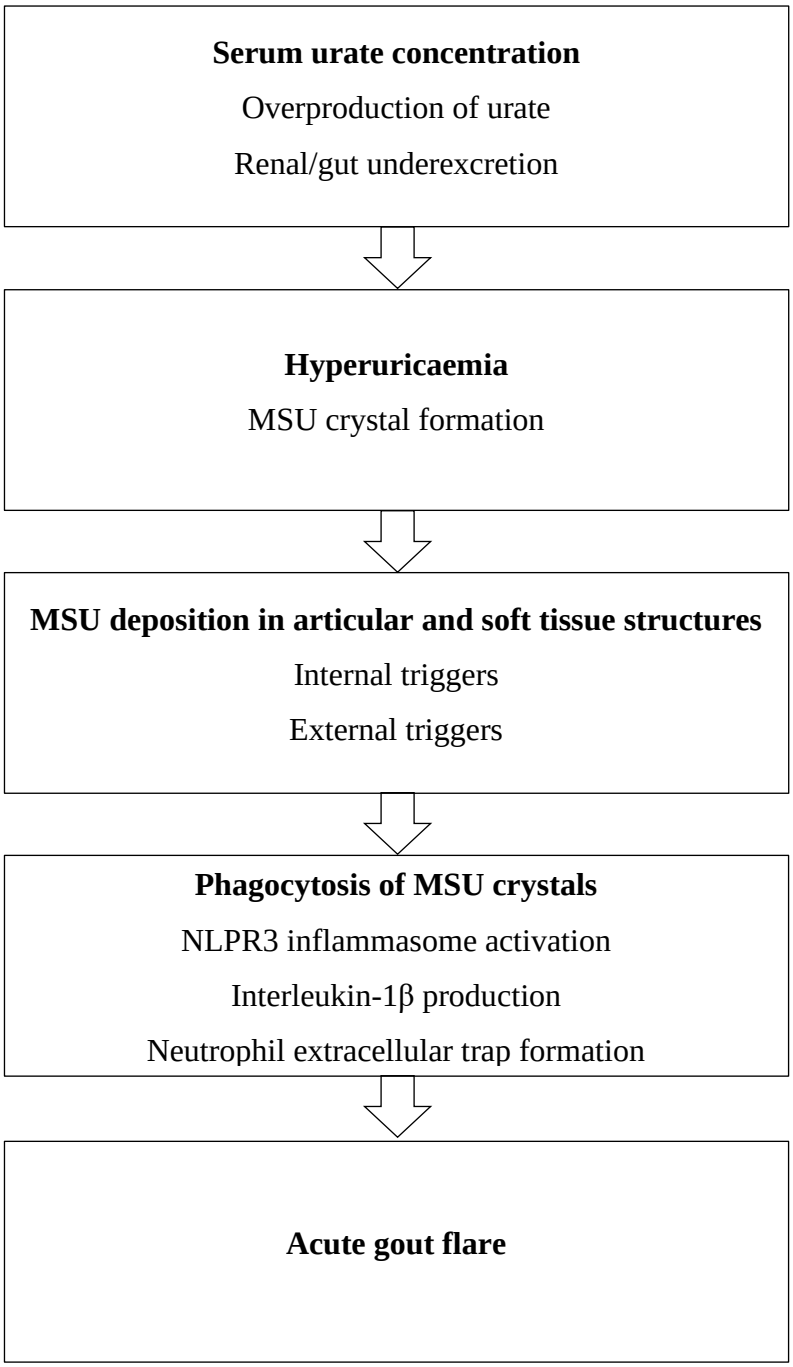

Figure 1.1 Pathophysiology of gout

The presence of MSU crystals leads to local infiltration of macrophages, monocytes, neutrophils, dendritic cells and mast cells to the joint synovium (23). Phagocytosis of MSU crystals leads to the activation of the NLPR3 inflammasome, leading to the production of pro-inflammatory cytokines interleukin-1β and the recruitment of neutrophils (24, 25). The formation of prostaglandins, bradykinin and sensitisation of nociceptors may trigger the intense pain associated with gout flares (26).

Resolution of symptoms is attributed to a number of factors including the formation of neutrophil extracellular traps (27), differentiated macrophages (28), stimulation of anti-inflammatory pathways (29) and pharmacological intervention (30). If left untreated, flare symptoms generally resolve within 1–2 weeks (21), leading to asymptomatic periods between flares (intercritical gout) ranging from months to years (31). Importantly, MSU crystal formation and low-level inflammation have been found to continue during clinically asymptomatic periods (32).

1.3.3 Advanced gout

The presence of long-standing hyperuricaemia and sub-optimal pharmacological management, may lead to the development of chronic gouty arthritis and/or tophi (2). Tophi may develop in soft tissue and articular structures (33). Tophi are collections of MSU crystals enclosed by inflammatory cells (macrophages, plasma cells, mast cells) and fibrovascular tissue (34). Neutrophil extracellular traps may also contribute to the formation of tophi (27). Tophi are surrounded by inflammatory cells that contribute to gouty bone erosion (35) and tendon damage (36) observed in people with gout. Clinically, tophi are observed as subcutaneous nodules in joints and soft tissue structures and are associated with reduced function (37, 38) and joint deformity (33). Tophi can appear anywhere, however they typically affect the peripheral joints of the body such as the feet, hands, knees and elbows (olecranon bursae) (39).

1.4 Epidemiology

Epidemiological studies from North America (40-43), Europe (44-46), Asia (47-49) and Australasia (3, 4, 50) report an increase in the prevalence of hyperuricaemia and gout. It has been suggested that this trend may be attributed to dietary and lifestyle changes,

advances in medical care and increased life expectancy (51). The level and duration of hyperuricaemia is correlated with the development of gout (52). Compared to those with normal serum urate levels, men with mild hyperuricaemia (0.39–0.47 mmol/L) were 11.2 times more likely to develop gout (53). The odds ratio for men developing gout with moderate (0.47–0.55 mmol/L) and severe hyperuricaemia (>0.56 mmol/L) was 107.1 and 624.8, respectively (53).

Globally, prevalence rates range from 3–6% in men and 1–2% in women in developed countries, with lower rates reported in developing countries (54). Prevalence rates of gout are strongly influenced by age, gender and geographical location (55). Gout is the most common form of inflammatory arthritis in men (56), who have four times the prevalence of gout compared to women (3, 41). The prevalence of gout in men increases with age (54). Women have a lower prevalence of gout at all time-points, but experience an increase in prevalence after menopause (54). This may be due to the uricosuric action of oestrogen influencing renal urate clearance (57). The highest prevalence rates are reported in Taiwanese Aborigines (58), Māori and Pacific Island populations (5), who experience over two times the prevalence compared to other ethnicities (54).

1.5 Risk factors

1.5.1 Comorbidities

Comorbidities are frequently observed in people with gout (59), many of which are independent risk factors for gout. The metabolic syndrome (hypertension, hyperglycaemia, dyslipidaemia and obesity) is reported in 63% of people with gout (60). Independent risk factors for incident gout include hypertension (61), chronic kidney disease (62), obesity and weight gain (61). People with diabetes also have a lower risk of developing gout (63), yet those with gout have a higher risk of developing

type 2 diabetes (64). This relationship may be explained by the uricosuric effect of glycosuria, whereby serum urate concentrations lower when haemoglobin A1c (HbA1c) levels exceed 53 mmol/L (65). Gout is also associated with an increased risk of cardiovascular disease and mortality (66). This may be due to low-grade inflammation present in gout promoting atherogenesis (67).

1.5.2 Dietary factors

Dietary factors have long been associated with gout (68). Purine-rich foods such as meat and seafood were associated with higher serum urate concentrations and an increased risk of gout (69). Purine-rich vegetables (beans, cauliflower, lentils, mushrooms, peas, spinach) and overall protein intake were not associated with an increased risk of gout, with dairy products associated with a reduced risk of gout (69). Sugar-sweetened beverages containing fructose are associated with increased serum urate levels and hyperuricaemia (70, 71). Alcohol consumption significantly increases the risk of gout, with beer having a stronger risk than spirits (72)

1.5.3 Genetics

Genome-wide association studies have focused on loci associated with increased urate reabsorption and hyperuricaemia (73-75). Of these genetic variants encoding the urate transporters, GLUT9 (*SLC2A9*) (76), URAT1 (*SLC22A12*) (77) and ABCG2 (*ABCG2*) (14) have been identified as playing a significant role in serum urate regulation. The higher prevalence of gout in Māori and Pacific Island populations may be attributed to the presence of variants of loci involved in urate transportation (78).

1.5.4 Medication use

Medications commonly used to treat other comorbidities have been associated with gout. Diuretics are commonly prescribed for hypertension and renal disease, but are an independent risk factor for gout (61). Diuretics have been found to reduce the secretion of urate (79) and increase the risk of developing gout 2.4 times (80). Other anti-hypertensive medications (beta-blockers, angiotensin converting enzyme inhibitors and non-losartan angiotensin II receptor blockers) have been found to increase the risk of incident gout by up to 1.5 times (81).

1.6 Clinical staging

Traditionally, gout has been classified into four progressive stages: asymptomatic hyperuricaemia, acute gouty arthritis, intercritical gout and chronic tophaceous gout (82). A limitation of this system is that it fails to capture those with the evidence of MSU deposition in the absence of a clinical history of gout (83). Furthermore, it portrays gout as an intermittently flaring condition, as opposed to a chronic disease of MSU deposition (19).

A new staging system has been proposed to better reflect the pathological changes and clinical symptoms associated with the disease (19) (**Figure 1.2**). The first two stages (A and B) represent asymptomatic disease states, with the remaining two stages (C and D) representing symptomatic disease (19).

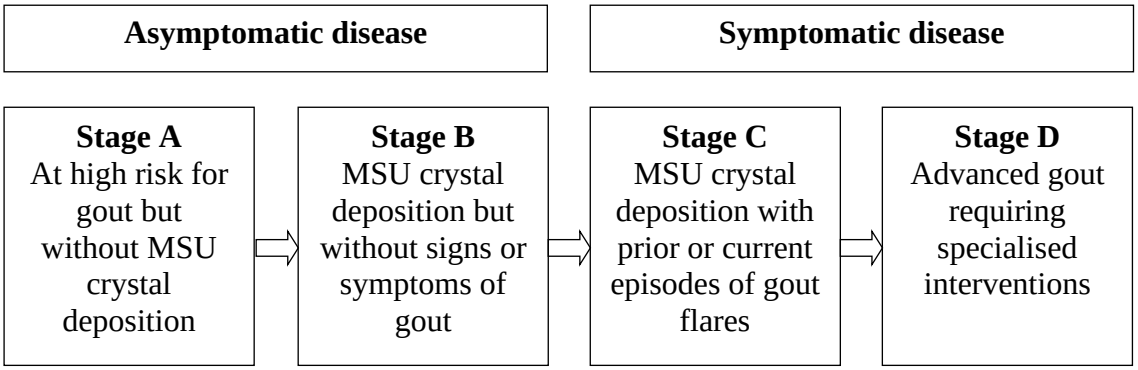

Figure 1.2 Revised staging system for hyperuricaemia and gout adapted from Dalbeth and Stamp (19)

1.6.1 Stage A: At high risk for gout but without MSU crystal deposition

Stage A represents people with hyperuricaemia and at risk of developing gout, but do not present with MSU crystal deposits within joints or soft tissue (19). Future screening of this population for the development of gout should be considered (84).

1.6.2 Stage B: MSU crystal deposition but without signs or symptoms of gout

Stage B represents people with MSU crystals, but no apparent clinical symptoms associated with gout (19). MSU crystals have been identified in people yet to display clinical symptoms of gout (83). Advanced imaging techniques have also identified subclinical characteristic features of gout such as tophus (85), urate deposition (86) and cartilage changes (87) in this asymptomatic population.

1.6.3 Stage C: MSU crystal deposition with prior or current episodes of gout flares

Stage C represents the presence of MSU crystals and the manifestation of clinical symptoms associated with gout (19). Gout flares are characterised by pain, erythema, swelling and reduced function (2, 21).

1.6.4 Stage D: Advanced gout requiring specialised interventions

Stage D represents the advanced stage of the disease characterised by clinically evident tophus, chronic gouty arthritis and the presence of radiographic erosions (19). People will typically progress through the stages in a linear fashion (19), however for some people, tophi may be the initial clinical presentation (progression from stage B to stage D) (88).

1.7 Diagnosis and classification criteria

A definitive diagnosis of gout is confirmed by the presence of MSU crystals from aspirates of synovial fluid or tophus deposits (89). Aspirates can be taken from symptomatic and asymptomatic joints (90). Diagnostic criteria are used to guide clinical care, whereas classification criteria are used to identify cohorts of people for research purposes (91). The most universal tool for the classification of gout is the American College of Rheumatology (ACR) preliminary criteria for the classification of the acute arthritis of primary gout (92) (**Table 1.1**). Classification of gout is based on the confirmation of aspirate proven MSU crystals or the presence of ≥6 of the clinical criteria (92).

Table 1.1 ACR criteria for the classification of acute arthritis for primary gout (92)
Clinical diagnosis requires A, B, or C to be met:
A. The presence of characteristic urate crystals in joint fluid, or
B. Tophus proven to contain urate crystals by chemical means or polarised light microscopy, or
C. Presence of 6 of the following clinical, laboratory and radiographic phenomena: 1. More than one attack of acute arthritis 2. Maximum inflammation developed within 1 day 3. Monoarthritis attack 4. Redness observed over joints 5. First metatarsophalangeal joint painful or swollen 6. Unilateral first metatarsophalangeal joint attack 7. Unilateral tarsal joint attack 8. Tophus (proven or suspected) 9. Hyperuricaemia 10. Asymmetric swelling within a joint on x-ray 11. Subcortical cysts without erosions on x-ray 12. Joint fluid culture negative for organisms during attack

Despite its widespread use, the ACR criteria is not without limitations. The criteria were developed for use in acute arthritis, where physician diagnosis and not the presence of MSU crystals was the gold standard (91, 93). Compared to synovial fluid aspirates, its criterion displays substandard sensitivity and specificity when applied across the disease spectrum (94, 95). Collaboration between ACR and European League Against Rheumatism (EULAR) led to the development of the 2015 ACR/EULAR classification

criteria for gout, to address these concerns (91). The 2015 ACR/EULAR classification criteria includes clinical characteristics (joint distribution, characteristics of acute episode and clinically evident tophus), laboratory investigations (serum urate level and synovial fluid analysis) and imaging (urate deposition and joint damage) (91). Each criterion is scored resulting in a total score out of 23 (91). Total scores ≥8 classify a person as having gout (91). The criteria are 92% sensitive and 89% specific (91), when compared against an existing data set of 983 consecutive patients who underwent synovial fluid or tophus aspiration (93).

1.8 Foot and ankle involvement

Typically, gout presents for the first time as an acute episode of arthritis (flare) affecting the foot (96). The first metatarsophalangeal joint (1MTP) is the most common site of initial involvement (96, 97), with flares at the 1MTP also referred to as podagra (98). Throughout the course of the disease, 48–97% will experience a flare at the 1MTP with a pooled prevalence of 73% (99). Reasons for this predilection to the 1MTP appear to be multi-factorial (98). Potential factors influencing MSU deposition at the 1MTP include: MSU crystal precipitation occurring at lower temperatures (12, 100), trauma (12, 101, 102), biomechanical loading (103) and the co-existence of osteoarthritis (104). MSU deposition is associated with structural joint damage (105). Other common sites of osseous involvement include the midfoot joints and ankle joint (106, 107).

Gout also affects the soft tissue structures of the foot and ankle (108). Studies using dual-energy computed tomography have reported the Achilles tendon as the most common site of MSU deposition (36–39%), followed by the peroneal tendons (15–18%) (106, 107). Less commonly affected soft tissue sites include tibialis anterior and the

extensor tendons (108). The presence of gouty disease in the foot is associated with foot-related pain, impairment and disability (109-111).

1.9 Foot pain, function, impairment and disability in people with gout

1.9.1 Foot pain

Foot pain is a characteristic feature of gout affecting the foot (98, 112). A survey of 1,884 people with gout, found that 22% had experienced foot pain in the preceding month, with over 60% of those reporting disabling symptoms (112). People with gout also have greater odds of experiencing disabling foot pain (OR 13.4) compared to controls (111). A prospective observational study reported foot pain during gout flares using a 100 mm visual analogue scale (VAS) as 60 mm (109). Foot pain reported using 100 mm VAS in the absence of a gout flare ranges from 6 mm to 38 mm (38, 109, 113, 114). These findings suggest that foot pain may be ever-present, even in the absence of a gout flare. People with gout also report significantly higher foot pain compared to age-matched controls (38). Foot pain has also been measured using the foot pain subscale of the Manchester Foot Pain and Disability Index (MFPDI), with those with gout reporting significantly higher scores than age-matched controls (115).

1.9.2 Function

Deficits in foot and lower limb function have been reported in people with gout (109, 116). Lower limb function has been measured using the Lower Limb Tasks Questionnaire (LLTQ) in people with gout. During gout flares, a significant reduction in LLTQ scores were observed in the activities of daily living and recreational subscales, compared to inter-critical periods (109). During inter-critical periods, people with gout

also display significant reductions in LLTQ scores for the activities of daily living and recreational subscales compared to age-matched controls (111, 117).

Walking difficulty is a discriminatory feature of gout (118). A case-control study reported that people with gout walk slower, with shorter steps and reduced cadence (110). Another case-control study reported reductions in walking speed and cadence, with increased step and stance time at self-selected and fast speeds, after adjusting for body mass index (BMI) and foot pain (115). Other work further supports that walking speed is reduced in those with gout (38, 119).

Altered joint function has also been observed at the foot. Reduced peak plantar pressures at the hallux and heel, with increased pressure at the midfoot have been observed in people with gout, compared to age-matched controls (120). People with gout display reduced joint range of motion and plantarflexion force at 1MTP (111) and reduced peak angular velocity at the ankle during walking, compared to age-matched controls (38). Reduced ankle plantarflexion, inversion and eversion strength during concentric contractions at 30°/s and 120°/s is also observed in people with gout compared to age-matched controls (115). The presence of foot tophi further limits function with deficits in ankle dorsiflexion, plantarflexion, inversion and eversion muscle force, compared to those without tophi (114). The reductions in walking velocity and altered kinematics and kinetics displayed by people with gout may be indicative of a pain avoidance strategy (110, 120) or an adaptation to foot pain and disability (38).

1.9.3 Impairment and disability

Foot problems such as reduced joint range of motion (111), hallux valgus (121), tophus (108) and ulceration (122) have been reported in people with gout. Foot-related

impairment and disability has also been reported using the Leeds Foot Impact Scale impairment/footwear ($LFIS_{IF}$) and activity limitation/participation ($LFIS_{AP}$) subscales. During flares, $LFIS_{IF}$ and $LFIS_{AP}$ scores are significantly higher than those measured during inter-critical periods (109). $LFIS_{IF}$ scores of >7 and $LFIS_{AP}$ scores of >10 are indicative of high levels of foot impairment and disability (123). During inter-critical periods high levels of foot impairment and disability remain with 30–54% reporting $LFIS_{IF}$ scores >7 and 30–60% reporting $LFIS_{AP}$ scores >10 (109, 117, 124). People with gout also report significantly higher $LFIS_{IF}$ and $LFIS_{AP}$ scores compared to aged-matched controls (110). When compared to age-matched controls, people with gout report significantly higher MFPDI scores (111, 115, 116). MFPDI scores are also worse in those with foot and ankle tophus compared to those without tophus (114).

1.10 Management

1.10.1 Pharmacological management

Pharmacological interventions are based on a treat-to-target approach directed towards lowering serum urate levels (125), reducing the impact of flares (126) and the regression of tophus (127). Urate lowering therapy (ULT) is the central pharmacological intervention for effective gout management (125, 128). The use of ULT is associated with a reduction in flares and the number of subcutaneous tophi (those detected on physical examination) (129). ACR (125), EULAR (128) and Evidence, Expertise, Exchange (3e) Initiative (130) guidelines state a target serum urate of 0.36 mmol/L for people with gout and 0.30 mmol/L for those with tophaceous disease. Reductions in flares (131) and tophi (132) may also be monitored to evaluate the success of ULT.

The ACR guidelines state that treatment of a gout flare should commence within 24 hours, with the initial decision based on clinical symptoms (126). Monotherapy using

non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids or colchicine is recommended for mild to moderate pain affecting 1 of a few small joints or 1–2 large joints (126). Combination therapy may be required in instances of severe polyarticular involvement or non-response to initial treatment (126). Prophylactic anti-inflammatory therapy (low-dose colchicine or prednisone) is often prescribed with the commencement of ULT and should be continued in the presence of clinical symptoms (126). When ULT is established, this should also be maintained during flares (126).

ACR, EULAR and 3e Initiative guidelines support xanthine oxidase inhibitors (most often allopurinol) as first-line ULT for reducing serum urate levels (125, 128, 130). In cases of intolerance, uricosurics (probenecid or benzbromarone) may also be offered as first line treatment. When target serum urate is not achieved, uricosurics and xanthine oxidase inhibitors may be prescribed in combination (125). For patients intolerant or refractory to first-line treatments may be prescribed pegloticase, a recombinant pegylated uricase administered intravenously (133); although, this drug is not available in New Zealand. Current guidelines (125, 126, 128) do not recommend ULT for those with asymptomatic hyperuricaemia.

1.10.2 Non-pharmacological management

ACR, EULAR and 3e Initiative guidelines surrounding non-pharmacological management include patient education, lifestyle modification and screening for comorbidities (125, 128, 130).

Education should be directed towards the pathophysiology of gout, associated comorbidities and principles of management (flares and treat-to-target) (128). Sub-optimal gout management is common, due to a lack of knowledge of gout and the importance of adherence to ULT (134). One (randomised controlled trial) RCT

compared nurse-led care to usual general practitioner (GP) care, with the primary outcome of achieving target serum urate after two years (135). In the nurse-led group, 95% achieved target serum urate compared to 30% in the GP group, with higher mean ULT dosages observed in the nurse-led group. Improvements in flare frequency, presence of tophi and health-related quality of life were also observed favouring the nurse-led group. An observational study of 106 people with gout who received an education package comprising of information regarding the disease, lifestyle changes and adherence to ULT, reported that 92% of participants achieved a serum urate of 0.36 mmol/L after 12 months (136).

Lifestyle modifications including weight loss (137, 138), dietary changes (69, 72) and the management of comorbidities (139) have been recommended to help reduce serum urate levels. Despite the evidence from observational studies, there are a lack in RCTs for lifestyle changes for people with gout (140, 141). One RCT where 120 people with gout received one of three milk products over a three month period reported a reduction in the number of gout flares across all three groups, although no significant changes in serum urate levels were observed (142). Another RCT reported that dietary education had little effect on serum urate levels, in patients currently on ULT (143).

Due to the association between gout and the metabolic syndrome, screening for and treating comorbidities should form part of the patient's wider management (130, 144). In addition there may be shared benefits to treating comorbidities, as some medications for hypertension (145) and dyslipidaemia (146) are associated with reductions in serum urate levels.

1.11 Non-pharmacological foot-specific interventions

Non-pharmacological interventions for foot-related problems in people with gout include podiatric care (112, 147) and commercially-available footwear (113, 148).

1.11.1 Podiatric care

A survey of 1,184 people with gout found that in the past year 43% had consulted their doctor and 24% had consulted a podiatrist regarding foot problems (112). Regular podiatric care is associated with a reduction in foot pain and disability in people with rheumatic diseases, including 14% with gout (147). Podiatric interventions for people with gout may include: management of nail conditions, callus reduction, wound care, padding, foot orthoses, footwear advice, foot health education and exercise (147). Of these, footwear advice was the most commonly used intervention, received by 29% of the study population (147), though there is limited evidence guiding this in people with gout.

1.11.2 Footwear

Footwear is of concern for people with gout (149). Previous qualitative work in gout populations has raised footwear-related issues such as not being able to wear footwear during acute flares (150-152), having difficulties finding footwear that accommodated for tophi (150, 153) and expressing concerns about knowing what the right type footwear is for their foot (153-155). The inability to find suitable footwear has been reflected in a study evaluating the footwear characteristics of people with gout (124). It was found that participants frequently wore footwear that was ill-fitting, worn and lacked cushioning and support (124). This is either due to the footwear being an inappropriate design at the point of purchase or that their use over time has resulted in

degradation of the footwear's structural components. Hence, these factors related to footwear may contribute to the high levels of foot pain, impairment and disability (124).

In order to reduce the impact of gout-related foot pain and disability, footwear has been used as an intervention (113). A prospective study of 36 people with gout investigated the effect of a range of footwear on foot pain and disability over an eight week period (113). Footwear with good characteristics (motion control, shock attenuation, rocker-sole, wide fitting) was found to reduce foot pain, general pain and disability after eight weeks. No benefits were observed in the participants who wore footwear with poor characteristics. The authors suggested that the structural characteristics in the good footwear improved the transition from heel contact to propulsion.

This was explored in a cross-sectional study of the same cohort that found footwear with good and poor structural properties altered peak plantar pressure and pressure time integrals (148). Footwear with good characteristics reduced pressure under the heel region and lateral metatarsal heads, whereas footwear with poor characteristics increased pressure under the heel and lesser digits (148). Wearing new footwear with good or poor characteristics is also associated with increased walking velocity, compared to when wearing their own footwear (148). These observations lend support to footwear with good characteristics promoting a more efficient gait pattern.

1.12 Conclusion

Gout is a significant problem in New Zealand, where it remains highly prevalent in Māori and Pacific Island populations and is inadequately managed. Gout frequently targets the foot and is associated with high levels of foot pain, impairment and disability. The high occurrence of foot involvement is reflected in the structural and function limitations seen in the foot and lower limb. There is emerging evidence that

foot-specific interventions such as podiatric care and footwear can have a role in the management of foot pain, function, impairment and disability for people with gout.

Chapter 2: Aims and hypotheses

2.1 Aims

1. To investigate the clinical effectiveness of footwear interventions on foot pain, function, impairment, and disability in people with foot and ankle arthritis
2. To explore the footwear experiences of people with gout.
3. To investigate the effectiveness of a footwear intervention on foot pain and disability in people with gout over six months.
4. To examine the effects of wear in commercially available athletic footwear by comparing the plantar pressures in footwear that had been worn for six months, compared to new footwear.

2.2 Hypotheses

1. People with gout receiving commercially available footwear and standardised podiatric care will have reduced foot pain compared to people with gout receiving standardised podiatric care over six months.
2. People with gout receiving commercially available footwear and standardised podiatric care will have reduced impairment and disability compared to people with gout receiving standardised podiatric care over six months.
3. There will be differences in footwear characteristics in people with gout wearing footwear for six months compared to new footwear.
4. There will be differences in peak plantar pressures in people with gout wearing new footwear compared to old footwear.

Chapter 3: Footwear interventions for foot pain, function, impairment and disability for people with foot and ankle arthritis: a literature review

This review was published in 2018 in Seminars in Arthritis and Rheumatism (156) and is included in **Appendix 1**.

3.1 Introduction

Foot problems are commonly observed in people with foot and ankle arthritis (112, 157). High levels of foot pain, impairment and disability are also reported in this population (109, 158). Foot problems in people with arthritis are also associated with reduced function (115) and health-related quality of life (159). Reduced walking velocity and increased plantar pressure is also observed in people with arthritis (160).

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 (147). Footwear can include off-the-shelf footwear, therapeutic footwear and therapeutic footwear combined with foot orthoses. People with arthritis affecting the foot and ankle often use footwear that may contribute to foot pain and associated disability (124) and describe difficulties in finding suitable footwear (155). While there are studies examining the effects of footwear, currently 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 foot and ankle arthritis.

3.2 Methodology

3.2.1 Identification of studies

The following electronic databases (CINAHL, MEDLINE, Scopus, SPORTDiscus and the Cochrane Library) were searched in October 2018. The search strategy comprised of the following keywords: arthritis, rheumatoid arthritis, gout, osteoarthritis, rheumatic disease, psoriatic arthritis, lupus erythematous, ankylosing spondylitis, systemic sclerosis and polymyalgia rheumatica *with* footwear, footwear intervention, foot orthoses, foot orthosis, foot orthotic, insole and shoe (**Table 3.1**). The term 'footwear interventions' encompassed the use of footwear, footwear with orthoses in the management of arthritic conditions.

Table 3.1 Search strategy

a	1	Arthritis
	2	Gout
	3	Osteoarthritis
	4	Rheumatoid arthritis
	5	Rheumatic disease
	6	Psoriatic arthritis
	7	Lupus erythematous
	8	Ankylosing spondylitis
	9	Systemic sclerosis
	10	Polymyalgia rheumatica
b	11	Footwear
	12	Footwear intervention
	13	Shoe
	14	Foot orthoses
	15	Foot orthosis
	16	Foot orthotic
	17	Insole
c	18	Combine 1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10
	19	Combine 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17
	20	Combine 18 AND 19

(a) search terms for arthritis, (b) search terms for footwear interventions, and (c) combination of search terms

3.2.2 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. Studies were included if they met the following criteria: being a RCT, 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 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 orthoses interventions. No limitations were placed on the date of publication. 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.

3.2.3 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 were recorded.

3.2.4 Assessment of methodological quality

Methodological quality was independently assessed by two authors (MF and MC) using the Quality Index Tool (161). 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 an a priori sample size calculation. Previous research has also adopted the same interpretation for this item (162). The tool displays high internal consistency, test-retest reliability and inter-rater reliability (161). Kappa statistic was used to assess inter-rater agreement between the two authors (163). All disagreements in scoring were resolved following discussion between the two authors, 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 (164). 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) (165).

3.3 Results

3.3.1 Search results

Following the removal of duplicates, 1,543 studies were screened with 1,384 records excluded with 68 full-text records obtained (**Figure 3.1**). A further 57 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 (**Table 3.2**). A total of 11 studies met the inclusion criteria for assessment. Of the included studies, seven investigated rheumatoid arthritis (RA) (166-172), two investigated gout (113, 148) and two investigated first metatarsophalangeal joint osteoarthritis (1MTP OA) (173, 174). Five studies were randomised clinical trials (167, 168, 170, 171, 173), three studies

were prospective observational intervention studies (113, 166, 172) and three studies were laboratory-based intervention studies (148, 169, 174).

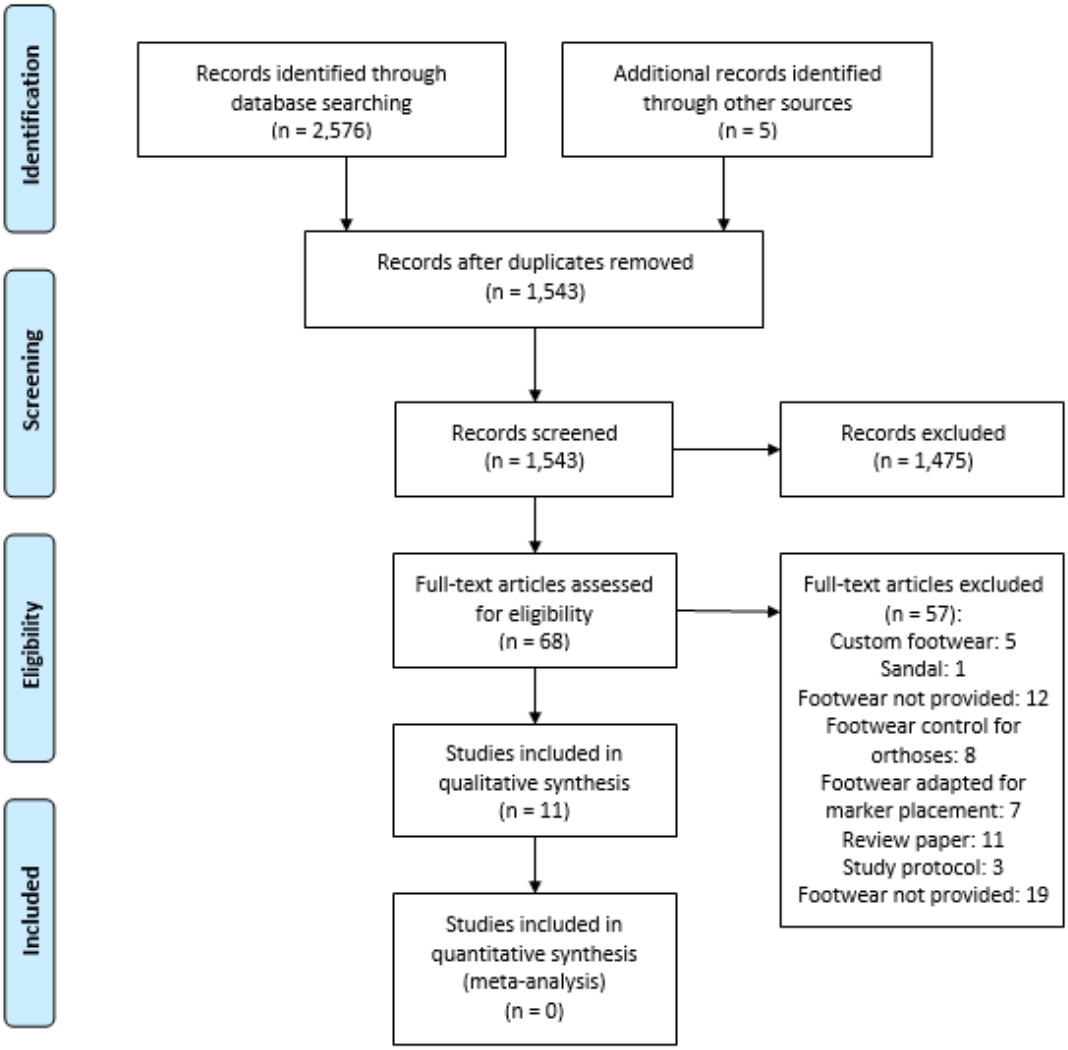

Figure 3.1 PRISMA flow diagram of search strategy

Table 3.2 Excluded full-text studies with reasons
Reason(s) for exclusion
Custom footwear (175-179)
Sandal (180)
Footwear provided as control for foot orthoses (181-188)
Adapted shoe for marker placement (3D analysis) (189-195)
Study design (primary outcome not foot pain/function/impairment/disability) (196)
Study design (sample included participants without arthritis) (197, 198)
Review paper (199-209)
Study protocol (210-212)
Footwear not provided (213-231)

3.3.2 Methodological quality of studies

The inter-rater agreement between reviewers for the 27 items of the Quality Index Tool showed good agreement (kappa statistic: 0.81). Quality Index Tool total scores ranged from 39–96% (**Table 3.3**). Quality assessment of the included 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.

Table 3.3 Quality assessment of scores of included studies

Study	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	Total
(166)	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	39%
(167)	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	54%
(168)	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	79%
(170)	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	71%
(169)	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	64%
(171)	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	61%
(113)	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	86%
(172)	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	50%
(148)	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	64%
(173)	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	1	96%
(174)	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	71%

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

3.3.3 Study characteristics

Study characteristics are displayed in **Tables 3.4-3.6**. 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.

Table 3.4 Characteristics of included randomised clinical trials

Study	N (% Female)	Sample characteristics Years, Mean (SD)	Follow-up	Intervention	Control	Outcome measures	Findings	Quality score
(167)	15 RA (80%) 15 Controls (67%)	**Intervention group** Age: 59 (14) Disease duration: 16 (10) **Control group** Age: 60 (9) Disease duration: 15 (12)	8 weeks	**Extra-depth footwear** (P.W. Minor & Son Inc.) Long inside counter (rear stability and arch support), foam padded heel counter (leather lining), soft leather upper, extra depth (orthoses accommodation).	**Participant's own footwear**	**Primary outcome** Not stated. **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).	**Between group measures** Not reported. **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	**54%**

							follow-up. No significant observed in control group at follow-up.	
(168)	28 RA (75%)	**Total sample** Age: 60 (10) Disease duration: 15 (9)	12 weeks	**Extra-depth footwear + soft orthoses** (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 Soft orthoses; 6mm Plastazote with medium density 6mm Plastazote metatarsal lifts. **Extra-depth footwear + semi-rigid orthoses** Firm heel counter, heel height 1.5–	**Extra-depth footwear** Firm heel counter, heel height 1.5–2.0 cm, instep lacing, wide deep toe box, thick composite sole.	**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. **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	**79%**

				2.0 cm, instep lacing, wide deep toe box, thick composite sole Semi-rigid orthoses; NWB cast, 3mm Subortholen, RF and FF Nickleplast posting, FF 3mm PPT foam, full length leather top cover.			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.	
(170)	40 RA (73%) 40 Controls (53%)	**Total sample** Age: not reported Disease duration: 17 (10)	12 weeks	**New therapeutic footwear** Front of shoe, heel and sole unit, leather and lining, ease of don/doff, heel height, sole thickness Firm contoured insole.	**Traditional therapeutic footwear** Soft, flat 6mm Plastazote, 3mm Poron insole.	**Primary outcomes** Foot pain, disability, activity limitation (FFI) Foot pain, foot function, physical activity (FHSQ).	**Between group measures** Significant improvement in FFI foot pain (p = 0.02), disability (p = 0.01), limitation (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 =	**71%**

		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 improvement in FHSQ foot pain (p = 0.00), foot function (p = 0.00) and physical activity scores (p = 0.02) for intervention group at follow-up. No significant within group improvement in the control group at follow-up.

(171)	22 RA (100%) 20 Controls (100%)	**Intervention group** Age: 49 (12) Disease duration: 8 (6) **Control group** Age: 49 (12) Disease duration: 7 (7)	24 weeks	**Extra-depth footwear + custom orthoses** Wide toe box, cushioned heel, forefoot rocker Custom orthoses; medial arch support, medial heel post, metatarsal pad.	**Extra-depth footwear + prefabricated insoles** Wide toe box, cushioned heel, forefoot rocker Prefabricated insole; 6mm Plastazote.	**Primary outcomes** Foot pain (VAS) Foot pain, disability, activity limitation (FFI).	**Between group measures** No significant differences in foot pain and FFI total scores between intervention and control group at follow-up. **Within group measures** Significant reduction in foot pain ($p < 0.05$) in intervention and control groups at follow-up.	**61%**
(173)	46 1MTPJ OA (61%) 52 Controls (44%)	**Intervention group** Age: 57 (11) Median disease duration: 2 **Control group** Age: 57(11) Median disease duration: 3	12 weeks	**Rocker-sole footwear** (Masai Barefoot Technology Mahuta/Matwa) Rounded sole, soft cushioned heel.	**Own footwear + orthoses** (Vasyli Customs) Full-length, cut out under 1st metatarsal, varus wedge (foot posture index >7).	**Primary outcome** Foot pain (FHSQ). **Outcomes assessed** Function (FHSQ) Foot pain, stiffness, difficulty, activity limitation, social issues (FFI-RSF) 1MTP walk pain, 1MTP rest	**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%**

	pain, 1MTP stiffness (VAS).

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 3.5 Characteristics of included prospective observational studies

Study	N (% Female)	Sample characteristics Years, Mean (SD)	Follow-up	Intervention	Control	Outcome measures	Findings	Quality score
(166)	25 RA (100%)	**Total sample** Age: 57 (not reported) Disease duration: not reported	12 weeks	**Heat-mouldable footwear** (Thermold, P. W. Minor Extra Depth Shoe Co) Extra depth, extra forefoot width, mouldable Plastomold lining, pillow top, leather upper, heat mouldable.	**No control condition**	**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%**
(113)	36 Gout (8%)	**Total sample** Age: 57 (13) Disease duration: 15 (11)	8 weeks	**Good footwear** (ASICS Cardio Zip) leather upper, rubber sole, dual density midsole, rigid heel counter, moderate midfoot sole stability, heel	**Participant's own footwear**	**Primary outcome** Foot pain (VAS). **Outcomes assessed** Function (HAQ-II) General pain (VAS)	**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	**86%**

	and forefoot cushioning. **Poor footwear** (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.	Lower limb function (LLTQ) Impairment and disability (LFIS).	(p = 0.004) observed in good footwear characteristics group at follow-up. No significant improvement in poor footwear characteristics group at follow-up.

				(Helix Viper) synthetic upper, Phylon sole, single density midsole, moderate heel counter stiffness, minimal midfoot sole stability, heel and forefoot cushioning.				
(172)	18 RA (100%)	**Total sample** Age: 47 (8) Disease duration: 8 (7)	4 weeks	**Rocker-soled footwear** High-top (decreased ankle ROM), wide toe box, Velcro (don/doff), heel-toe rocker.	**No control condition**	**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 3.6 Characteristics of included lab-based intervention studies

Study	N (% Female)	Sample characteristics Years, Mean (SD)	Interventions	Control	Outcome measures	Findings	Quality score
(169)	20 RA (80%)	**Total sample** Age: 60 (11) Disease duration: not reported	**Running footwear** (Brooks Glycerin 3, Texas Peak Pty Ltd.) Commercially available, 'premium' cushioned running shoe. **Orthopaedic footwear** (P.W. Minor and Son) Extra-depth, cushioning.	**Thin flexible footwear** (Dunlop volley) Sock liner removed (reduce pressure relief), 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 ($p < 0.001$) with the orthopaedic shoe compared to the control. **Within group measures** Not assessed.	**64%**

(148)	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** (ASICS Cardio Zip) leather upper, rubber sole, dual density midsole, rigid heel counter, moderate midfoot sole stability, heel and forefoot cushioning. **Poor footwear** (Dunlop Asteroid) synthetic upper, rubber sole, single density midsole, minimal heel counter stiffness, minimal midfoot sole stability, no cushioning. (Dunlop Apollo) synthetic upper,	**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), 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.	**64%**

			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.			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 intervention groups compared to control.	
(174)	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** (Masai Barefoot Technology 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,	**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	**71%**

		cadence, stance phase %).	percentage in footwear intervention group. **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 ($p = 0.021$).

PPP: peak plantar pressure, PTI: pressure time integral, MTP: metatarsophalangeal joint

3.3.4 Footwear interventions

Footwear interventions included off-the-shelf footwear (113, 148, 169, 173, 174), therapeutic footwear (166, 167, 169, 170, 172) and therapeutic footwear combined with foot orthoses (168, 171).

3.3.4.1 Off-the-shelf footwear

The use of off-the-shelf footwear was reported in people with RA (169), gout (113, 148) and 1MTP OA (173, 174). In one study in people with RA, an athletic shoe was used with the footwear characteristic of this shoe being cushioning for forefoot pain (169). 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 (113, 148). Poor footwear characteristics included a single density midsole, no cushioning, minimal heel counter stiffness and midsole stability (113, 148). 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 (173, 174).

3.3.4.2 Therapeutic footwear

The use of therapeutic footwear was reported in five studies for people with RA (166, 167, 169, 170, 172). Footwear characteristics included extra-depth in the forefoot region to accommodate for foots orthoses and forefoot deformity, soft leather upper and

smooth lining to offer protection, laces, padded heel counter to improve fit at the heel, a long inside counter to improve rearfoot stability and arch support (167).

3.3.4.3 Therapeutic footwear combined with foot orthoses

The use of therapeutic footwear with foot orthoses was reported in two studies for people with RA (168, 171). 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.

3.3.5 Foot pain

3.3.5.1 Rheumatoid arthritis

Three RCTs (168, 170, 171) and one prospective observational study (172) measured foot pain in people with rheumatoid arthritis. One RCT (170) 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 (168) 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 (171) 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 (172) 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.

3.3.5.2 Gout

One prospective observational study (113) 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).

3.3.5.3 1MTP OA

One RCT (173) 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).

3.3.6 Patient-reported outcomes

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

3.3.6.1 Rheumatoid arthritis

One RCT (167) 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 (170) 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 (171) 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 (166) reported a significant within group improvement

in self-reported walking ability with heat-mouldable footwear (unable to calculate effect size). Another prospective observational study (172) reported within group improvements in foot function, activity limitation and disability with rocker-sole footwear use at four weeks (d = 1.03; large effect).

3.3.6.2 Gout

One prospective observational study (113) 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).

3.3.6.3 1MTP OA

One RCT (173) 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).

3.3.7 Plantar pressure and temporal-spatial parameters

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

3.3.7.1 Rheumatoid arthritis

One cross-sectional study (169) reported significant reductions in total foot, rearfoot and forefoot peak plantar pressure (PPP) in the running footwear (d = 1.84, 1.07, 1.78, respectively; large effects) and orthopaedic footwear (d = 0.86, 0.82, 0.84, respectively; large effects) groups compared to the control group. Significant reductions in total foot (d = 1.72, 1.06; large effects) and forefoot (d = 1.74, 1.14; large effects) pressure time integrals (PTI) in the running footwear and orthopaedic footwear groups compared to the control group. A significant reduction 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 (167) 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 (168) 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).

3.3.7.2 Gout

One cross-sectional study (148) 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 were 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).

3.3.7.3 1MTP OA

One cross-sectional study (174) 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) were 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.

3.4 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. 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 what type of intervention was preferable. Between group findings indicated the majority of studies were 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 (232). 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 were 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 that 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 (160). Reduced walking velocity and increased stance time are indicative of foot related-impairment and disability (233). 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 (233) and increased forefoot plantar pressure have been reported people with RA (234). Footwear with cushioned midsoles can significantly reduce forefoot plantar pressure in people with RA (169). 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 that may be associated with improvements to foot pain and disability include cushioning and support for people with gout (113). These benefits may be related to changes in plantar pressure and temporal-spatial parameters (148). Footwear with an absence of cushioning, minimal heel counter and midsole stability were not associated with improvements to foot pain in people with gout (113). Footwear with poor cushioning and support is common in people with gout and is associated with higher levels of foot-related impairment and disability (124). Difficulties finding footwear that fits appropriately, accommodates existing deformity and is suitable for activities of daily living has been identified by people with gout (150-155). 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 (174). 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 (235).

This review is not without limitations. The literature search and screening of literature was undertaken by a single researcher. 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. 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 that 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. Most 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.

3.5 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 first

metatarsophalangeal joint osteoarthritis and improve walking velocity in rheumatoid arthritis and gout.

Chapter 4: Methodology

4.1 Introduction

This chapter will outline in detail the methods used for studies 1, 2 and 3, specifically the study design, participants, recruitment, procedures surrounding data collection and the methods of analyses used.

4.2 Study 1

4.2.1 Study design and philosophical stance

This study employed a qualitative descriptive methodology (236, 237), using semi-structured interviews to enable a deep exploration of views, and to gain insight on experiences of barriers and facilitators relating to footwear for people living with gout. Qualitative description aims to provide a comprehensive summary of an experience or event in the everyday terms of that experience or event (the *who*, *what* and *where*) (236). This approach draws on the principles of naturalistic enquiry (238), which aims to study something (experiences of footwear) in its natural state. This requires the researcher to remain close to the data and present a descriptive summary of the experience (236). This approach is further supported by the use of thematic analysis, which focuses on an explicit account of the data to develop themes, rather than through interpretation of the data (239). Whilst qualitative description may not be as interpretive as other qualitative methodologies (236), there is a level of interpretation placed on the description of the data (237).

4.2.2 Ethical approval

Ethical approval was obtained from the Auckland University of Technology Ethics Committee (14/233) (**Appendix 2**). All participants read the Participant Information Sheet (**Appendix 3**) and signed a Consent Form (**Appendix 4**) prior to participation. Participants were provided with vouchers to cover the cost of transport to and from the Auckland University of Technology (AUT).

4.2.3 Participants

Participants were included if they met the ACR classification criteria for gout (92) and were ≥20 years of age. Participants were excluded if they: had a history of other inflammatory arthritis or neuromuscular disease; were experiencing a gout flare at time of screening; had taken medication for foot pain in past four weeks; had received prescription of footwear and/or foot orthoses in past three months; had previous foot and/or ankle surgery; or were unable to walk 10 metres unaided.

4.2.4 Recruitment and sampling framework

Participants were recruited by a single researcher (MF) through public newspaper advertising in Auckland, New Zealand using purposeful sampling. Eligible participants were purposefully selected based on the characteristics of the sampling framework (**Table 4.1**). Both male and female participants were included to reflect the gender ratio of the gout population in New Zealand. Characteristics such as gender, ethnicity, disease duration, presence of tophus, serum urate levels and the frequency of acute gout flares were included to explore the impact these may have on experiences surrounding footwear. Characteristics such as ethnicity, disease duration, foot tophus, serum urate levels and acute gout flares have been associated with poorer health-related outcomes in

people with gout. Following purposeful selection and consent, participants were contacted to arrange an appointment for a face-to-face interview.

Table 4.1 Sampling framework

Participant characteristic	Reason for inclusion
Gender	Gout is more common in men with a 4:1 ratio (3).
Ethnicity	In New Zealand, gout is more prevalent in Māori and Pacific Island people (3). Both Māori and Pacific Island people also experience increased disease severity (4, 7).
Disease duration	Clinical manifestations such as tophi and joint damage are typically features of established disease (96).
Presence of foot tophus	People with foot tophi experience greater levels of foot pain and disability compared to those without tophi (114). People with foot tophi have also described concerns around finding suitable footwear (153).
Serum urate level	People with well controlled disease experience a decrease in flares, tophus size and the total number of tophi (240).
Frequency of gout flares	Acute gout flares are associated with high levels of foot pain, impairment and disability (109). People have difficulties wearing footwear when experiencing a gout flare (150-152).

4.2.5 Data collection

Data collection took place between February 2016 and August 2018. Interviews were conducted by a single researcher, and audio-recorded. Interviews ranged from 20–90 minutes. Participants had the choice of whether the interview was conducted at either AUT or at their home. Participants had the option of a support person being present during the interview, however, this was not taken up by any of the participants. Reasons for this were not explored.

An interview guide (**Appendix 5**) was used during interviews. Interview questions were developed based on areas of interest related to footwear highlighted in previous gout studies (113, 124). Topics covered in the interviews included exploring experiences of footwear, barriers to footwear selection and the role of footwear in the management of

gout. An initial definition of footwear was shared with participants to familiarise them towards the area of interest. Participants were also invited to bring pairs of their own footwear to further enhance discussion. An opening question of “tell me about your experiences of footwear?” was asked, followed by additional trigger questions, and the opportunity for participants to express additional ideas they felt were important. Additional trigger questions for the initial interview guide included; “what are the most important things you look for in footwear?”; “what feelings do you have about the footwear currently available to you?”; “what barriers have you experienced related to footwear?”; “what effect has footwear had on your feet?”; “what impact has footwear had on your ability to do the things you wanted to do?”; and further discussion surrounding the ‘ideal shoe’. Prompts were used if conversation came to a halt or to gain a deeper understanding of a participant’s experience. Participants were given the opportunity to express further ideas they feel are important to the research question. Finally, a summary of the interview and discussion was presented to the participant prior to the conclusion of the interview.

4.2.6 Analysis

Data collection and analysis occurred simultaneously and iteratively, and it emerged that this created new insights and additional dialogue, which influenced subsequent interviews and analyses. Interviews continued until diversity across the sampling framework and saturation were achieved with no new concepts emerging from the data, and sufficient information to achieve an understanding of the themes generated.

Data was analysed using constant comparative thematic analysis (239). An assumption of thematic analysis is that the ‘data’ is more-or-less accurate and truthful, which helps to fulfil the obligation of the researcher to remain close to the data in qualitative

description (236) and naturalistic enquiry (238). Analysis was guided by the six step process described by Braun and Clarke (239); (1) familiarising yourself with the data; (2) generating initial codes; (3) searching for themes; (4) reviewing themes; (5) defining and naming themes; and (6) producing the report. Each of the six phases and processes followed will be discussed in detail below.

4.2.6.1 Phase 1: Familiarising yourself with the data

Following each interview, the audio recordings were transcribed verbatim by the researcher (MF). Transcripts were then anonymised to ensure participant confidentiality and analysed after each interview. Audio recordings of interviews were further reviewed to ensure accuracy of the transcriptions and to explore 'the way things were said'. Field notes taken during interviews were also reviewed to direct the researcher to key points identified during interviews. Transcripts were read and re-read to immerse the researcher in the data with initial ideas, patterns and concepts recorded against the transcripts.

4.2.6.2 Phase 2: Generating initial codes

Extracts from the transcripts were then manually coded by single researcher (MF). Consideration was given to each extract whether it was coded a single time, coded under multiple items, or not coded at all. The data surrounding an extract was included to ensure the context of that extract was not lost. Coding was initially undertaken on a hard copy of the transcript by highlighting and labelling the relevant extracts. These codes were then transferred to a Word document of each transcript and added as comments to the relevant extracts. The supporting extracts from all transcripts were then

copied and collated in a single document and grouped under their respective codes. Codes and supporting extracts were then reviewed by a second researcher (AW).

4.2.6.3 Phase 3: Searching for themes

Following the initial coding of the data, the generated codes were then sorted into potential themes. Codes and their supporting extracts were grouped under potential themes and sub-themes. Potential themes and sub-themes were then sorted into tables and an initial thematic map was developed to help explore the relationship between codes, themes and sub-themes.

4.2.6.4 Phase 4: reviewing themes

Potential themes were reviewed to determine that there was sufficient supporting data and that a clear distinction existed between each theme. Themes were reviewed and refined in two stages. The first involved reviewing the appropriateness of each theme in relation to the coded extracts, to ensure that a coherent pattern existed amongst the extracts. This refinement led to a more developed thematic map. The second involved reviewing whether the themes and thematic map were reflective of the entire data set.

4.2.6.5 Phase 5: defining and naming themes

Themes were then named and defined to capture the essence of each theme and how it relates to the entire data set. This led to the development of an overall thematic map. The final themes generated, and the thematic map were agreed upon by members of the supervisory team (KR, ND, AW).

4.2.6.6 Phase 6: producing the report

This phase involved the refinement of thesis chapters four (results) and five (discussion). Illustrative quotes from the transcripts were selected to provide evidence of each theme. The findings where then discussed in relation to the study aim and their wider implications in the context of the current literature.

4.2.7 Rigour

The trustworthiness of qualitative research can be assessed against the following criteria of credibility, transferability, dependability and confirmability (238, 241).

4.2.7.1 Credibility

Credibility represents the strength of the link between the data and the phenomena of interest (experience of footwear) (238, 241). Several steps were taken to enhance credibility. The study followed an established research method (236) and analysis process (239). Prior to data collection, the researcher attended a qualitative research methods course covering the study design, interview techniques and analysis methods for qualitative descriptive research. Using an iterative approach to data collection encouraged the exploration of new insights, ideas and concepts, through open-ended discussions with participants. Regular discussions between the researcher and members of the supervisory team occurred to scrutinise the research processes and subsequent findings.

4.2.7.2 Transferability

Transferability is the degree to which the findings from the study can be applied to a different population or context (238, 241). To enhance transferability, a detailed

description of the study methodology allowed for the findings to be found within the context in which the study was conducted. This included a clear description of the participants in reference to the sampling framework; methods of data collection including the location and duration of interviews; and the process by which the data was analysed.

4.2.7.3 Dependability

Dependability suggests that if a study was repeated using the same/similar participants, study design and analysis processes, the subsequent findings would be comparable to those of the original study (238, 241). To enhance dependability, the raw data (audio file), field notes from the interviews, transcripts and a reflexive journal were maintained to outline an audit trail of the study implementation. This was further supported through regular consultation with members of the supervisory team (KR, ND and AW).

4.2.7.4 Confirmability

Confirmability aims to ensure that the findings of the study are the thoughts of the participants and not those of the researcher (238, 241). To enhance confirmability, each interview concluded with a summary of the discussions to ensure the researcher had best captured the essence of their experience. Illustrative quotes were also embedded within the presented findings. Shorter quotes were used to demonstrate the prevalence of themes, with longer quotes helping to preserve the context from where the data was obtained.

4.3 Study 2

4.3.1 Study design

The study was a six-month, two-arm, parallel randomised controlled trial comparing two foot care packages for people with gout. The study was registered as a clinical trial with the Australian New Zealand Clinical Trials Registry (ACTRN12614000209695).

4.3.2 Ethical approval

The trial was approved by the Health and Disability Ethics Committees (14/CEN/117) (**Appendix 6**). Locality approval was obtained from Auckland District Health Board (A+6423) (**Appendix 7**) and Counties Manukau District Health Board (1878) (**Appendix 8**). Māori consultation was also sought from the Auckland District Health Board Māori research advisor on 01/09/2014. All participants read the Participant Information Sheet (**Appendix 9**) and signed a Consent Form (**Appendix 10**) prior to participation. Participants were provided with vouchers to cover the cost of transport to and from the Auckland University of Technology (AUT). There were no costs incurred by the participants for the podiatric care and footwear.

4.3.3 Participants

4.3.3.1 Recruitment

Participants were recruited from public hospital rheumatology clinics (Auckland and Counties Manukau District Health Boards) and through public newspaper advertising throughout Auckland, New Zealand. Participants were recruited between October 2014 and June 2016.

4.3.3.2 Inclusion and exclusion criteria

Participants were included if they met the ACR classification criteria for gout (92) and were ≥20 years of age. Participants were excluded if they: had a history of other inflammatory arthritis or neuromuscular disease; were experiencing a gout flare at time of screening; had taken medication for foot pain in past four weeks; had received prescription of footwear and/or foot orthoses in past three months (those prescribed foot orthoses more than three months ago were eligible); had previous foot and/or ankle surgery; or were unable to walk 10 metres unaided.

4.3.4 Randomisation and blinding

Participants were allocated 1:1 to the control group (podiatric care and gout education) or intervention group (podiatric care and gout education plus a commercially available athletic shoe) using unstratified block randomisation with random block sizes (between four and six). Centralised randomisation allowed the use of a sealed opaque envelope system. This approach has been successfully used in other gout studies (113). Participants could not be blinded to their study group. Participants invited into the study were informed they would receive a foot care package, without specific mention of footwear. Post-randomisation, participants were not informed of the intervention modalities in the other randomisation group. The researcher (MF), supervision team and data analysts were blinded to allocation.

4.3.5 Assessment

Participants attended study visits at the AUT Podiatry Clinic from November 2014 to February 2017.

4.3.5.1 Clinical assessment

All data collected were recorded on a clinical report form (**Appendix 11**). Baseline assessment included the recording of age (years), gender (male/female) and ethnicity (European/Māori/Pacific Island/Asian). Weight (kg) and height (m) were measured using standardised tools to calculate BMI (kg/m^2). Foot type was assessed using the Foot Posture Index (**Appendix 12**), which classifies the foot against six parameters; talar head palpation, supra- and infra-lateral malleolar curve, prominence of the talonavicular joint, congruence of the medial longitudinal arch, abduction/adduction of the forefoot and inversion/eversion of the calcaneus (242). Each parameter is scored on a five point scale (-2 to +2) with scores combined to provide an overall value ranging from -12 (highly supinated) to +12 (highly pronated). The Foot Posture Index is reliable and valid tool (242, 243), and has been used in previous gout studies (109, 111, 124).

Current medical history including the presence of hypertension, cardiovascular disease, type 2 diabetes, peripheral vascular disease and peripheral neuropathy were recorded. Current medications including the use of urate-lowering therapy (allopurinol, probenecid, benzbromarone, febuxostat), colchicine, prednisone, NSAIDs and diuretics were recorded.

Disease-specific characteristics were obtained from clinical records and patient-reported data. This included the ACR classification criteria that the participant fulfilled, disease duration (years), the latest serum urate recording (mmol/L), the number of gout flares in last three months and the total number of tophi in the body and at the foot.

Foot problems including the presence of hallux valgus, lesser digital deformity and hyperkeratotic lesions were recorded on a foot manikin.

4.3.5.2 Footwear assessment

The footwear worn by both groups was assessed for age, type and wear using the Footwear Assessment Tool (244) (**Appendix 13**). The Footwear Assessment Tool is a reliable and valid measure (244) and has been used in previous gout studies (113, 124). The age of the footwear was self-reported by the participant and categorised as either <6 months old, 6–12 months old, or >12 months old. Footwear type was classified as good, moderate or poor (245). Good footwear included walking, athletic, therapeutic, or Oxford footwear. Moderate footwear included boots. Poor footwear included flip-flops, sandals, slippers, moccasin and mule footwear. Classification of footwear into these categories has been used in previous gout studies (124).

Wear was assessed at the upper, midsole, tread and outsole. Upper wear (degrees) was categorised as either neutral, medial tilt (greater than 10°), or lateral tilt (greater than 10°). Midsole wear was categorised as either neutral, medial midsole compression, or lateral midsole compression. Tread pattern was categorised at two levels as either textured or smooth; and as either no wear, partly worn, or fully worn. Outsole wear was categorised as either neutral (wear from lateral heel to medial forefoot), medial (greater medial wear at the heel/forefoot), or lateral (greater lateral wear at the heel/forefoot). The use of existing foot orthoses was also recorded.

4.3.6 Interventions

Participants attended four visits (baseline, two months, four months and six months) over the trial period. At each study visit, participants in both groups received standardised podiatric care comprising of palliative care of nails and skin, temporary padding, wound care, emollient use, footwear advice, foot care advice and gout education delivered by an experienced podiatrist (Trish Morpeth). The inclusion of these interventions were selected based on previous work (147).

Gout education was delivered using a pamphlet produced by the New Zealand Ministry of Health including information on the causes of gout; the role of urate in development of gout; pharmacological management; monitoring of serum urate levels; and general footwear advice (**Appendix 14**).

In addition, participants in the footwear intervention group received a pair of ASICS Cardio Zip 3 shoes to wear during daily activities (**Figure 4.1**).

Figure 4.1 Men's and women's ASICS Cardio Zip shoes

This footwear was selected based on the findings of a previous feasibility study (113), and its characteristics including heel/forefoot cushioning, dual density midsole, wide fitting and a zip for ease of fit. The gel-based cushioning present under the heel and forefoot region helps to improve shock attenuation (245). The incorporation of a rocker-sole is associated with an improved heel-to-toe transition during walking and a reduction in forefoot loading in people with other forms of arthritis (171, 172). Footwear incorporating laces and other forms of fixation (zips) allow for adjustment of the shoe to accommodate for foot deformity (113). This footwear was also the most commonly selected shoe compared to three other shoes of a similar style in the feasibility study (113).

To determine the appropriate footwear size, the participant's foot length and width were measured by the podiatrist using a Brannock device. Women had the option of choosing between a black or white colour, with men having a black colour only. Footwear was then fitted by the podiatrist. For participants with existing foot orthoses, the sock-liner of the shoe was removed and replaced by the orthoses. The intervention group also completed self-reported footwear daily diaries to record footwear use and adverse events measured over the six months in the footwear (**Appendix 15**). Footwear diaries were dispensed at each study visit and returned at the subsequent visit. Previous footwear studies (113) have reported a high completion rate using self-reported diaries to monitor footwear use. Participants were also asked at each visit about whether they had experienced a gout flare since the last study visit.

4.3.7 Outcomes

The following outcome measures were assessed at baseline, two, four and six months. The primary outcome was participant-reported foot pain. Secondary outcomes included

participant-reported overall pain, patient global assessment, activity limitation, lower limb function, foot impairment and disability and participant-reported footwear comfort, fit, ease and weight.

4.3.7.1 Foot pain

The severity of foot pain was assessed with a 100 mm VAS (**Appendix 16**). Foot pain severity was rated on a 100 mm horizontal line, with leftmost anchor representing ‘no pain’ (0 mm) and the rightmost anchor representing ‘very severe pain’ (100 mm). Participants marked a cross on the line at the point that they thought best represented their foot pain. The distance from the left anchor to the cross was measured in mm and scored out of 100. This tool has been used in previous gout studies to measure foot pain (38, 109, 113, 114).

4.3.7.2 General pain (secondary outcome)

The severity of general pain was assessed with a 100 mm VAS (**Appendix 16**). General pain severity was rated on a 100 mm horizontal line, with leftmost anchor representing ‘no pain’ (0 mm) and the rightmost anchor representing ‘very severe pain’ (100 mm). Participants marked a cross on the line at the point that they thought best represented their overall pain. The distance from the left anchor to the cross was measured in mm and scored out of 100. This tool has been endorsed by Outcome Measures in Rheumatology (OMERACT) for evaluating general pain in people with gout (246) and validated as an outcome measure for use in gout studies (247).

4.3.7.3 Patient global assessment (secondary outcome)

Overall wellbeing was assessed with a 100 mm VAS (**Appendix 16**). Overall wellbeing was rated on a 100 mm horizontal line, with leftmost anchor representing ‘completely well’ (0 mm) and the rightmost anchor representing ‘extremely unwell’ (100 mm). Participants marked a cross on the line at the point that they thought best represented their overall wellbeing. The distance from the left anchor to the cross was measured in mm and scored out of 100. This tool has been endorsed by OMERACT for evaluating overall wellbeing in people with gout (246) and validated as an outcome measure for use in gout studies (247).

4.3.7.4 Activity limitation (secondary outcome)

Activity limitation was assessed with the Health Assessment Questionnaire II (HAQ-II) (248) (**Appendix 17**). The HAQ-II comprises of 10 items for that participants are asked to rate the difficulty associated with each task in the past week (without difficulty = 0, some difficulty = 1, much difficulty = 2, unable = 3). The sum is calculated and then divided by the number of questions answered to give a total score ranging from 0 to 3. Lower scores are indicative of better functional status. If less than eight questions were answered the HAQ-II was not scored. This tool has been endorsed by OMERACT for evaluating activity limitation in people with gout (246).

4.3.7.5 Lower limb function (secondary outcome)

Lower limb function was assessed with the Lower Limb Tasks Questionnaire (LLTQ) (249) (**Appendix 18**). The LLTQ comprises of two (2) sections (activities of daily living and recreational activities) each with 10 items for that participants are asked to rate the difficulty associated with each task in the past 24 hours (unable = 0, severe

difficulty = 1, moderate difficulty = 2, mild difficulty = 3, no difficulty = 4). The sum of each section is calculated to give a total score ranging from 0 to 40, with higher scores indicative of better lower limb function. In addition, the importance of each item was rated on a 4-point Likert scale (1 = not important, 2 = mildly important, 3 = moderately important, 4 = very important). The LLTQ has been used in previous gout studies (109, 113).

4.3.7.6 Foot impairment and disability (secondary outcome)

Foot-related impairment and disability was assessed with the Leeds Foot Impact Scale (LFIS) (250) (**Appendix 19**). The LFIS comprises of two (2) sections; impairment/footwear ($LFIS_{IF}$) containing 21 questions and activity limitation/participation ($LFIS_{AP}$) containing 30 questions. Each question is answered as 'true' or 'false', with true response recorded as one point and false responses as zero points. The sum of each section is calculated to give a score ranging from 0–21 for $LFIS_{IF}$, 0–30 for $LFIS_{AP}$ and a total LFIS score between 0–51, with higher scores are indicative of greater levels of impairment and disability. The LFIS has been used in previous gout studies (109, 113).

4.3.7.7 Footwear evaluation (secondary outcome)

Participant perceptions of footwear comfort, fit, ease of putting on and taking off and weight were each evaluated using 100 mm VAS (**Appendix 20**). Footwear comfort was rated on a 100 mm horizontal line, with leftmost anchor representing 'extremely comfortable' (0 mm) and the rightmost anchor representing 'extremely uncomfortable' (100 mm). Participants marked a cross on the line at the point that they thought best represented their footwear comfort. The distance from the left anchor to the cross was

measured in mm and scored out of 100. This tool has been used in previous footwear research (251, 252).

Footwear fit was rated on a 100 mm horizontal line, with leftmost anchor representing ‘best possible fit’ (0 mm) and the rightmost anchor representing ‘poorest fit possible’ (100 mm). Participants marked a cross on the line at the point that they thought best represented their footwear fit. The distance from the left anchor to the cross was measured in mm and scored out of 100. This tool has been used in previous footwear research (252).

Footwear ease of putting on and taking off was rated on a 100 mm horizontal line, with leftmost anchor representing ‘as easy as imaginable’ (0 mm) and the rightmost anchor representing ‘most difficult as possible’ (100 mm). Participants marked a cross on the line at the point that they thought best represented their footwear ease. The distance from the left anchor to the cross was measured in mm and scored out of 100. This tool has been used in previous footwear research (252).

Footwear weight was rated on a 100 mm horizontal line, with leftmost anchor representing ‘extremely light’ (0 mm) and the rightmost anchor representing ‘extremely heavy’ (100 mm). Participants marked a cross on the line at the point that they thought best represented their footwear weight. The distance from the left anchor to the cross was measured in mm and scored out of 100. This tool has been used in previous footwear research (252).

4.3.8 Sample size

Initial sample size calculations were based on the previous feasibility study (113). To detect the minimally important difference of -15 mm in the foot pain VAS (-17.2mm detected in feasibility study, $p = 0.003$) with power 0.80, using the repeated measures

model detailed below with a baseline to 6 month correlation of 0.30, would require 52 participants in each group (correlation extrapolated from feasibility study). Gains in efficiency expected from the repeated measures and added covariates make this sample size conservative.

The attrition rate extrapolated to 6 months from the feasibility study had a 95% confidence interval of (18%, 70%), too broad for use in design. However, previous clinical trials conducted in Auckland involving people with gout have reported drop-out rates of 15% over 4 months (142) and 8% after 12 months (253). Using a conservatively estimated loss to follow-up rate of 25% at 6 months, the initial aim was to recruit 140 participants.

A protocol amendment containing a revised sample size computation due to a decline in participant recruitment was submitted to and approved by an independent data monitoring committee (DMC) on 06/05/2016. The revision used a new estimated baseline to 6 month correlation of 0.49 in the primary outcome and a new dropout rate supplied by the DMC, based on the first 38 completions. A revised sample size of 39 completions per group was determined. At an estimated loss to follow-up rate of 15%, the target recruitment was 92 participants (46 per group).

4.3.9 Statistical analyses

4.3.9.1 Blind review

A blind review of the data was undertaken at the end of the trial to consider the specific regression models to use, inclusion of covariates, the appropriateness of multiple imputations for any missing covariate, any necessary data transformation and the selection of an appropriate covariance structure for the repeated measures.

4.3.9.1.1 Model selection

The distribution of the residuals from the linear mixed models for all continuous outcomes were assessed for skewness and kurtosis to determine the appropriateness of the linear mixed models. A model involving the baseline outcome, all planned common covariates and a selection of other baseline outcomes was assessed. Visual inspection of residual histograms, normal Q-Q plots and scatterplots of the values fitted against the residuals was undertaken. Focus was placed on qualitative appraisal of the parametric assumptions by graphical means such as Q-Q plots and measures of association between mean outcome and residual variance, rather than testing. Under clearly evinced non-normality, the selection of an appropriate generalised linear model and link was preferred to data transformation.

4.3.9.1.2 Selection of covariates

Age, gender, ethnicity, BMI, colchicine use, NSAID use, prednisone use and the presence of subcutaneous tophi at baseline were considered for inclusion in the regression models during the blind review, absent all knowledge of group allocation. Partial R^2 was used as the main selection criterion for these covariates.

4.3.9.3 Missing data

Missing covariate data was resolved using multiple imputation. The repeated measures model allows for the accommodation of missing data without requiring additional adjustment. Ten multiple imputed data sets were produced, using all observed data, under an assumption of Missingness at Random. No data transformation was found to be needed.

4.3.9.4 Descriptive statistics

Gender, ethnicity, history of diabetes, cardiovascular disease, peripheral vascular disease and peripheral neuropathy, gout classification, tophus count (total and foot), current pharmacological management and foot problems were described as number (percentage). All other clinical characteristics were described as mean (SD).

4.3.9.5 Inferential analyses

4.3.9.5.1 Analysis set

Primary and secondary analyses were based on an intention-to-treat (ITT) analysis set, from which only participants with no baseline nor post-randomisation data were excluded. Participant assessments were included in the per-protocol (PP) analysis set if the participants fulfilled the criteria of the ITT set and did not present any major protocol violation, such as eligibility violation or other protocol violations adjudicated as major by the supervisory team. All other protocol deviations were considered minor and would not lead to exclusion of participants from the PP analysis set.

4.3.9.5.2 Repeated measures framework

Primary and other outcomes were compared across the treatment groups using repeated measures models of outcome data at two, four and six months adjusted for baseline.
A participant-associated random effect was used to account for the covariance between the repeated measurements. The covariance structure was amended for particular outcomes as a result of the blind review, to account for possible heteroscedasticity of the measures and more complex covariance structure. When the inferential focus was on a particular time-point (for example, six months) the appropriate contrast was obtained from the full model with assessment time-point treated as a factor.

4.3.9.6 Significance levels

All tests were carried out at a significance level of 0.05 against two-sided alternatives. No correction for multiple testing was applied.

4.4.9.7 Software

Data were analysed using SAS version 9.4 and R version 3.2 including package *gamlss* (254, 255).

4.4 Study 3

4.4.1 Study design

The study was a cross-sectional repeated measures study, comparing worn and new footwear in people with gout.

4.4.2 Ethical approval

Ethical approval was obtained from the Auckland University of Technology Ethics Committee (14/233) (**Appendix 2**). All participants read the Participant Information Sheet (**Appendix 21**) and signed a Consent Form (**Appendix 22**) prior to participation. Participants were provided with vouchers to cover the cost of transport to and from the Auckland University of Technology (AUT). There were no costs incurred by the participants for the footwear.

4.4.3 Participants

4.4.3.1 Recruitment

Participants with gout were recruited from rheumatology clinics and through public newspaper advertising throughout Auckland, New Zealand. Participants were recruited between March 2016 and January 2017.

4.4.3.2 Inclusion and exclusion criteria

Participants were included if they met the ACR classification criteria for gout (92) and were ≥20 years of age. Participants were excluded if they: had a history of other inflammatory arthritis or neuromuscular disease; were experiencing a gout flare at time of screening; had taken medication for foot pain in past four weeks; had received prescription of footwear and/or foot orthoses in past three months; had previous foot and/or ankle surgery; or were unable to walk 10 metres unaided.

Participants were fitted with a new pair ASICS Cardio Zip 3 footwear. This footwear was chosen based on the findings of a previous feasibility study (113), and its characteristics including heel/forefoot cushioning, dual density midsole, wide fitting option and a zip for ease of fit. To determine the appropriate footwear size, the participant's foot length and width were measured by a single researcher using a Brannock device. Women had the option of choosing between a black or white colour, with men having a black colour only. Footwear was then fitted by the podiatrist. For participants with existing foot orthoses, the sock-liner of the shoe was removed and replaced by the orthoses. All participants wore footwear for six months, with self-reported diaries used to record the number of hours the footwear was worn (**Appendix 15**). These diaries have been used in previous gout studies (113). Participants then returned for a study visit where they were tested with the worn shoes and new shoes in a random order.

4.4.4 Randomisation and blinding

Testing order of the two footwear conditions was randomised using unstratified block randomisation with random block sizes (between four and six). Centralised randomisation allowed the use of a sealed opaque envelope system. This method has been used in previous gout studies (148). Participants and assessors could not be blinded.

4.4.5 Assessment

After six months of wearing the footwear, participants attended a second study visit at the AUT Podiatry Clinic between April 2016 and August 2017. All assessments were undertaken on a single study visit.

4.4.5.1 Clinical assessment

Clinical assessment included the recording of age (years), gender (male/female) and ethnicity (European/Māori/Pacific Island/Asian). Weight (kg) and height (m) were measured using standardised tools to calculate BMI (kg/m^2). Foot type was assessed using the foot posture index (**Appendix 12**).

Current medical history including the presence of hypertension, cardiovascular disease, type 2 diabetes, peripheral vascular disease and peripheral neuropathy were recorded. Current medications including the use of urate-lowering therapy (allopurinol, probenecid, benzbromarone, febuxostat), colchicine, prednisone, NSAIDs and diuretics were recorded.

Disease-specific characteristics were obtained from clinical records and patient-reported data. This included the ACR classification criteria that the participant fulfilled, disease

duration (years), the latest serum urate recording (mmol/L), the number of gout flares in last three months and the total number of tophi in the body and at the foot.

4.4.5.2 Footwear assessment

The Footwear Assessment Tool (**Appendix 13**) was used to assessed the structural properties of the new and worn footwear (244). The Footwear Assessment Tool is a reliable and valid measure (244) and has been used in previous gout studies (113, 124). The Footwear Assessment Tool classifies footwear based on general structure, motion control properties, cushioning and wear (**Figure 4.2)**.

The general structure of the footwear was assessed under the categories of heel height and forefoot height. Heel height (cm) was an average of heights measured at the medial and lateral heel using a digital Vernier calliper (Workzone, NSW, Australia) (**Figure 4.2**). Forefoot height (cm) was an average of heights measured at the level of the first and fifth metatarsals using a digital Vernier calliper (**Figure 4.2**).

Figure 4.2 Assessment of heel and forefoot height

The motion control properties of the footwear were assessed under the categories of heel counter stiffness, midfoot sagittal stability and midfoot frontal stability. Heel counter stiffness (degrees) was measured as a visual estimate by applying force to posterior aspect of the heel counter and was categorised as either rigid (<10°), moderate (10–45°), or minimal (>45°) (**Figure 4.3**). Midfoot sagittal stability (degrees) was measured as a visual estimate by grasping the heel and forefoot of the shoe and bending the shoe in the sagittal plane at the midfoot and was categorised as either rigid (<10°), moderate (10–45°), or minimal (>45°) (**Figure 4.3**). Midfoot frontal stability (degrees) was measured as a visual estimate by grasping the heel and forefoot of the shoe and twisting the shoe in the frontal plane at the midfoot and was categorised as either rigid (<10°), moderate (10–45°), or minimal (>45°) (**Figure 4.3**).

Figure 4.3 Assessment of heel counter, midfoot torsion and sagittal stability

The cushioning properties of the footwear were assessed under the categories of heel sole hardness, lateral midsole hardness and medial midsole hardness. Midsole hardness was measured using a Shore A durometer (Sauter, Balingen, Germany) that was

calibrated with a calibration plate (Shore A 21) prior to testing. Heel sole hardness was measured using the durometer at the inferior aspect of the heel inside the shoe (**Figure 4.4**). Lateral midsole hardness was measured using the durometer at the lateral aspect of the midsole at the level of the heel (**Figure 4.4**). Medial midsole hardness was measured using the durometer at the lateral aspect of the midsole at the level of the heel (**Figure 4.4**).

Figure 4.4 Assessment of heel, lateral and medial midsole hardness

The amount of wear in the footwear was assessed under the categories of upper wear, midsole wear, tread and outsole wear. Upper wear (degrees) was categorised as either neutral, medial tilt (greater than 10°), or lateral tilt (greater than 10°). Midsole wear was categorised as either neutral, medial midsole compression or lateral midsole compression. Tread pattern was categorised as either no wear, partly worn or fully worn. Outsole wear was categorised as either neutral (wear from lateral heel to medial

forefoot), medial (greater medial wear at the heel/forefoot), or lateral (greater lateral wear at the heel/forefoot).

4.4.6 Interventions

Two footwear conditions were evaluated; (1) a new pair ASICS Cardio Zip 3 (new footwear); and (2) a pair of ASICS Cardio Zip 3 worn by the participant over a six month period (worn footwear). The footwear tested was the same size and model for both footwear conditions. The appropriate footwear size was determined using a Brannock device (Brannock Device Company Inc., NY, USA). For participants with existing foot orthoses, the sock-liner of the footwear was removed and replaced by the orthoses for testing.

4.4.7 Outcomes

Prior to randomisation, participants were instructed to walk across the GAITRite® walkway (CIR Systems, Inc., New Jersey, US) at a self-selected speed to determine their average walking speed over three trials. GAITRite® is a 700cm × 90cm electronic walkway with an active sensor area of 609.6cm long and 60.96cm wide. The active area contains sensor pads (2,204 pressure activated sensors per 0.61cm^2), with a spatial resolution of 1.27cm and a sampling rate of 120Hz. Participants started two steps behind the walkway and were instructed to walking two steps beyond the end of the walkway. Participants were instructed to walk at their normal, comfortable speed (256). The walkway is triggered by the first foot contact with the walkway. Following each trial, data was reviewed visually to screen check that the left and right footfalls had been correctly identified and that each footfall was fully in contact with walkway. In cases where footfalls were partially in contact with the walkway, these were removed prior to processing.

The primary outcome was plantar pressure (peak plantar pressure and pressure time integrals), measured using the F-Scan® Mobile system (Tekscan Inc., South Boston, MA, USA). Each insole contains 954 sensors (3.9 sensors per $1cm^2$). The system was calibrated prior to data acquisition (257). Data obtained using the five-stride protocol (110, 148), where seven strides are recorded for each foot with the first and last strides removed. During each trial participants walked across the GAITRite® walkway to monitor walking speed, with reference to the average walking speed determined prior to randomisation (**Figure 4.5**). GAITRite® has been used to measure walking velocity in previous gout studies (115, 120) and is reliable measure in people with inflammatory arthritis (258).

Figure 4.5 GAITRite® walkway with F-Scan® system

Three trials were completed in both pairs of footwear, with seated breaks between trials. Following each trial, if the walking speed was 5% outside of the average self-selected speed determined prior, participants were asked to repeat the trial (259). The following temporal spatial parameters were also calculated for each trial using GAITRite® gold, Version 3.2b software.; walking speed (cm/s), step length (cm), stride length (cm), cadence (steps/min), base of support (cm), step time (s), stance time (s), cycle time (s), swing percentage (%), stance percentage (%), single limb support percentage (%) and double limb support percentage (%).

After each trial, the pressure data was also reviewed visually on screen to check for sensor failure or slippage/bunching of the sensor within the shoe. If this was found to have occurred, the trial was repeated. The F-Scan® software package (Tekscan Inc., Version 5.24) was used to analyse the plantar pressure data. The foot was manually masked into 7 regions (heel (0–30% of foot length), midfoot (30–60% of foot length), first metatarsal (1MTP) (60–85% of foot length), second metatarsal (2MTP) (60–85% of foot length), lesser metatarsals (345MTP) (60–85% of foot length), hallux (85–100% of foot length) and lesser digits (85–100% of foot length)) to calculate mean peak plantar pressure (kPa) and pressure time integrals (kPa*sec) (**Figure 4.6**). This method has been found to be reliable in the gout population (intraclass correlation coefficients 0.92–0.97) (257). All pressure data was reviewed during analysis to determine if any sensor failure or sensor slippage/bunching had been missed during the initial visual inspection. Data at these regions were excluded from the analysis.

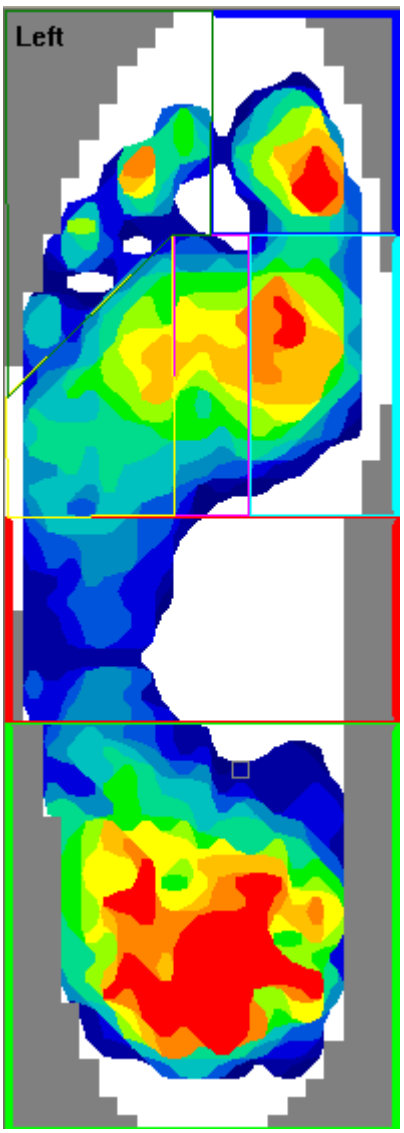

Figure 4.6 Masking of the seven regions of the foot

4.4.8 Sample size

The sample size estimation is based on a previous plantar pressure study of gout and footwear (148). In this study, the participant's own shoes and the intervention footwear were worn on the same visit and plantar pressure measurements taken under both conditions. Plantar pressure was remeasured at eight weeks with the intervention footwear that had been in use during this period (unpublished data). The standard deviation of the differences was 152. A sample size of 40 allowed the detection of a difference of 69 kPa (effect size 0.45) between new and worn intervention footwear

with 80% power at a significance level of 5% using a paired t-test. The use of a linear mixed model on repeated measures makes this power assessment conservative.

4.4.9 Statistical analyses

4.4.9.1 Descriptive statistics

Gender, ethnicity, history of diabetes, cardiovascular disease, peripheral vascular disease and peripheral neuropathy, gout classification, tophus count (total and foot) and current pharmacological management were described as number (percentage). All other clinical characteristics were described as mean (SD).

4.4.9.2 Inferential analyses

4.4.9.2.1 Model selection

Linear mixed models were used to determine differences between plantar pressure and temporal-spatial parameters, and the two footwear conditions: worn footwear and new footwear. The two footwear conditions were entered as fixed effects, with the paired-foot data (left side and right side) and variables measured entered as random effects (260). This model accounts for repeated measures taken from the left and right side. Walking velocity and cadence were not paired for foot side. All measures taken over three trials were not averaged and included in the analysis as separate observations.

To determine differences in wear between the new and worn footwear, linear mixed models were used to test for statistical differences in the continuous variables. The two footwear conditions were entered as fixed effects, with the paired-foot data and variables measured entered as random effects. Fisher's exact test was used to test for statistical differences in the categorical outcomes. No adjustments for covariates were made for this cross-over trial, as participants acted as their own control.

4.4.9.2.2 Missing data

Linear mixed models are not biased under an assumption of Missingness at Random (261). We therefore elected not to use other methods to account for missing data such as multiple imputation.

4.4.9.3 Significance levels

Observed significance levels were presented. Significance at the 0.05 level was declared accounting for a Bonferroni correction based on the seven plantar pressure outcomes, twelve temporal spatial outcomes, or twelve footwear outcomes. All tests were carried out against two-sided alternatives.

4.4.9.4 Software

Data were analysed using SAS version 9.4 and R version 3.2.

Chapter 5: Results

5.1 Introduction

This chapter presents the findings from the qualitative study (study 1), RCT (study 2) and cross-sectional study (study 3). Data from each study is presented under sub-sections.

5.2 Study 1

5.2.1 Participant characteristics

A total of 30 participants were sent invitations to the study, of these 11 did not respond to contact, 8 responded to the invitation but declined and 11 consented to participate. The demographic and clinical characteristics of the participants specific to the sampling framework are displayed in **Table 5.1**. There was diversity across age, gender, ethnicity and clinical features, consistent with the sampling framework. Nine males and two females with a median age of 53 years (range 40–83 years) were interviewed. Across the clinical features, participants had a median disease duration of 10 years (range 2–25 years), median serum urate level of 0.41 mmol/L (range 0.27–0.59 mmol/L), median number of flares in the past year was 3 flares (range 0–6 flares) and 27% participants had foot tophus.

Table 5.1 Participant characteristics

Participant	Gender	Age	Ethnicity	Disease duration	Foot tophus	Serum urate	Flare frequency (past year)
1	F	61	South African	12 years	Y	0.27	3
2	M	54	NZ Māori	25 years	N	0.40	3
3	M	83	NZ Māori	10 years	N	0.27	2–3
4	M	40	NZ European	3 years	N	0.43	5
5	M	49	Pacific Island	2 ½ years	N	0.45	2–3
6	M	40	Pacific Island	10 years	Y	0.59	6
7	F	53	NZ Māori	1 ½ years	N	0.41	1–2
8	M	72	NZ European	10 years	N	0.29	1–2
9	M	58	NZ European	5 years	N	0.54	0
10	M	48	Pacific Island	20 years	N	0.36	6
11	M	70	NZ European	15 years	Y	Not recently checked	0

5.2.2 Themes

Four central themes were derived from the data; (i) comfort as a priority, (ii) knowing what to buy, (iii) knowing what to wear and (iv) challenges of different environments. A thematic map outlining the central themes and sub-themes is demonstrated in **Figure 5.1**.

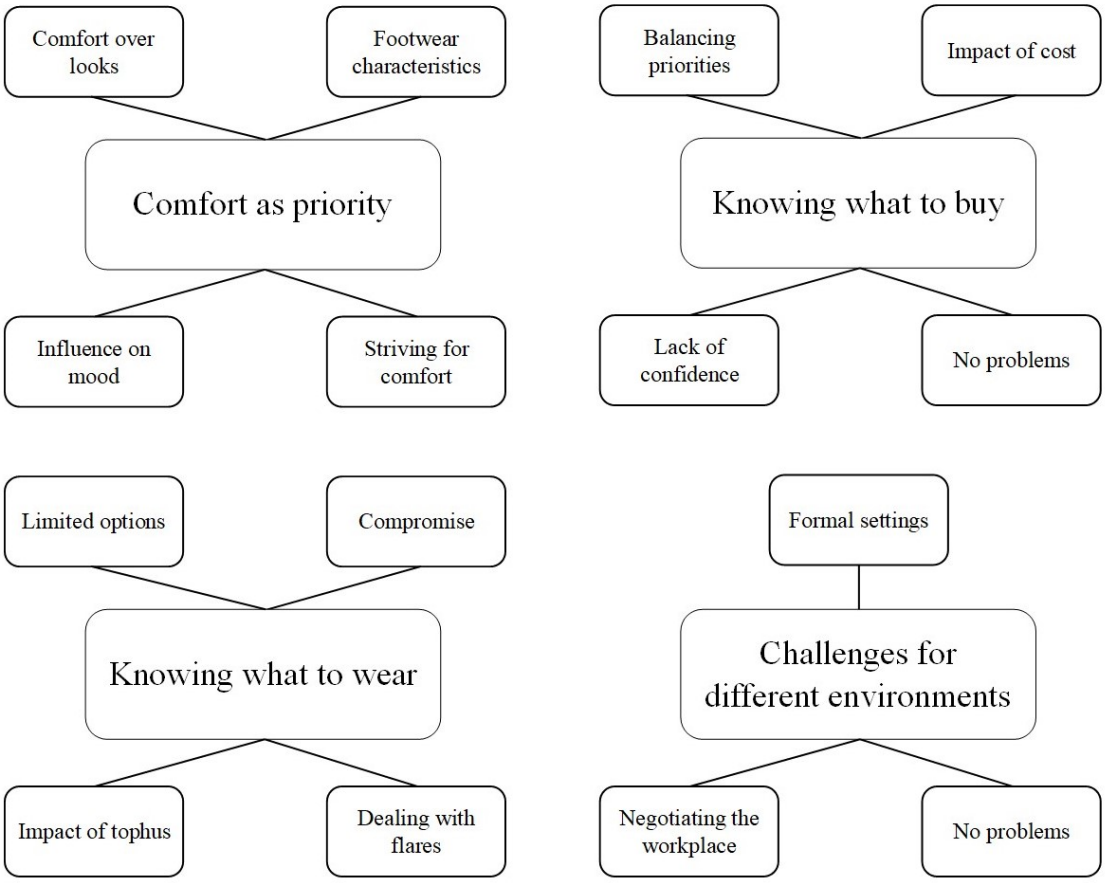

Figure 5.1 Thematic map showing the central four themes and sub-themes

5.2.2.1 Theme 1: Comfort as a priority

All participants stated the importance of comfort, supporting the idea that having comfortable footwear was a priority. For some, feeling comfortable was more important than 'looking good';

> *"I'm far more thinking about being comfortable you know and not really worrying about what people say or think"* *Participant 1, female, 61 years old*
>
> *"I've been wearing shoes in the past that don't look good, but they are comfortable. That's, and then, I mean I always get eyes and looks and weirds, but I didn't really care I was just like 'oh, I'm comfortable man'"* *Participant 6, male, 40 years old*

The concept of striving for comfort was evident, with feelings of satisfaction upon finding comfortable footwear;

> *"They were the first wide fit ASICS I've ever had and the relief of being able to walk pain free was magnificent"* *Participant 7, female, 52 years old*
>
> *"I didn't realise that you can have comfortable shoes, cause I've never had comfortable shoes before"* *Participant 10, male, 48 years old*

Specific footwear characteristics such as having a good fit, being lightweight and having enough room to accommodate the foot, were identified as important influencers of footwear comfort;

> *"I, ah, choose shoes that are comfortable, and ah, that don't constrict, my, my feet"* *Participant 3, male, 83 years old*
>
> *"I find that if I wear a heavy shoe it umm inflamm… it-it aggravates it as well so, my choice would be a lighter shoe with a little bit more room in it"* *Participant 4, male, 40 years old*
>
> *"The fit of the shoe is important if it's too, if it's too tight then it's not comfortable"* *Participant 8, male, 72 years old*

"They're comfortable you know because they've got the cushioning in them" *Participant 9, male, 58 years old*

Having uncomfortable footwear led to foot pain, which in turn could influence one's mood and ability to participate. This consequence was viewed with frustration;

"I'm the person who has to sit with a problem when I get home tonight because my feet are sore, and then I can't sleep, and then you don't sleep, and then you're miserable as H the next morning, and then you've got to work, and you're grumpy" *Participant 1, female, 61 years old*

5.2.2.2 Theme 2: Knowing what to buy

Barriers to shoe shopping were described including budgetary constraints, limited range and a lack of confidence in knowing what the right shoe is to buy. Finding a balance between comfort and appearance was frequently described;

"Comfort is, is ah probably right up there with looking good but if it looks good but doesn't, and it's not comfortable forget it if it's comfortable and it's not, doesn't look good yea, oh yea, yea probably but just depends but if you can get a bit of both then oh yea she's a winner" *Participant 10, male, 48 years old*

For others, this balance was strongly influenced by cost, placing further limitations on the footwear available forcing some to 'work with' what was left;

"I think it's just my um, my budget wise. What am I able to afford um, compared to what is out of my price range" *Participant 6, male, 40 years old*

Obtaining advice was difficult creating uncertainty surrounding the right type of footwear to buy. This resulted in a lack of confidence with purchases based on negative past experiences, such as footwear becoming uncomfortable shortly after leaving the shop;

"I can try something on in the store and think 'oh my god this is so comfortable, fantastic, problem solved' and then, um it might not be for two or three wears then I'll be walking, and that pain will come back and it's like if I don't take these shoes off well it's just going to escalate" *Participant 7, female, 53 years old*

In contrast, some found shoe shopping relatively straight-forward, with gout playing little role in the decision-making process when purchasing footwear.

"I haven't even really thought about buying shoes related to the gout" *Participant 11, male, 70 years old*

5.2.2.3 Theme 3: Knowing what to wear

Despite owning multiple pairs of shoes, participants described a lack of suitable options with respect to the footwear in the cupboard. Having gout meant that footwear that was previously suitable, was no longer appropriate;

"In terms of shoes pre-gout, the only shoes I can still wear are these, that I had before I ever had gout" *Participant 7, female, 53 years old*

Those with tophi described difficulties in accommodating for deformity and how affected sites were irritated by certain footwear;

"Anything that rubs on there or that puts pressure on there, within half an hour, yeah, I'm starting to get really sort of antsy because of the pressure and the rubbing and that. And that can sometimes last for a good, maybe, week, ten days after that, that it's irritated enough for me to have a thing of gout, attack of gout. So, I steer clear very. I know that that's a trigger" *Participant 1, female, 61 years old*

"If I go out I'll wear leather, proper leather shoes. Trouble is with that bump on my toe it's a bit of a pain aye. You know, um, very restrictive actually" *Participant 6, male, 40 years old*

The unpredictable nature of not knowing whether footwear would remain comfortable or exacerbate their foot problems was described. For some, inappropriately fitting footwear could lead to a flare;

"I bought a pair of those to wear to walk on the beach because I find walking on sea sand very uncomfortable if I'm barefoot but if I wear shoes it's more comfortable so I wore those and it basically, again longer shoe but not enough width so that just aggravated it and kind of spoiled a day or two of the holiday because my foot was flared up and I didn't want to go to the beach so walking was difficult so I just spent most of the time sitting at the campsite not enjoying anything really" *Participant 4, male, 40 years old*

For some, there was resignation that finding footwear compatible with their foot and beliefs may not be possible, with others accepting that their current footwear may be as good as it gets. Feelings of dejection were evident;

"Having this gout there's not much, there's not much around. It's almost like here's what you've got to try and fit into, try to make it part of you, sort of um your footwear" *Participant 6, male, 40 years old*

5.2.2.4 Theme 4: Challenges of different environments

Participants described that their footwear requirements were different depending on the situation. In formal settings, there was a disconnect between having comfortable footwear and maintaining appearance. The trade-off of sacrificing footwear comfort was to put up with the pain during and after the occasion;

"You've got a formal or a fancy event to go to, you kind of, you just sacrifice as I've said earlier you deal with the consequence tomorrow because this looks right or this is more appropriate for that activity so you just basically suck it up and consequences come tomorrow" *Participant 4, male, 40 years old*

Health and safety requirements dictated the footwear choices for several participants. Steel cap boots were viewed as limiting due to being heavy, inflexible and restrictive in the forefoot. Some would adapt their footwear habits to accommodate for their gout symptoms during a flare;

"When I got the gout, I still go to the work, one safety boot, one sneaker" *Participant 2, male, 54 years old*

For others footwear discomfort resulted in a change in workplace practise;

"Footwear is pretty important with respect to comfort and functionality and as for the gout like I said I'm blessed to know what I can wear. It doesn't make the pain go away (researcher) but it makes it tolerable cause if I've got to go to work, I've got to go to work, and I work eight hours and even though I can work with the footwear I don't stay on my feet as long so I'll try and stay on the hoist, I've changed my work structure to suit the ailment" *Participant 5, male, 49 years old*

In contrast, some participants did not report any significant issues as they had found footwear that was comfortable and acceptable for the environments that they interacted in;

"I don't ah spend a lot of time thinking about my shoes I wear them and that's that. And once I, and once you've got a comfortable pair you don't need to think a lot about it" *Participant 3, male, 83 years old*

5.3 Study 2

5.3.1 Participants

5.3.1.1 Participant flow

Figure 5.2 shows the flow of participants through the study. There were 187 potential participants screened, and 94 randomised. Recorded protocol violations included randomisation of three participants who consented but did not complete the initial study visit (excluded from the ITT set) and the withdrawal of one participant who consented but was later found to have had foot surgery with a toe amputation, post-randomisation (included in the ITT set).

Four participants in the footwear intervention group were unable to wear their allocated footwear due to discomfort. Of these participants, three remained enrolled in the trial and continued to receive the other facets of their allocated intervention with one participant withdrawal. Participants in the footwear intervention group reported wearing their allocated footwear on average 24 hours per week during the study period. At the six month follow-up, 89% of the control intervention group and 91% of the footwear intervention group completed the study.

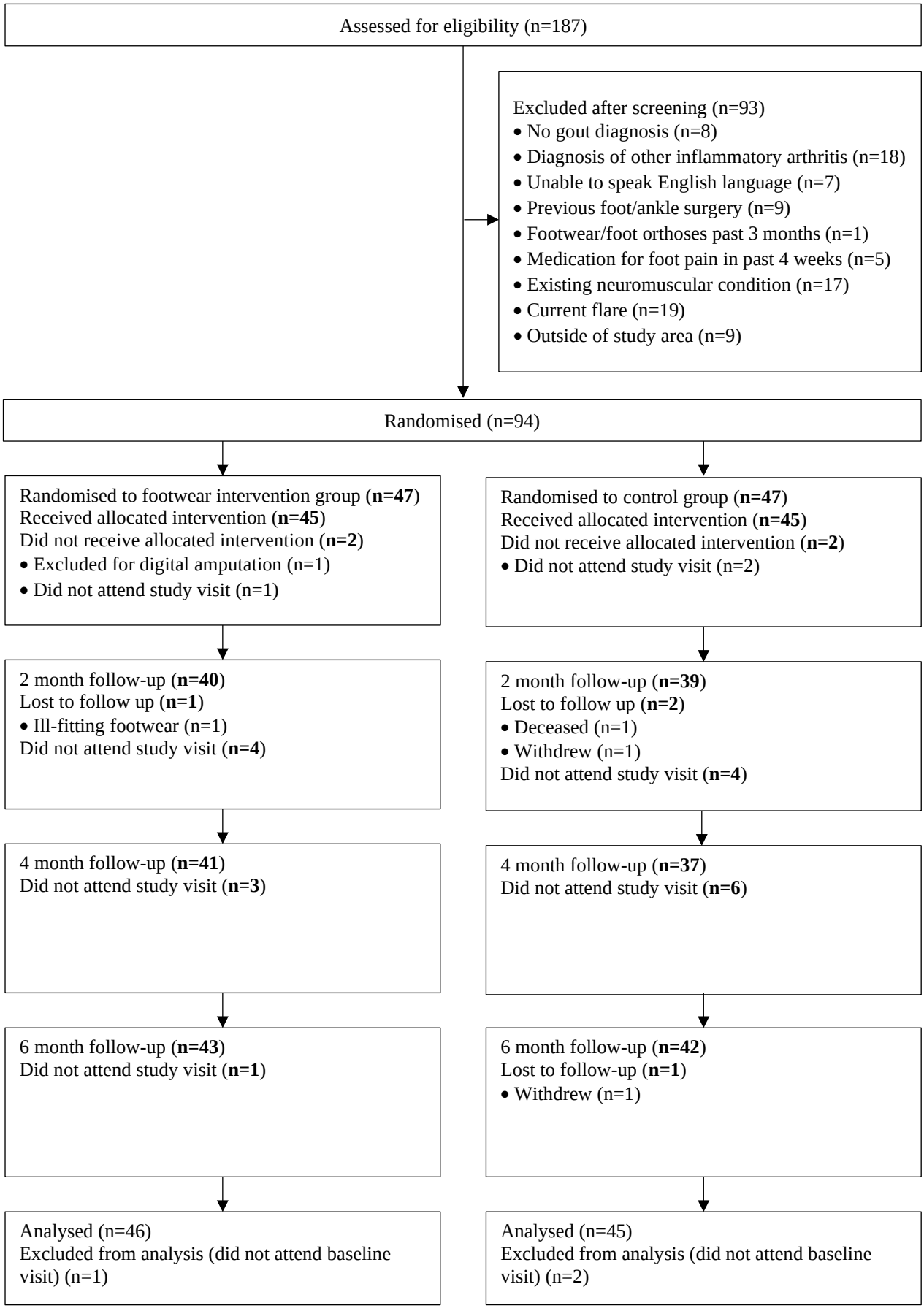

Figure 5.2 Participant flow through study

5.3.1.2 Descriptive statistics

Baseline descriptive statistics are displayed in **Table 5.2**. Participants were predominantly male of New Zealand European ethnicity, with over 10 year's disease duration and on urate lowering therapy. High rates of obesity and comorbidities such as hypertension and cardiovascular disease were observed. Foot problems such as hallux valgus, lesser digital deformity and hyperkeratotic lesions were prevalent in both groups.

Table 5.2 Baseline descriptive statistics

Variable	**Footwear intervention group (n=47)**	**Control group (n=47)**
Sex, male, n (%)	40 (85%)	43 (91%)
Age, years, mean (SD)	62.6 (17.0)	62.4 (13.7)
BMI, kg/m^2, mean (SD)	30.2 (6.4)	32.0 (7.0)
Foot posture index, mean (SD)	4 (4)	4 (4)
Ethnicity, n (%)		
NZ European	28 (62%)	26 (57%)
Pacific	6 (13%)	11 (23%)
Asian	7 (16%)	5 (11%)
Māori	4 (9%)	4 (9%)
Gout history, mean (SD)		
Disease duration (years)	12.2 (11.2)	13.6 (12.3)
Flares prior three months	0.7 (0.9)	0.4 (0.7)
Foot tophus, n (%)	9 (19%)	17 (36%)
Any tophus, n (%)	13 (28%)	24 (51%)
Serum urate, mmol/L, mean (SD)	0.39 (0.13)	0.38 (0.11)
Medications, n (%)		
Urate-lowering therapy	33 (72%)	30 (64%)
Colchicine	15 (33%)	17 (36%)
Prednisone	9 (20%)	10 (21%)
NSAID	12 (27%)	13 (29%)

Diuretic	8 (18%)	5 (11%)
Medical History, n (%)		
Hypertension	22 (48%)	22 (54%)
Cardiovascular disease	13 (28%)	11 (24%)
Type 2 diabetes	7 (15%)	3 (7%)
Peripheral vascular disease	4 (9%)	3 (7%)
Peripheral neuropathy	3 (7%)	5 (11%)
Foot problems, n (%)		
Hallux valgus	28 (62%)	23 (51%)
Lesser digital deformity	26 (58%)	28 (62%)
Hyperkeratotic lesions	25 (56%)	26 (58%)

BMI: body mass index, NSAID: non-steroidal anti-inflammatory drug

5.3.2 Clinically assessed outcomes

5.3.2.1 Footwear characteristics

Baseline footwear characteristics are displayed in **Table 5.3**. Poor footwear was a common occurrence, with the majority wearing footwear that was worn and over 12 months old.

Table 5.3 Baseline footwear characteristics

Variable	**Footwear intervention group (n=47)**	**Control group (n=47)**
Footwear type, n (%)		
Good	23 (51%)	23 (51%)
Athletic	5	11
Oxford	10	5
Therapeutic	2	0
Walking	6	7
Moderate	3 (7%)	2 (4%)
Boot	3	2
Poor	19 (42%)	20 (44%)

Sandal	8	4
Moccasin	4	7
Flip-flop	4	4
Slipper	2	4
Court	1	0
Mule	0	1
Footwear age, n (%)		
<6 months	8 (18%)	12 (27%)
6-12 months	5 (11%)	9 (20%)
>12 months	31 (70%)	24 (53%)
Upper wear, n (%)		
Neutral	34 (77%)	26 (58%)
Medial	9 (20%)	17 (38%)
Lateral	1 (2%)	2 (4%)
Midsole wear, n (%)		
Neutral	38 (86%)	31 (69%)
Medial	9 (20%)	9 (20%)
Lateral	1 (2%)	5 (11%)
Tread pattern, n (%)		
Textured	42 (95%)	37 (86%)
Smooth	2 (5%)	6 (14%)
Outsole wear, n (%)		
None	2 (4%)	7 (16%)
Partly worn	35 (78%)	29 (64%)
Fully worn	8 (18%)	9 (20%)
Outsole wear pattern, n (%)		
None	1 (2%)	6 (13%)
Normal	17 (38%)	19 (42%)
Lateral	27 (60%)	20 (44%)

5.3.3 Inferential statistics

5.3.3.1 Normality

The distribution of the residuals from the linear mixed models for all continuous outcomes were assessed with the most non-linear of these being the footwear-related visual analogue scale outcomes (footwear comfort, fit, ease and weight), principally in terms of significant leptokurtosis, excess kurtosis and left skewness of the residuals, after adjusting for baseline VAS values. These footwear outcomes were fitted with a scaled zero-inflated beta regression model (generalised additive model for location, scale and shape). The distribution of the residuals for all other continuous outcomes demonstrated sufficient normality to carry out parametric testing and were fitted using linear mixed models.

5.3.3.2 Covariates

Analyses were adjusted for the covariates presented in **Table 5.4**. Baseline values for an outcome were included in the model in all cases.

Table 5.4 Included covariates for primary and secondary outcomes

	Baseline covariate									Covariance
Outcome	**Baseline value**	**Age**	**Gender**	**Ethnicity**	**BMI**	**Colchicine**	**NSAID**	**Prednisone**	**Tophi**	
Foot pain VAS	•									RI+RS
Overall pain VAS	•				•					RI
Patient global VAS	•				•					RI+RS
HAQ-II	•									RI+RS
LFIS total	•									RI
LFIS IS	•				•					RI
LFIS AP	•			•						RI+RS
LLTQ ADL	•									RI
LLTQ REC	•	•								RI+RS
Footwear comfort VAS	•				•			•		RI+RS
Footwear fit VAS	•		•		•					RI+RS
Footwear ease VAS	•			•	•					RI+RS
Footwear weight VAS	•		•		•					RI

VAS: visual analogue scale, HAQ-II: Health Assessment Questionnaire II, LFIS Total: Leeds Foot Impact Scale total score, LFIS IS: Leeds Foot Impact Scale impairment/shoes subscale, LFIS AP: Leeds Foot Impact Scale activity limitation/participation subscale, LLTQ ADL: Lower Limb Tasks Questionnaire activities of daily living score, LLTQ REC: Lower Limb Tasks Questionnaire recreational activities score, RI=random intercept, RI+RS=random intercept and random slope on visit number

5.3.3.4 Primary outcome

All efficacy endpoints and covariate adjustments are shown in **Table 5.5**. Baseline foot pain scores were low. There was no difference in foot pain at any time-point over the six month study period between the two groups (adjusted effect estimate: -6.7, 95% CI -16.4 to 2.9, P=0.17).

5.3.3.5 Secondary outcomes

Improvements between groups in overall pain scores (adjusted effect estimate: -13.2, 95% CI -22.2 to -4.3, P<0.01) favouring the footwear intervention were observed at two months, but there was no difference between the groups at four or six months (adjusted effect estimate at six months: -4.0, 95% CI -13.6 to 5.7, P=0.42). Foot-related impairment and disability was reduced at two months in the footwear intervention group (adjusted effect estimate: -4.7, 95% CI -9.7 to -0.3, P=0.04), but there was no difference between groups at four or six months (adjusted effect estimate at six months: -3.0, 95% CI 0.2 to -1.8, P=0.21). No between-group differences in patient global assessment, HAQ-II and LLTQ were observed (**Table 5.5**).

Between-group differences favouring the footwear intervention were observed in footwear comfort at two months (adjusted effect estimate: -10.4, 95% CI -19.9 to -0.9, P=0.03) and four months (adjusted effect estimate: -11.3, 95% CI -21.4 to -1.3, P=0.03), but not at six months (adjusted effect estimate: -8.0, 95% CI -19.2 to 3.3, P=0.16). Similarly, between-group differences favouring the footwear intervention were observed in footwear fit (adjusted effect estimate: -11.1, 95% CI -23.0 to -1.0, P=0.03), footwear ease (adjusted effect estimate: -13.2, 95% CI -23.8 to -2.7, P=0.01) and footwear weight (adjusted effect estimate: -10.3, 95% CI -19.8 to -0.8, P=0.03) at all time-points over the six month study period.

Table 5.5 Outcome measure scores and effect estimates adjusted from baseline

	Footwear intervention Mean (SD)	**Control intervention Mean (SD)**	**Adjusted effect estimate Estimate (95% CI)**	**P[a]**
Foot pain VAS				
Baseline	14.8 (18.7)	17.5 (22.4)		
2 months	10.7 (13.0)	16.8 (21.8)	-5.0 (-12.9 to 2.8)	0.21
4 months	13.8 (23.0)	16.1 (22.3)	-1.8 (-10.1 to 6.4)	0.66
6 months	13.1 (20.8)	20.5 (26.1)	-6.7 (-16.4 to 2.9)	0.17
Overall pain VAS*				
Baseline	18.7 (19.6)	17.7 (23.9)		
2 months	9.7 (13.6)	23.3 (27.5)	-13.2 (-22.2 to -4.3)	**<0.01**
4 months	16.2 (19.4)	17.9 (22.8)	-2.3 (-0.5 to 0.6)	0.65
6 months	16.3 (19.2)	20.7 (26.8)	-4.0 (-13.6 to 5.7)	0.42
Patient global assessment VAS*				
Baseline	22.7 (24.5)	21.5 (25.8)		
2 months	17.7 (24.2)	16.4 (21.6)	1.2 (-7.4 to 9.9)	0.78
4 months	14.6 (16.6)	16.6 (20.2)	-2.8 (-11.9 to 6.3)	0.55
6 months	15.3 (19.4)	18.8 (21.9)	-3.4 (-12.6 to 5.7)	0.46
HAQ-II				
Baseline	0.5 (0.6)	0.4 (0.5)		
2 months	0.5 (0.6)	0.4 (0.4)	-0.1 (-0.3 to 0.1)	0.36
4 months	0.6 (0.6)	0.3 (0.5)	0.0 (-0.2 to 0.2)	0.84

6 months	0.5 (0.5)	0.4 (0.6)	-0.1 (-0.3 to 0.1)	0.28
LFIS total score				
Baseline	15.5 (11.5)	15.4 (12.5)		
2 months	13.8 (13.0)	16.4 (14.1)	-4.7 (-9.1 to -0.3)	**0.04**
4 months	14.9 (14.2)	14.2 (12.3)	-1.3 (-6.1 to 3.5)	0.59
6 months	14.4 (13.6)	16.9 (14.2)	-3.0 (0.2 to 1.8)	0.21
LFIS impairment/shoes*				
Baseline	6.5 (4.4)	6.2 (4.8)		
2 months	5.3 (4.7)	6.5 (5.5)	-1.9 (-4.0 to 0.3)	0.09
4 months	5.9 (5.2)	5.9 (4.9)	-0.3 (-2.4 to 1.9)	0.81
6 months	5.8 (4.8)	6.7 (5.6)	-0.9 (-3.0 to 1.2)	0.39
LFIS activity limitation/participation**				
Baseline	9.1 (9.0)	9.1 (9.0)		
2 months	8.5 (9.5)	9.9 (10.0)	-2.7 (-5.2 to -0.1)	**0.04**
4 months	9.1 (9.8)	8.3 (5.8)	-0.4 (-3.4 to 2.5)	0.77
6 months	8.7 (9.7)	10.1 (9.5)	-1.4 (-4.4 to 1.7)	0.38
LLTQ activities of daily living				
Baseline	32.7 (8.2)	33.8 (6.8)		
2 months	34.8 (7.2)	32.9 (8.0)	2.2 (-0.2 to 4.6)	0.07
4 months	32.9 (8.1)	35.4 (6.7)	-0.4 (-3.1 to 2.3)	0.77
6 months	34.0 (6.9)	33.8 (7.7)	1.1 (-1.2 to 3.4)	0.35
LLTQ recreational activities***				
Baseline	22.7 (11.8)	21.1 (11.6)		

2 months	23.5 (14.2)	22.8 (11.5)	0.8 (-2.8 to 4.4)	0.66
4 months	20.8 (12.8)	25.1 (9.9)	-3.4 (-7.5 to 0.8)	0.11
6 months	21.7 (12.6)	22.2 (12.0)	-0.9 (-4.8 to 3.0)	0.66
Footwear comfort VAS****				
Baseline	24.0 (21.9)	27.6 (28.0)		
2 months	10.3 (13.1)	26.2 (26.5)	-10.4 (-19.9 to -0.9)	**0.03**
4 months	9.1 (9.8)	24.0 (21.0)	-11.3 (-21.4 to -1.3)	**0.03**
6 months	17.5 (23.5)	27.9 (28.4)	-8.0 (-19.2 to 3.3)	0.16
Footwear fit VAS*****				
Baseline	20.6 (20.1)	24.0 (27.2)		
2 months	9.8 (16.0)	22.2 (21.3)	-9.5 (-17.2 to -1.8)	**0.02**
4 months	10.3 (13.6)	22.2 (20.4)	-11.1 (-19.9 to -2.4)	**0.01**
6 months	11.9 (20.0)	27.9 (28.4)	-11.1 (-21.1 to -1.0)	**0.03**
Footwear ease VAS******				
Baseline	20.9 (23.0)	19.3 (23.8)		
2 months	12.7 (19.1)	26.8 (28.2)	-9.8 (-19.4 to -0.3)	**0.04**
4 months	10.2 (16.6)	23.8 (25.2)	-12.3 (-23.0 to -1.6)	**0.02**
6 months	11.3 (19.7)	27.9 (28.4)	-13.2 (-23.8 to -2.7)	**0.01**
Footwear weight VAS*****				
Baseline	21.9 (21.9)	22.7 (24.6)		
2 months	12.7 (17.8)	27.0 (26.6)	-9.7 (-19.5 to 0.0)	**0.05**
4 months	13.6 (20.3)	24.6 (20.4)	-10.8 (-20.6 to -0.9)	**0.03**
6 months	11.4 (19.7)	27.9 (28.4)	-10.3 (-19.8 to -0.8)	**0.03**

[a] bolded values indicate statistical significance

VAS: visual analogue scale, HAQ-II: Health Assessment Questionnaire II, LFIS: Leeds Foot Impact Scale, LLTQ: Lower Limb Tasks Questionnaire, BMI: body mass index

*BMI adjusted

**Ethnicity adjusted

***Age adjusted

****BMI and prednisone adjusted

*****Sex and BMI adjusted

******Ethnicity and BMI adjusted

5.3.3.6 Per-protocol analyses

Four participants were identified as not being able to wear the footwear. However, adherence to the intervention could not be determined with certainty in the other participants (for example, those who did not return footwear diaries but wore the footwear). For this reason, it was decided not to perform per-protocol analysis.

5.3.4 Adverse events

Two participants (4%) in the footwear intervention group developed foot blisters and one participant (1%) in the footwear intervention group withdrew from the study due to footwear discomfort. During the trial period, 16 participants (34%) in the control intervention group and 14 participants (30%) in the footwear intervention group experienced an acute gout flare.

5.4 Study 3

5.4.1 Participants

5.4.1.1 Participant flow

Figure 5.3 shows the flow of participants through the study. There were 94 potential participants screened, and 50 enrolled in the study and received footwear. Of those, 40 attended the study visit. Three participants were unable to wear their allocated footwear due to discomfort.

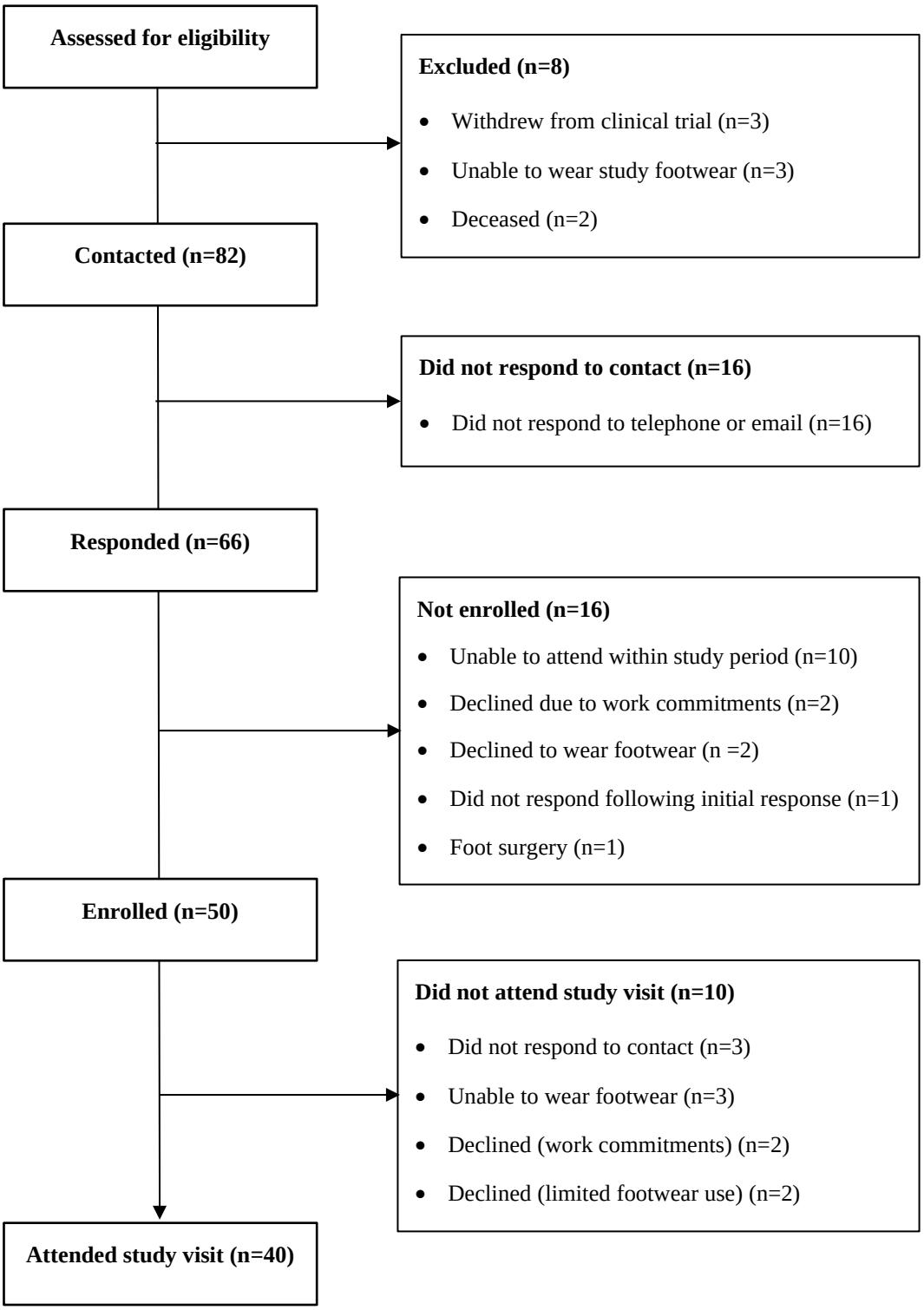

Figure 5.3 Flow chart of participants

5.4.1.2 Descriptive statistics

Demographic and clinical characteristics are displayed in **Table 5.6**. The majority of participants were European with a mean (SD) age of 67 (13) years and disease duration of 13 (12) years. Footwear diaries were completed by 80% of participants with footwear reported being worn on average of 20 hours per week (range 7–63 hours per week).

Table 5.6 Demographic and clinical characteristics

Variable	**Summary**
Sex (male), n (%)	35 (88%)
Age (years), mean (SD)	67 (13)
BMI (kg/m^2), mean (SD)	30.5 (6.5)
Foot posture index, mean (SD)	4 (4)
Ethnicity, n (%)	
European	30 (75%)
Pacific Island	4 (10%)
Māori	3 (8%)
Asian	3 (8%)
Gout history	
Disease duration (years), mean (SD)	13 (12)
Self-reported flares in previous 3 months, mean (SD)	0.4 (0.8)
Foot tophus, n (%)	12 (30%)
Any tophus, n (%)	15 (35%)
Serum urate, mmol/L, mean (SD)	0.34 (0.11)
Medications, n (%)	
Urate lowering therapy	25 (63%)
Colchicine	8 (20%)
Prednisone	8 (20%)
NSAID	14 (35%)
Diuretic	6 (15%)
Medical history, n (%)	
Hypertension	21 (53%)
Cardiovascular disease	12 (30%)

Diabetes	4 (10%)
Peripheral vascular disease	3 (8%)

BMI: body mass index, NSAID: non-steroidal anti-inflammatory drug

5.4.2 Clinically assessed outcomes

5.4.2.1 Footwear characteristics

Reductions in heel height (P<0.0001), forefoot height (P<0.0001), heel counter stiffness (P<0.0001), midfoot sagittal stiffness (P<0.0001) and midfoot frontal stiffness (P=0.001) were observed in the worn footwear (**Table 5.7**). Increases in medial midsole hardness (P<0.0001), lateral midsole hardness (P<0.0001) and heel midsole hardness (P<0.0001) were observed in the worn footwear. Signs of outsole wear was evident in the worn footwear, with the majority displaying normal upper (P<0.0001), midsole (P=0.05) and outsole (P<0.0001) wear patterns.

Table 5.7 Footwear characteristics

Characteristic*	**New shoe**	**Worn shoe**	**P[a]**
Heel height (cm), mean (SD)	3.7 (0.1)	3.6 (0.1)	**<0.0001**
Forefoot height (cm), mean (SD)	2.1 (0.0)	1.9 (0.1)	**<0.0001**
Heel counter stiffness, n (%)			**<0.0001**
Minimal (>45°)	0 (0%)	1 (3%)	
Moderate (10–45°)	0 (0%)	12 (30%)	
Rigid (<10°)	40 (100%)	27 (68%)	
Midfoot sagittal stiffness, n (%)			**<0.0001**
Minimal (>45°)	0 (0%)	1 (3%)	
Moderate (10–45°)	0 (0%)	18 (45%)	
Rigid (<10°)	40 (100%)	21 (53%)	
Midfoot frontal stiffness, n (%)			**0.001**
Minimal (>45°)	0 (0%)	1 (3%)	
Moderate (10–45°)	0 (0%)	9 (23%)	
Rigid (<10°)	40 (100%)	30 (75%)	

Lateral midsole hardness (Shore A), mean (SD)	57.0 (0)	58.3 (0.9)	**<0.0001**
Medial midsole hardness (Shore A), mean (SD)	54.0 (0)	56.2 (1.2)	**<0.0001**
Heel midsole hardness (Shore A), mean (SD)	56.0 (0)	58.8 (1.3)	**<0.0001**
Upper wear, n (%)			**<0.0001**
None	40 (100%)	0 (0%)	
Medial tilt	0 (0%)	17 (43%)	
Neutral	0 (0%)	23 (58%)	
Lateral tilt	0 (0%)	0 (0%)	
Midsole wear, n (%)			0.005
None	40 (100%)	0 (0%)	
Medial	0 (0%)	8 (20%)	
Neutral	0 (0%)	32 (80%)	
Lateral	0 (0%)	0 (0%)	
Tread, n (%)			**<0.0001**
Not worn	40 (100%)	0 (0%)	
Partly worn	0 (0%)	40 (100%)	
Fully worn	0 (0%)	0 (0%)	
Outsole wear, n (%)			**<0.0001**
None	40 (100%)	0 (0%)	
Medial	0 (0%)	0 (0%)	
Normal	0 (0%)	40 (100%)	
Lateral	0 (0%)	0 (0%)	
*data presented for left shoe only, [a] bolded values indicate significance after Bonferroni correction at P<0.004			

5.4.3 Inferential statistics

5.4.3.1 Normality

The distribution of the residuals from the linear mixed models for all continuous outcomes were assessed with the most non-linear of these, principally in terms of skewness of the residuals, occurring at the 345MTP region. To assess the robustness of the linear model on non-normal peak pressure data; this data was isolated, run as a

linear model using a bootstrap to determine how well or poorly the standard error for the new versus worn effect is estimated.

The standard error for the fixed effect of the new versus worn footwear according to the normal linear mixed model was 4.42, with a bootstrap sample of size 1,000 yields a robust estimator of 4.52. The estimated effect by the model was 9.78, while the bootstrap mean effect was 10.09 (as the effect size is not a pivotal quantity for the bootstrap, we do not necessarily expect these values to be close). Therefore, it was concluded that inference using the linear mixed model is robust to the departures from normality that may be present in the peak plantar pressure data. The distribution of the residuals for all other plantar pressure, temporal-spatial and footwear data demonstrated sufficient normality to carry out parametric testing.

5.4.3.2 Missing data

One participant withdrew during testing due to discomfort meaning there was missing data for plantar pressure in the worn footwear. After screening the data, there were outliers for peak plantar pressure at a total six sites (heel or midfoot), where extreme peak pressures were registered on a single sensor at the edge of the insole. As these values were significantly higher than the readings at the adjacent sensors, it suggests that the insole was compressed against the side of the shoe (visual inspection of box plots and F-Scan® software package). Pressure readings at these sites were subsequently excluded from the analyses, with readings from other sites retained for analysis.

5.4.3.3 Primary outcome

No significant differences in peak plantar pressure were observed across the seven regions of the foot (**Table 5.8**). Reductions in pressure time integrals were observed at 1MTP ($P<0.0001$), 2MTP ($P<0.0001$) and the hallux ($P=0.003$) in the worn footwear compared to the new footwear (**Table 5.9**). No significant differences in pressure time integrals were observed across the other masked regions.

Table 5.8 Peak plantar pressure (kPa)

Parameter	Condition	Mean Estimate	Difference	95% Confidence Intervals		P
				Lower	Upper	
Heel	New	318.8	-4.2	-20.3	11.9	0.61
	Worn	323.0				
Midfoot	New	154.2	-3.1	-19.1	12.9	0.70
	Worn	157.3				
1MTP	New	318.5	1.7	-14.3	17.7	0.83
	Worn	316.8				
2MTP	New	316.2	0.6	-15.4	16.6	0.94
	Worn	315.5				
345MTP	New	266.6	-9.0	-25.0	6.9	0.27
	Worn	275.6				
Hallux	New	284.3	6.9	-9.0	22.9	0.39
	Worn	277.4				
Lesser toes	New	188.1	-4.1	-20.1	11.8	0.61
	Worn	192.2				

Table 5.9 Pressure time integrals (kPa*s)

Parameter	Condition	Mean Estimate	Difference	95% Confidence Intervals		P[a]
				Lower	Upper	
Heel	New	43.8	-0.3	-1.5	0.9	0.60
	Worn	44.1				
Midfoot	New	32.5	-0.2	-1.4	1	0.75
	Worn	32.7				
1MTP	New	50.9	4.2	3.0	5.3	**<0.0001**
	Worn	46.7				
2MTP	New	48.9	2.6	1.4	3.7	**<0.0001**
	Worn	46.3				
345MTP	New	45.9	0.8	-0.4	2.0	0.18
	Worn	45.1				
Hallux	New	31.6	2.2	1.0	3.3	**0.0003**
	Worn	29.5				
Lesser toes	New	25.2	1.2	-0.02	2.3	0.05
	Worn	24.0				

[a] bolded values indicate significance after Bonferroni correction at P<0.007

5.4.4.4 Temporal-spatial parameters

Temporal spatial gait parameters are displayed in **Table 5.10**. No differences were observed in walking velocity, step length, cadence, swing percentage and stance percentage ($P>0.05$). Differences were observed in stride length ($P<0.001$) between the new and worn footwear conditions, though these were minimal in size.

Table 5.10 Temporal-spatial gait parameters

Parameter	Condition	Mean Estimate	Difference	95% Confidence Intervals		P[a]
				Lower	Upper	
Base of support (cm)	New	11.82	-0.08	-0.33	0.16	0.51
	Worn	11.90				
Cadence (steps/min)	New	105.6	-0.32	-0.88	0.24	0.26
	Worn	106.0				
Cycle time (s)	New	1.15	0.01	-0.23	0.25	0.94
	Worn	1.14				
DLS (%)	New	28.89	-0.17	-0.42	0.07	0.17
	Worn	29.10				
SLS (%)	New	35.55	0.03	-0.21	0.28	0.79
	Worn	35.52				
Stance (%)	New	64.46	-0.03	-0.27	0.22	0.82
	Worn	64.49				
Stance time (s)	New	0.57	0.00	-0.24	0.25	0.97
	Worn	0.57				
Step length (cm)	New	65.97	0.21	-0.03	0.46	0.09
	Worn	65.75				
Step time (s)	New	0.57	0.00	-0.24	0.25	0.97
	Worn	0.57				
Stride length (cm)	New	131.91	0.50	0.25	0.74	**<0.0001**

	Worn	131.42				
Swing (%)	New	35.55	-0.00	-0.24	0.24	0.99
	Worn	35.55				
Walking speed (cm/s)	New	1.16	0.06	-0.5	0.6	0.84
	Worn	1.16				

DLS: double limb support, SLS: single limb support

[a] bolded values indicate significance after Bonferroni correction at P<0.004

5.4.4 Adverse events

During the six months of wear prior to data collection, two participants (5%) developed blisters and ten (25%) participants experienced a gout flare. One participant (3%) withdrew during testing due to discomfort.

Chapter 6: Discussion

6.1 Introduction

This chapter presents the discussion of studies 1, 2 and 3. Firstly, the participant characteristics will be discussed. The key findings and strengths and limitations of each study will then be examined, followed by an overview of the thesis. Finally, the clinical implications and future directions will be explored. The results discussed in this chapter for study 1 have been published in the Journal of Foot and Ankle Research (**Appendix 23**). The results discussed in this chapter for study 2 have been published in Arthritis Research and Therapy (**Appendix 24**).

6.2 Participant characteristics

Across the three studies, participants were predominantly men of European ethnicity. Mean disease duration, flare frequency and presence of tophus were indicative of established disease. The proportion of Māori and Pacific Island participants in the study is reflective of the gout population in New Zealand (9). This may be explained by the geographical location of recruitment and that the purposefully sampling strategy included ethnicity. Comorbidities such as obesity, hypertension, diabetes and cardiovascular disease were frequently observed, consistent with gout studies in New Zealand (38, 111, 113, 124). Consideration of these comorbidities is important due to their association with hyperuricaemia (262, 263) and the added complexity in achieving appropriate pharmacological management (125).

The number of participants on urate lowering therapy was lower than recent studies conducted in Auckland, New Zealand (38, 264), but higher than national averages (9).

This may be attributed to the recruitment of participants who were managed in both primary and secondary settings, where differences in pharmacological management may exist.

6.3 Study 1: Footwear experiences of people with gout: a qualitative study

This study offers unique insights into the footwear experiences and the footwear-related issues of people with gout, with four themes described. Factors contributing towards comfortable and acceptable footwear were readily identified, but the practicalities of finding and choosing footwear that met these requirements was challenging. There was uncertainty in knowing what the best footwear was and whether footwear would exacerbate foot problems.

Participants in this study placed footwear comfort as a priority, which aligns with previous research (124). However, what was additionally revealed is that ‘comfort’ was linked to individual footwear characteristics, supporting the concept that good footwear characteristics help to reduce the burden of foot pain and disability in those with gout (113).

Our findings demonstrate that some people with gout struggle with finding appropriate footwear, aligning with previous research (153). When shopping, there was a desire to find footwear that met requirements for both comfort and appearance. Factors such as cost (124) added further constraints on footwear choice. Participants described limited footwear options and reduced confidence with their footwear purchases, which may

help to explain the high occurrence of poor-quality footwear worn by people with gout (124).

Prior studies have shown the impact of gout flares (151) and tophi (150, 153) on footwear habits. Whilst participants in this study described similar narratives, we also found that footwear could in turn exacerbate gout symptoms. Having gout meant that footwear needed to meet their current foot health status rather than their previous footwear expectations.

The impact of footwear extended beyond foot symptoms. In social settings, the link between footwear and the outfit was inseparable meaning footwear decisions were made to the detriment of comfort. Where health and safety requirements determined choice, strategies such as not wearing a safety boot during flares demonstrates how footwear can be a limiting factor, resulting in potentially unsafe workplace behaviour. This is a particular challenge in gout, which frequently affects men of working age (3) and adds another element to the difficulty that people with gout face when managing their gout symptoms and maintaining employment participation (10, 152, 153).

We found some participants did not have any foot problems or difficulty with footwear and others who do not consider gout in their decision-making surrounding footwear, even if their gout is problematic. This appears to contrast with previous studies highlighting the difficulties encountered by people with gout (150-152, 154), yet is similar to other work (153) reporting a diversity of experience with gout, and that not everyone with gout has foot problems or has the same foot problems. This suggests a need for more individualised approaches based on the patient experience.

The lack of suitable options both when purchasing footwear and lack of choice in those already owned was acknowledged by participants. Potential solutions to assist finding appropriate footwear through online resources have been proposed for people with foot problems (265). Health care practitioners involved in foot health and footwear can use this information to help those with gout reduce the disease burden on foot health. Footwear manufacturers and those in the retail setting should consider the challenges that people with gout face in finding suitable footwear.

There were similarities between the participant's experiences in this study to those described in other arthritic conditions. The importance of having comfortable footwear aligns with qualitative studies in rheumatoid arthritis (266, 267), osteoarthritis (155) and lupus (268). Some participants also expressed how having gout had resulted in a change in their footwear beliefs and expectations. A similar shift in thought regarding footwear needs has also been reported in those with rheumatoid arthritis (266, 267).

In addition to comfort, the appearance of footwear was an important factor as has been reported in females with rheumatoid arthritis (269) and osteoarthritis (270), but not males. The importance of balancing comfort and appearance was also shared by both male and female participants in the current study. A potential reason for this difference may be due to the male participants in the current study being younger than those in other studies (269, 270). During formal situations, participants described the role of footwear as being part of the outfit, with similar narratives expressed in those with rheumatoid arthritis (267).

6.4 Study 2: Effects of a footwear intervention on foot pain and disability in people with gout: a randomised controlled trial

This study found that no significant difference in foot pain was observed between groups throughout the trial period. This rejects the first hypothesis that people with gout receiving commercially available footwear and standardised podiatric care will have reduced foot pain compared to people with gout receiving standardised podiatric care.

The low levels of foot pain at the time of the baseline visit may have contributed to a floor effect, suggesting that clinical meaningful changes in foot pain could not be detected. Foot pain was not part of the inclusion criteria based on the previous feasibility study (113), which may have contributed to the baseline foot pain levels observed. This highlights the challenge of studying pain as an outcome in gout, which is an intermittently flaring condition. We observed baseline serum urate levels were close to target guidelines [15] and participants reported a low number of flares in the three months prior to the trial, which suggests generally well-controlled disease. Our findings for baseline foot pain levels were lower than the previous feasibility study (113), however, were consistent with previous studies measuring foot pain in people with longstanding gout during an intercritical period (109, 114).

Short-term improvements in both overall pain and foot-related impairment and disability favouring the footwear intervention group were observed at the two month time-point, however, these were not observed at six months. This rejects the second hypothesis that people with gout receiving commercially available footwear and standardised podiatric care will have reduced impairment and disability compared to people with gout receiving standardised podiatric care over six months. The

improvements in overall pain and foot-related impairment and disability are consistent with the previous feasibility study (113), which reported similar findings at eight weeks. The baseline overall pain and LFIS scores were lower than previous studies (113), which may have reduced the likelihood of observing change over a six month period. In addition, the prevalence of foot tophus in the current study was less than previous footwear studies in gout (113, 148). Greater levels of foot-related disability are observed in those with tophus compared to those without tophus (114).

Improvements in footwear comfort, fit, ease and weight were observed in the intervention group throughout the study period. Comfort and fit have been identified as important factors in footwear selection for people with gout (124). Footwear is an important concern for people with gout, who often describe difficulty finding suitable footwear (153). At baseline, a high proportion of poor footwear that was worn and over 12 months old was observed in both groups, consistent with previous work in people with gout (124). The footwear received by the footwear intervention group had a number of characteristics that have been identified as beneficial for people with gout when compared to participants own footwear (113). Footwear characteristics including correct footwear fit, the presence of cushioning and good torsional stiffness have previously been identified as influencers of subjective footwear comfort (271). The wide fit of the intervention footwear may have been beneficial in accommodating for the high occurrence of foot problems such as hallux valgus and lesser digital deformity. In the footwear intervention group, the fitting of footwear by a clinician may also be a factor in the improved perception of footwear.

6.5 Study 3: Effects of worn and new footwear on plantar pressure in people with gout

Our findings show that signs of upper, midsole and outsole wear occurred following six months of use. Although peak plantar pressures did not differ between the new and worn footwear, reduced pressure time integrals were observed at the 1MTP, 2MTP and hallux in the worn footwear.

The hypothesis that wear would be observed between the new and worn footwear is supported by the *p* values observed. The amount of wear in the footwear was smaller than previous studies, with the differences in midsole height and hardness being less than 5%. Other studies have reported a 19% reduction in midsole height (272) and a 17% increase in midsole hardness (273) due to wear, resulting in reduced shock attenuation properties of the footwear. These studies were undertaken in running populations where the impact forces are higher, and this may contribute to greater levels of wear. In contrast to previous reports of greater levels of asymmetrical outsole wear (274), normal outsole wear patterns were found in the current study. This may be due to the cushioning (148), dual density midsole (244) and rocker-profile (275) of the footwear improving the transfer of load through stance. The foot type of participants was consistent with normative values (276), which may also be a factor in the normal wear patterns observed. Mean foot posture index scores were consistent with previous gout studies (109, 111, 124).

No differences were observed in peak plantar pressures between the footwear conditions. This provides evidence to reject the fourth hypothesis that there would be differences in peak plantar pressures between the new and worn footwear. These

findings contrast previous plantar pressure studies in gout during shod walking (110, 148). Reductions in peak plantar pressures have been observed at 3MTP and 5MTP in new footwear with good characteristics compared to the participant's own worn footwear (148). Reduced peak plantar pressures at the hallux have also been reported in people with gout compared to age and sex-matched controls, when wearing their own footwear (110). The differences between the findings of the current study and other work (110, 148) may be due to the variation in methodology, where comparisons have been made between different types of footwear. This means that the previously observed differences in peak pressures are potentially due to the variation in footwear characteristics, as opposed to differences in wear of the same characteristics as with the current study.

The amount of degradation in the footwear over six months may not have been large enough to have a significant impact on peak plantar pressures. Small pressure changes (<10%) have been reported at the heel and forefoot following prolonged periods of footwear use (277). The authors suggested that this may be due to the quality of materials used in modern athletic footwear (277). The level of wear observed in the current study may be reflective of the study duration and the material properties of the footwear. The footwear used in the current study was of high-quality with characteristics including a dual density midsole, heel/forefoot gel cushioning, a rocker profile and a stable heel counter. These characteristics may also contribute to the longevity of the footwear, thus reducing the likelihood of observing differences between the footwear conditions.

Another potential reason could be due to no differences being observed in walking velocity between the two footwear conditions, as increased walking velocity is

associated with increased plantar pressures (259). Previous work reporting differences in peak plantar pressures and pressure time integrals found that people with gout walk faster in new footwear compared to their existing worn footwear (148). The walking velocity observed in the current study was faster than previous shod studies (110, 148), but slower than normative values for people of the same age without gout (256). This may be due to a lower percentage of participants with foot tophus. The presence of foot tophus is associated with reduced foot and ankle muscle strength (114).

The reduced pressure time integrals at the hallux, 1MTP and 2MTP observed in the worn footwear condition, aligns with previous research of people with gout assessed during shod walking (110). People with gout have reduced pressure time integrals under the hallux when walking in their own worn footwear, which may be a pain-avoidance mechanism to offload the 1MTP (110). The changes in loading observed in the worn footwear condition suggest a normalisation of gait pattern over time in people with gout. The level of wear occurring in the footwear and improvements in footwear comfort may further encourage this strategy. Attempts to reduce the loading time under the 1MTP may explain why differences were observed in pressure time integrals and not peak plantar pressures. Similar findings have also been reported in people with gout compared to age-matched controls during barefoot walking (120). The authors suggested that reductions in hallux pressures may be due to impaired function of the 1MTP joint, causing load to be shifted from the hallux towards the lateral digits during propulsion (120). Qualitatively, attempts to offload the hallux have also been reported by people with gout during flares (278), however, no participants were experiencing symptoms of a flare at data collection. The reduced pressure time integrals at the hallux,

1MTP and 2MTP supplements the growing body of evidence that people with gout adopt gait strategies to offload symptomatic areas (38, 117, 120).

6.6 Methodological strengths and limitations

This thesis has several strengths. The qualitative study used an established research methodology (236) and analysis procedure (239). Following a robust methodology allows for an in-depth exploration into the phenomenon of interest (footwear experiences) and enhances the reproducibility of the results. The sampling framework contained a range of demographic and disease-specific characteristics. The purposeful sampling lead to diversity across the sampling framework, representing a broad range of people living with gout in Auckland, New Zealand. Another strength was the sample included a Māori and Pacific Island participants who experience a higher prevalence of gout (9), increased disease severity (4, 7) and increased disease burden (5). The sample size of eleven may be considered small, however, is consistent with qualitative descriptive methodology (236, 279). The final three interviews generated no new codes or themes, indicating that additional interviews would not have had a significant impact on the findings presented.

The RCT used OMERACT-endorsed patient-reported outcomes for gout (246, 247). In addition, there were high retention rates in both the intervention and control groups. The RCT also has novelty as the first randomised controlled trial of a podiatric intervention in people with gout.

In the cross-sectional study, the comparison between new and worn footwear of the same model and size had not previously been undertaken in people with gout. No

differences in walking velocity between the footwear conditions, is a particular strength as plantar pressure readings are influenced by walking velocity (259). The use of reliable tools for measuring plantar pressure (257) and temporal spatial parameters (258) is also a strength.

The thesis is also not without limitations. Participants were classified under the 1977 ACR criteria (92) due to the commencement of recruitment occurring before the publication of the 2015 ACR/EULAR classification criteria (91). All studies were conducted in an urban region and may not represent the experiences of people in rural locations who may have different footwear needs. Participants in the qualitative study were aware at the time of recruitment that the study was about footwear experiences, and those with negative experiences may have been more interested in participating, therefore, the study findings may not be generalisable to all people with gout. In addition, the findings may not be representative of the participants who did not respond to the study invitation, or those who did respond but chose not to participate.

In the RCT, the key study limitation was that participants could not be blinded to the footwear intervention, which may have biased the study outcomes, as all end-points were patient-reported. We did attempt to reduce this bias by informing participants that they would be receiving a foot care package without the specific mention of receiving footwear and ensuring that all participants received a comprehensive foot care intervention.

The footwear used in the RCT and cross-sectional studies was a high cost and quality shoe with a dual density midsole, heel and forefoot cushioning and a rocker profile. The findings may not be translatable to other types of footwear, such as non-athletic

footwear, open-toed footwear, or lower cost footwear with different material properties. There was also variation in the number of reported hours worn in the footwear across participants in both the RCT and cross-sectional studies.

There may be additional changes to footwear characteristics and loading patterns that occur beyond six months of wear. Whether the observed changes to pressure time integrals translate into patient-centred outcomes such as foot pain and footwear comfort in people with gout is unknown. In the cross-sectional study, no adjustments were made for covariates such as age or BMI due to the nature of the cross-over trial where participants act as their own control. This leaves an assumption that no interaction between the footwear conditions and the covariates in question, and no lag effect of the footwear conditions on one another.

6.7 Thesis Overview

The findings highlight the importance of footwear comfort for people with gout. The qualitative study (study 1) showed the challenges people with gout face when trying to find comfortable footwear. The RCT (study 2) lends support to this with the high proportion of poor quality and worn footwear observed in the study sample at baseline. Narratives from the qualitative study also found that comfort is influenced by footwear characteristics. This aligns with the findings from the RCT, where footwear comfort was improved with the footwear intervention that included footwear characteristics known to be beneficial to people with gout.

No differences in the foot pain were observed in the RCT, which may have been due to a floor effect in the primary outcome. However, short-term improvements in overall

pain and foot impairment and disability were observed. A potential reason these benefits were not observed beyond two months could be due to wear of the footwear. In the cross-sectional study (study 3) early signs of wear were evident in the footwear following six months of use, however, these did not have a significant impact on peak plantar pressures. There were small changes in pressure time integrals suggestive of a normalisation of gait pattern following the implementation of the footwear intervention. Whether these changes influenced patient-reported outcomes is unknown.

6.8 Implications for clinical practice

The main findings indicate that footwear comfort is a priority for people with gout, hence helping people with gout find comfortable footwear should be of importance for health care professionals working with this population. The qualitative study highlighted the difficulty that people with gout experience navigating the retail setting and not knowing what to wear. These findings suggest that people with gout need further support in finding appropriate footwear. Podiatrists are well-positioned to help people with gout manage their problems, with over 90% of New Zealand podiatrists seeing people with gout in the clinical setting (280). The diversity in experience suggests a patient-centred approach is required to ensure that the footwear needs of people with gout are met when guiding clinical decisions surrounding footwear. This may help podiatrists and other clinicians guide patients in finding appropriate footwear, thus reducing the high occurrence of poor footwear in people with gout (124).

Footwear comfort may be influenced by footwear characteristics, which is supported by the narratives in the qualitative study and the findings from the RCT. Footwear

manufacturers may use these findings to influence the future footwear design to improve footwear comfort for people with gout. Cost is a major barrier to footwear choice, so the challenge exists to produce comfortable footwear at an appropriate price point. Greater understanding of the difficulties when shoe shopping may also assist footwear retailers and their staff in helping those with gout find footwear that promotes comfort.

The findings of the qualitative study also highlight the need for increased awareness surrounding footwear habits in the workplace. The limiting effects of gout on footwear use, such as not being able to wear a safety boot can result in potentially unsafe situations for both employers and employees. Acknowledging these issues could assist employers in implementing strategies to promote workplace safety, employment participation and help reduce the potential risk of workplace injury.

The findings from the three studies indicate that people with gout wear multiple pairs of shoes, suggesting that a single shoe may not be the most appropriate recommendation. Focus should be directed towards assisting people with gout find footwear with good characteristics for their feet. Helping people with gout to apply these principles to a variety of shoes may better address their needs with respect to footwear comfort and their use across different environments.

6.9 Future directions

As footwear comfort was identified as the most important concern for people with gout in relation to footwear in the qualitative study, warrants consideration for its inclusion as the primary outcome for future footwear intervention studies, rather than foot pain.

Tools measuring foot pain may not capture the full spectrum of disease in those with fluctuating symptoms (232), such as the gout. Measures of footwear comfort were more responsive to change than other endpoints such as foot pain in the RCT. Current OMERACT endorsed core outcome domains for gout do not capture footwear concerns, despite difficulties with footwear being ranked highly by people with gout (149). Determining the most appropriate method for measuring footwear comfort also needs to be explored. This could be achieved in the form of a questionnaire including quantitative measures and open-ended questions exploring footwear comfort. In addition, identifying what clinical features of the disease and footwear characteristics have the greatest influence on comfort may help to inform the design of future footwear interventions for people with gout.

The loading patterns observed in the cross-sectional study were consistent with previous work (38, 117, 120) in established gout, and are suggestive of apropulsive or antalgic gait adaptations. Future work may look to explore the development of these strategies in people with early and established gout.

The participants in the cross-sectional study walked faster than previous gout studies (110, 148), suggesting that the effects of footwear interventions on walking velocity warrants further investigation. As walking velocity is associated with functional limitation and work/leisure difficulty in people with gout (115), identifying interventions that increase walking velocity may be of benefit to people with gout.

Flip-flops (jandals) and sandals are commonly worn by people with gout (124, 281). Reasons for wearing open-toed footwear may be due to seasonal variation (281) or needing to accommodate for footwear length and width (124). This suggests that further

investigation into the role of open-toed footwear as an intervention for people with gout, is warranted.

The podiatric care package in the RCT was limited to standardised care, with or without the footwear intervention, and the role of other interventions such as foot orthoses is unknown. In the RCT, 20% of participants had reported previously wearing foot orthoses, however, there are currently no studies exploring the effectiveness of foot orthoses in people with gout. Foot orthoses have been reported to offer benefits for people with RA (220), 1MTP osteoarthritis (173) and midfoot osteoarthritis (193). The therapeutic benefit from foot orthoses may be due to the reduction of plantar pressure in these populations (174, 205). People with gout display altered plantar pressure loading as shown in the cross-sectional study, consistent with previous studies (110, 120, 148). Further to this, changes in ankle (38) and 1MTP (111) function have been found in people with gout, suggesting that foot orthoses may have a role as an intervention for people with gout.

Chapter 7: Conclusion

The aims of this thesis were to investigate the: clinical effectiveness of footwear interventions on foot pain, function, impairment and disability in people with foot and ankle arthritis, footwear experiences of people with gout, the long-term effects of footwear on foot pain and disability in people with gout and the effects of worn and new footwear on plantar pressure in people with gout. A systematic review and three research studies were undertaken. The systematic review presented in chapter 2 found that footwear is associated with improvements to foot pain, function, impairment and disability in people with RA; improvements to foot pain, function and disability in people with gout; and improvements to foot pain and function in people with 1MTP osteoarthritis. In addition, there was a lack long-term studies investigating the effectiveness of footwear as an intervention for people with gout.

The first study was the first qualitative investigation of the experiences of footwear in people with gout. Footwear comfort was of great importance and linked to characteristics of footwear, with uncomfortable footwear negatively influencing participation. The balancing of comfort, appearance and cost, led to less options and reduced confidence when shoe shopping. Footwear use was further limited by foot tophi and flares, resulting in compromise across footwear choice. Environments such as formal settings and the workplace, led to different footwear requirements. Some participants described no foot problems or footwear problems. These findings show the diversity in footwear-related problems experienced and their wider impact on life for people with gout.

The second study was the first randomised controlled trial of a footwear intervention in people with gout. The results showed that the addition of footwear to a foot care

package did not improve foot pain in people with gout over six months. The low levels of foot pain at baseline may have resulted in a floor effect in the primary outcome. Short-term improvements in overall pain and foot impairment/disability were observed with the footwear intervention, however, these were not sustained over the trial. More durable improvements in footwear comfort, fit, ease and weight were observed with the footwear intervention throughout the trial. These findings highlight the challenge of measuring foot pain in gout due to its flaring nature and lend support to the assessment of footwear comfort due to its responsiveness to change.

The third study tested the effects of wear by comparing the plantar pressures between new and worn footwear. The results showed there were reductions in heel and forefoot height, increases in midsole hardness and normal upper and outsole wear patterns following six months of footwear use. No significant differences in peak plantar pressures were observed, however, lower pressure time integrals were observed at the 1MTP, 2MTP and hallux in the worn shoes. These changes in the mechanical properties of the footwear may impact foot function, as observed by alterations in forefoot loading patterns between new and worn footwear.

This work is of clinical importance, suggesting that footwear comfort is a priority for people with gout, and additional support is required to help people with gout find comfortable footwear for the environments that they interact in. Future work is needed to consider the inclusion of footwear comfort as the primary outcome in studies of footwear interventions for people with gout. The role of other interventions such as open-toed footwear and foot orthoses warrants further investigation, with the goal of improving patient-reported outcomes such as footwear comfort and functional outcomes such as walking velocity in people with gout.

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Appendices

Appendix 1. Footwear interventions for foot pain, function, impairment and disability for people with foot and ankle arthritis: a literature review

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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 to 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.

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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

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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 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 (M.F.). Full-text articles were obtained from selected abstracts and compared against the following inclusion criteria by a single reviewer (M.F.). 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 and 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 (M.F. and M.C.) 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 (K.R.) 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 (Fig.). 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) [13,17–22], two investigated gout [11,23], and two investigated first metatarsophalangeal joint osteoarthritis (1MTP OA) [12,24]. Five studies were randomised clinical trials [12,13,18,19,21], 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% to 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 and 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

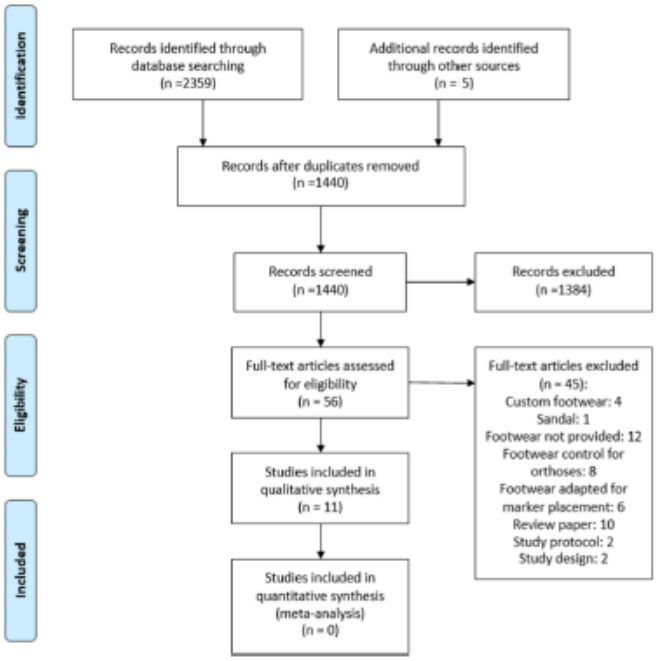

Fig. PRISMA flow diagram of search strategy.

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 and Ward [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 and Edmonds [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. [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. [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. [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. [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. [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. [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 al. [23]	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
Menz et al. [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	1
Menz et al. [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 (wk)	Intervention	Control	Outcome measures	Findings	Quality score
Fransen and Edmonds [18]	15 RA (80%) 15 Controls (67%)	• Intervention group • Age: 59 (14) • Disease duration: 16 (10) • Control group • Age: 60 (9) • Disease duration: 15 (12)	8	Extra-depth footwear (P.W. Minor & Son Inc.) Long inside counter (rear stability and arch support), foam padded heel counter (leather lining), soft leather upper, extra depth (orthoses accommodation)	Own footwear	Primary outcome Not stated Outcomes assessed • Lower limb walk pain, lower limb stair pain, lower limb NWB pain (VAS) • Function (HAQ) • Pain-free walk time (min) • Temporal-spatial (normal and fast walking velocity, cadence, stride length)	Between group measures Not reported. 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.	54%
Chalmers et al. [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; 6 mm Plastazote with medium density 6 mm Plastazote metatarsal lifts • Extra-depth footwear + semi-rigid orthoses • Semi-rigid orthoses; NWB cast, 3 mm Subortholen, RF and FF Nickleplast posting, FF 3 mm PPT foam, full length leather top cover		• Primary outcome MTP pain (VAS) • Outcomes assessed • Lower extremity function (RB, TADL, 50 ft 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 50 ft walk time between groups. 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 50 ft walk time and joint count within groups.	79%
Williams et al. [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, heel height, sole thickness • Firm contoured insole	• Traditional therapeutic footwear • Soft, flat 6 mm Plastazote, 3 mm Poron insole	• Primary outcomes • Foot pain, disability, activity limitation (FFI) • Foot pain, foot function, physical activity (FHSQ)	Between group measures • Significant improvement in FFI foot pain ($p = 0.02$), disability ($p = 0.01$), limitation ($p = 0.02$) 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.	71%

Table 2 (*continued*)

Author	Nos. (% female)	Sample characteristics, mean (SD)	Follow-up (wk)	Intervention	Control	Outcome measures	Findings	Quality score
							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 improvement in FHSQ foot pain ($p = 0.00$), foot function ($p = 0.00$) and physical activity scores ($p = 0.02$) for intervention group at follow-up. • No significant within group improvement in the control group at follow-up.	
Cho et al. [21]	22 RA (100%) 20 Controls (100%)	Intervention 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 + prefabricated insoles • Wide toe box, cushioned heel, forefoot rocker • Prefabricated insole; 6 mm Plastazote	Primary outcomes • Foot pain (VAS) • Foot pain, disability, activity limitation (FFI)	Between group measures • No significant differences in foot pain and FFI total scores between intervention and control group at follow-up. Within group measures • Significant reduction in foot pain ($p < 0.05$) in intervention and control groups at follow-up.	61%
Menz et al. [12]	• 46 1MTPJ OA (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 (wk)	Intervention	Control	Outcome measures	Findings	Quality score
Moncur and 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. [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 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 sole stability, heel and forefoot cushioning	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 ($p = 0.004$) observed in good footwear characteristics group at follow-up. • No significant improvement in poor footwear characteristics group at follow-up.	86%
Bagherzadeh Cham et al. [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 Glycerine 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 ($p < 0.001$) with the orthopaedic shoe compared to the control. Within group measures Not assessed.	64%
Stewart et al. [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, 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	• 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 ($p = 0.003$), 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 intervention groups compared to control.	64%

Menz et al. [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/Mairwa) • 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. 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 ($p = 0.021$).	71%

Peak Plantar Pressures; PTI, pressure time integral; MTP, metatarsophalangeal joint.

between group effect sizes were observed for foot pain, function impairment and disability.

Footwear interventions

Footwear interventions included off-the-shelf footwear [11,12,20,23,24], therapeutic footwear [13,17,18,20,22] 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 [11,23] 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 [13,17,18,20,22]. 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 [13,19,21] 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 8-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 ft 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 1MTP 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.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at http://dx.doi.org/10.1016/j.semarthrit.2017.10.017.

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Appendix 2. AUTEC ethical approval (14/233)

AUTEC
SECRETARIAT

13 August 2014

Keith Rome
Faculty of Health and Environmental Sciences

Dear Keith

Ethics Application: **14/233 The clinical effectiveness of footwear in the reduction of foot pain and disability in people with gout.**

Thank you for submitting your application for ethical review to the Auckland University of Technology Ethics Committee (AUTEC). I am pleased to confirm that the Chair and I have approved your ethics application for three years until 11 August 2017

As part of the ethics approval process, you are required to submit the following to AUTEC:

- A brief annual progress report using form EA2, which is available online through http://www.aut.ac.nz/researchethics. When necessary this form may also be used to request an extension of the approval at least one month prior to its expiry on 11 August 2017;
- A brief report on the status of the project using form EA3, which is available online through http://www.aut.ac.nz/researchethics. This report is to be submitted either when the approval expires on 11 August 2017 or on completion of the project;

It is a condition of approval that AUTEC is notified of any adverse events or if the research does not commence. AUTEC approval needs to be sought for any alteration to the research, including any alteration of or addition to any documents that are provided to participants. You are responsible for ensuring that research undertaken under this approval occurs within the parameters outlined in the approved application.

AUTEC grants ethical approval only. If you require management approval from an institution or organisation for your research, then you will need to obtain this.

To enable us to provide you with efficient service, we ask that you use the application number and study title in all correspondence with us. If you have any enquiries about this application, or anything else, please do contact us at ethics@aut.ac.nz.

All the very best with your research,

Kate O'Connor
Executive Secretary
Auckland University of Technology Ethics Committee

Cc: Mike Fecklington

Auckland University of Technology Ethics Committee
WX5058 Level 5 WA Building City Campus
Private Bag 92006 Auckland 1142 Ph: +64-9-921-9999 ww8316 email ethics@aut.ac.nz

Appendix 3. Participant information sheet

Participant Information Sheet

AUT UNIVERSITY
TE WĀNANGA ARONUI O TAMAKI MAKAU RAU

Date Information Sheet Produced:

5th June 2015

Project Title

The clinical effectiveness of foot-care treatments in the reduction of foot pain and disability in people with gout

An Invitation

My name is Keith Rome, a Professor in Podiatry and I would like to extend a warm invitation to you to participate in my research project. This is also part of a PhD being undertaken at AUT University. This project will contribute towards a good understanding of how foot-care treatments can reduce pain and disability in people with gout. The project is funded by the Auckland Medical Research Foundation (AMRF).

What is the purpose of this research?

Gout is a major cause of pain and disability in Aotearoa New Zealand. Foot pain occurs in most people with gout. We propose a long-term clinical trial examining the effects of foot-care treatments on foot pain and disability. The trial will assess the effect of two different foot care packages. The study findings will be used to make evidence-based recommendations regarding foot-care treatments for people with gout.

How was I identified and why am I being invited to participate in this research?

This project invites participants of any age above 20 years old who have gout. You are welcome to participate if you are over 20 years of age with a good grasp of the English language. However, if you have a medical history of foot or ankle surgery, neuromuscular problems or rheumatoid arthritis I will be unable to include you in this study regrettably. Your involvement in this project is voluntary and you are welcome to withdraw your participation at any time without reason.

What will happen in this research?

We will ask you to attend AUT School of Podiatry clinic over at the North Shore. We will then ask you some questions about your experiences with footwear. You will also have an opportunity to discuss any other points of information during the interview.

What are the discomforts and risks?

There are no risks associated with the research. All information recorded from interviews will be confidential.

How will these discomforts and risks be alleviated?

Not applicable.

What are the benefits?

The aim of the proposal is to improve foot pain and impairment in people with gout. The study proposed will be immediately impact into clinical practice. All participants will receive a summary of findings. The research will also highlight the role that a health care professional can play in the assessment and management of patients with chronic gouty arthritis.

What compensation is available for injury or negligence?

In the unlikely event of a physical injury as a result of your participation in this study, rehabilitation and compensation for injury by accident may be available from the Accident Compensation Corporation, providing the incident details satisfy the requirements of the law and the Corporation's regulations.

How will my privacy be protected?

Your name, birthdate and any personal information that could identify you as an individual will not be used in this study or published in any medium. All the information that is provided by you will be treated as confidential and strict access will only be available to the researchers and yourself upon request.

What are the costs of participating in this research?

There will be no financial cost to you if you decide to participate in this research. We would like to offer you the costs of travelling from home to AUT North Shore and back to home.

What opportunity do I have to consider this invitation?

You have one-week to decide whether or not you would like to accept this invitation. I would like to arrange an appointment time with you at least two (2) weeks beforehand so that I can secure the equipment needed for this study. Please make sure you thoroughly read this Information Sheet and have any concerns answered before you participate.

How do I agree to participate in this research?

If you would like to participate in this study please contact Katie Hayden via the details given below. I will then give you a Consent Form (or send one if requested) to fill out and sign, to secure your place in the study.

Will I receive feedback on the results of this research?

If you are interested to see the outcomes of this research please indicate so on the applicable section of the consent form. The results will be sent to you in the form of a written summary and any papers that may be published as a result of this study can be accessed upon request.

What do I do if I have concerns about this research?

Any concerns regarding the nature of this project should be notified in the first instance to the Project Supervisor, Professor Keith Rome (contact details below)

Concerns regarding the conduct of the research should be notified to the Executive Secretary of AUTEC, Kate O'Connor, *ethics@aut.ac.nz* , 921 9999 ext 6038.

Whom do I contact for further information about this research?

Researcher Contact Details:

Katie Hayden

Phone: 0800 4688 288 or 022 164 3962

Email: khayden@aut.ac.nz

Project Supervisor Contact Details:

Professor Keith Rome

Phone: 921 9999 extension 7688

Email: k.rome@aut.ac.nz

Approved by the Auckland University of Technology Ethics Committee on *09/06/2015*, AUTEC Reference number *14/233*.

Appendix 4. Consent form

Consent Form

Project title: ***The clinical effectiveness of foot-care treatments in the reduction of foot pain and disability in people with gout***

Project Supervisor: ***Professor Keith Rome***

Researcher: ***Mike Frecklington***

- ○ I have read and understood the information provided about this research project in the Information Sheet dated 05 June 2015.
- ○ I have had an opportunity to ask questions and to have them answered.
- ○ I understand that notes will be taken during the interviews and that they will also be audio-taped and transcribed.
- ○ I understand that I may withdraw myself or any information that I have provided for this project at any time prior to completion of data collection, without being disadvantaged in any way.
- ○ If I withdraw, I understand that all relevant information including tapes and transcripts, or parts thereof, will be destroyed.
- ○ I truthfully state that I have not received treatment with foot orthoses or footwear within the previous three (3) months, or had any history of rheumatoid arthritis
- ○ I henceforth agree to take part in this research.
- ○ I wish to receive a copy of the report from the research (please tick one): Yes○ No○

Participant's signature: .....

Participant's name: .....

Participant's Contact Details (if appropriate):

.....

.....

.....

.....

Date:

Approved by the Auckland University of Technology Ethics Committee on 09/06/2015 AUTEC Reference number 14/233

Note: The Participant should retain a copy of this form.

Appendix 5. Interview guideline

1. Definition of footwear
    1.1. Discussion to orientate the participant towards the topic of interest
        1.1.1. What shoes do you normally wear?
        1.1.2. Asking the participant to bring out their shoes (if comfortable doing so)
2. Opening question (with additional prompts/probes)
    2.1. Tell me about your experiences of footwear
        2.1.1. Has this changed post gout diagnosis?
3. Trigger questions (with additional prompts/probes)
    3.1. What are the most important things you look for in footwear?
    3.2. What feelings do you have about the footwear currently available to you?
        3.2.1. Where do you find your footwear?
    3.3. What barriers have you experienced related to footwear?
    3.4. What effect has footwear had on your feet?
    3.5. What impact has footwear had on your ability to do the things you wanted to do?
        3.5.1. Work, daily living, social settings, exercise
    3.6. Design features of an ‘ideal shoe’
4. Participant driven questions/topics
    4.1. Any other points that the participant wishes to raise and/or discuss
5. Conclusion of interview (with a summary of main points)

Appendix 6. Health and Disability Ethics Committees ethical approval (14/CEN/117)

Health and Disability Ethics Committees

Health and Disability Ethics Committees
1 The Terrace
C/- MEDSAFE, Level 6, Deloitte House
10 Brandon Street
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@moh.govt.nz

06 August 2014

Professor Keith Rome
AUT University
90 Akoranga Drive
AA270, AA Building
Northcote 0627

Dear Professor Rome

Re:	Ethics ref:	14/CEN/117
	Study title:	The clinical effectiveness of footwear in the reduction of foot pain and disability in people with gout

I am pleased to advise that this application has been *approved* by the Central Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Central Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at *any* locality in New Zealand, it must be registered in a WHO-approved clinical trials registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au).

3. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

Note from Chair:

4. The consent form indicates that upon withdrawal, all data for that participant would be destroyed, this is not standard practice with data, normally retained up until the participants withdrawal as part of intention to treat analysis and limit withdrawal bias.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 6 August 2015.

Participant access to ACC

The Central Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

Mrs Helen Walker
Chairperson
Central Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix 7. Auckland District Health Board locality approval

Research Office
Level 14, Support Bldg
Auckland City Hospital
PB 92024, Grafton, Auckland
Phone: 64 9 307 4949 Extn. 23854
Fax: 64 9 307 8913
Email: mwoodnorth@adhb.govt.nz
Website: www.adhb.govt.nz/ResearchOffice

Date 3 September 2014

Institutional Approval

Keith Rome
School of Podiatry
Dept of Rehabilitation & Occupational Studies
Auckland University of Technology
90 Akoranga Drive
Northcote, Auckland 0627

Dear Keith

RE: Research project A+ 6423 (14/CEN/117), The clinical effectiveness of footwear in the reduction of pain and disability of people with gout.

The Auckland DHB Research Review Committee (ADHB-RRC) would like to thank you for the opportunity to review your study and has given approval for your research project.

Your Institutional approval is dependant on the Research Office having up-to-date information and documentation relating to your research and being kept informed of any changes to your study. It is your responsibility to ensure you have kept Ethics and the Research Office up to date and have the appropriate approvals. ADHB approval may be withdrawn for your study if you do not keep the Research Office informed of the following:

- Any communication from Ethics Committees, including confirmation of annual ethics renewal
- Any amendment to study documentation
- Study completion, suspension or cancellation

More detailed information is included on the following page. If you have any questions please do not hesitate to contact the Research Office.

Yours sincerely

On behalf of the ADHB Research Review Committee
Dr Mary-Anne Woodnorth
Manager, Research
ADHB

c.c. Julia Martin, Nicola Dalbeth

...../continued next page

Appendix 8. Counties Manukau District Health Board locality approval

COUNTIES MANUKAU HEALTH

Ko Awatea Research Office
Counties Manukau DHB
Clinical Support Building
Room 253, Level 2
Middlemore Hospital

29 August 2014

Dear Keith

Thank you for the information you supplied to the Ko Awatea Research Office regarding your research proposal:

Research Registration Number: **1878**

Ethics Reference Number: **14/CEN/117**

Research Project Title: **The clinical effectiveness of footwear in the reduction of foot pain and disability in people with gout**

I am pleased to inform you that the CMDHB Research Committee and Director of Hospital Services have approved this research with you as the CMDHB Co-ordinating Investigator.

Your study is approved until 29 August 2015.

Amendments:

- All amendments to your study must be submitted to the Research Office for review.
- Any substantial amendment (as defined in the *Standard Operating Procedures for HDECs*, May 2012) must also be submitted to the Ethics Committee for approval.

All external reporting requirements must be adhered to.

Please note that failure to submit amendments and external reports may result in the withdrawal of Ethical and CMDHB Organisational approval.

We wish you well in your project. Please inform the Research Office when you have completed your study (including when a study is terminated early) and provide us with a brief final report (1-2 pages) which we will disseminate locally.

Yours sincerely

Alex Poor
Health Intelligence and Informatics Lead
Counties Manukau District Health Board
Under delegated authority from CMDHB Research Committee and Director of Hospital Services

Appendix 9. Participant information sheet

Participant Information Sheet

Project Title

The clinical effectiveness of foot-care treatments in the reduction of foot pain and disability in people with gout

An Invitation

My name is Keith Rome, a Professor in Podiatry and I would like to extend a warm invitation to you to participate in my research project. This project will contribute towards a good understanding of how foot-care treatments can reduce pain and disability in people with gout. The project is funded by the Auckland Medical Research Foundation (AMRF).

What is the purpose of this research?

Gout is a major cause of pain and disability in Aotearoa New Zealand. Foot pain occurs in most people with gout. *We propose a long-term clinical trial examining the effects of foot-care treatments on foot pain and disability. The trial will assess the effect of two different foot care packages.* The study findings will be used to make evidence-based recommendations regarding foot-care treatments for people with gout.

How was I chosen for this invitation?

This project invites participants of any age above 20 years old who have gout. You are welcome to participate if you are over 20 years of age with a good grasp of the English language. However, if you have a medical history of foot or ankle surgery, neuromuscular problems or rheumatoid arthritis I will be unable to include you in this study regrettably. Your involvement in this project is voluntary and you are welcome to withdraw your participation at any time without reason.

Where will the research take place?

This project will take place at the AUT Podiatry Clinic on the North Shore Campus.

When will the research take place?

It is proposed that this project will commence in *October 2014*. You will be contacted at least 2 weeks prior to your presence being required to arrange a suitable date and time. I will require your participation three times (every 8 weeks) over 6 months, for around 40 minutes each time.

What will happen in this research?

We will ask you to attend AUT School of Podiatry clinic over at the North Shore. We will then ask you to complete questionnaires relating to current foot problems. We will also ask you about your general everyday activities and any other foot problems you have relating to your gout. *After completing the questionnaires everyone will be treated by one of our experienced clinicians which may include a combination of nail cutting, removal of hard skin, use of emollients, footwear and advice on foot care and gout.* You may also be required to complete a diary to monitor the effects

of the treatment. All people in the study will be treated at the AUT School of Podiatry clinic every 8 weeks over the 6-months.

What are the risks that I might face?
There are minimal risks. You may encounter a blister or rubbing. If blistering or rubbing does occur and prevents you undertaking everyday activities we will treat the foot complaint.

What are the benefits?

The aim of the proposal is to improve foot pain and impairment in people with gout. The study proposed will be immediately impact into clinical practice. All participants will receive a summary of findings. The research will also highlight the role that a health care professional can play in the assessment and management of patients with chronic gouty arthritis.

What compensation is available for injury or negligence?

It is very unlikely that an event of physical injury occur during your participation in this study. However the Accident Compensation Corporation (ACC) may provide compensation in the event of an accident and rehabilitation for any injury sustained. This is provided that the details of the incident fulfill the criteria of ACC and any legal requirements.

How will my privacy be protected?

Your name, birthdate and any personal information that could identify you as an individual will not be used in this study or published in any medium. All the information that is provided by you will be treated as confidential and strict access will only be available to the researchers and yourself upon request.

What are the costs of participating in this research?

There will be no financial cost to you if you decide to participate in this research. We would like to offer you the costs of travelling from home to AUT North Shore and back to home. There is no treatment costs.

What opportunity do I have to consider this invitation?

You have one-week to decide whether or not you would like to accept this invitation. I would like to arrange an appointment time with you at least 2 weeks beforehand so that I can secure the equipment needed for this study. Please make sure you thoroughly read this Information Sheet and have any concerns answered before you participate.

How do I agree to participate in this research?

If you would like to participate in this study please contact Caroline Holder via the details given below. I will then give you a Consent Form (or send one if requested) to fill out and sign, to secure your place in the study.

Will I receive feedback on the results of this research?

If you are interested to see the outcomes of this research please indicate so on the applicable section of the consent form. The results will be sent to you in the form of a written summary and any papers that may be published as a result of this study can be accessed upon request.

What do I do if I have any concerns about this research?

Any concerns that regard the nature of this study should be directed to the Principal Investigator, Professor Keith Rome (contact details below). Concerns regarding the conduct of the research should be directed to the Executive Secretary, AUTEC, Kate O'Connor, *koconnor@aut.ac.nz*, 921-9999 ext. 6038.

Who can I contact for further details about this research project?

Researcher contact details:

Caroline Holder

Phone: 0221643962

Email: caroline.holder@aut.ac.nz

Project Supervisor contact details:

Professor Keith Rome

Phone: 921-9999 ext. 7688

Email: k.rome@aut.ac.nz

Appendix 10. Consent form

Participant Consent Form

The clinical effectiveness of foot-care treatments in the reduction of foot pain and disability in people with gout

Project Supervisor: ***Professor Keith Rome***

☐ I have read and understood the Information Sheet provided which outlines all the procedures and practices that will be utilised in this study.

☐ I have had opportunities to have all my questions and concerns answered.

☐ I acknowledge the fact that prior to the conclusion of data collection I may withdraw any personal information and myself without reason. In doing so I will not be treated unfairly or disadvantaged in any way.

☐ I understand that upon withdrawal, all personal information and individual data will be destroyed.

☐ I agree to have foot measurements undertaken and understand that they will only be used for academic purposes. Publications outside of this project cannot eventuate without my written permission.

☐ I understand that all personal information that could potentially identify myself will be strictly confidential and safeguarded in a password-protected file. This information will only be used for the requirements of this study.

☐ I truthfully state that I have not received treatment with foot orthoses or footwear within the previous 3 months, or had any history of foot and ankle surgery or rheumatoid arthritis.

☐ I henceforth agree to take part in this research project.

☐ I wish to receive a copy of the findings from this study (please tick one):

Yes ☐ No ☐ (If yes, please state your email or postal address below)

Participant's signature:.....

Participant's name:.....

Participant's contact details (if appropriate):.....

.....

.....

Date:...../...../.....

Appendix 11. Clinical report form

Study number: Date: Visit 1

Clinical Data: Visit 1 **Study Number:**

Current Medical history:

Study number:	Date:
Age:	NHI:
Gender:	Ethnicity:
Weight (kg):	
Height: (m):	BMI:

Patient agrees to their GP/Rheumatologist getting information about their assessments Y/N

Patient agrees to researcher accessing relevant medical records, medications and latest blood test results from GP/Rheumatologist Y/N

Medical History:

Diabetes?	Y/N
Hypertension?	Y/N
CVD?	Y/N

If yes, state which:

PVD?	Y/N
Peripheral neuropathy?	Y/N

Other:

Medications (dosage):	
Urate-lowering therapy	Y/N
If yes, state which and dose:	
Colchicine?	Y/N
NSAIDs?	Y/N
Prednisone?	Y/N
Diuretics?	Y/N, if yes, state which
Other medications	

Study number: Date: Visit 1

Checklist:		
Meets inclusion criteria	Y/N	
≥20 years old		☐
Previous episode of acute gout		☐
Able to walk >10m unaided		☐
Does not currently have an acute gout attack		☐
Does not have a history of surgery to the foot or ankle		☐
Have not had orthotic/footwear treatment in last three months		☐
Have not had medication for foot pain in past four weeks		☐
Completed Informed Consent:	Y/N	
Footwear Size:	_____	
Footwear Width:	_____	
Randomisation process:	Y/N	
Pain VAS:	Y/N	
Foot Pain VAS:	Y/N	
Patient global VAS:	Y/N	
Foot problem score:	Y/N	
Foot posture index:	Y/N	
Homunculus man (tophus foot count):	Y/N	
Homunculus man (total tophus count):	Y/N	
HAQ-II:	Y/N	
LLTQ:	Y/N	
LFIS:	Y/N	
Footwear VAS:	Y/N	
Footwear classification, age and wear:	Y/N	

Study number: Date: Visit 1

Gout history and examination:	
Latest serum urate:	
Disease duration:	
Age of first episode:	
Number of gout attacks in last three months:	
Days off work in last three months due to gout:	
Subcutaneous tophi present:	Y/N

Patient fulfils criteria for gout classification: Y/N

A: The presence of characteristic urate crystals in the joint fluid: Y/N

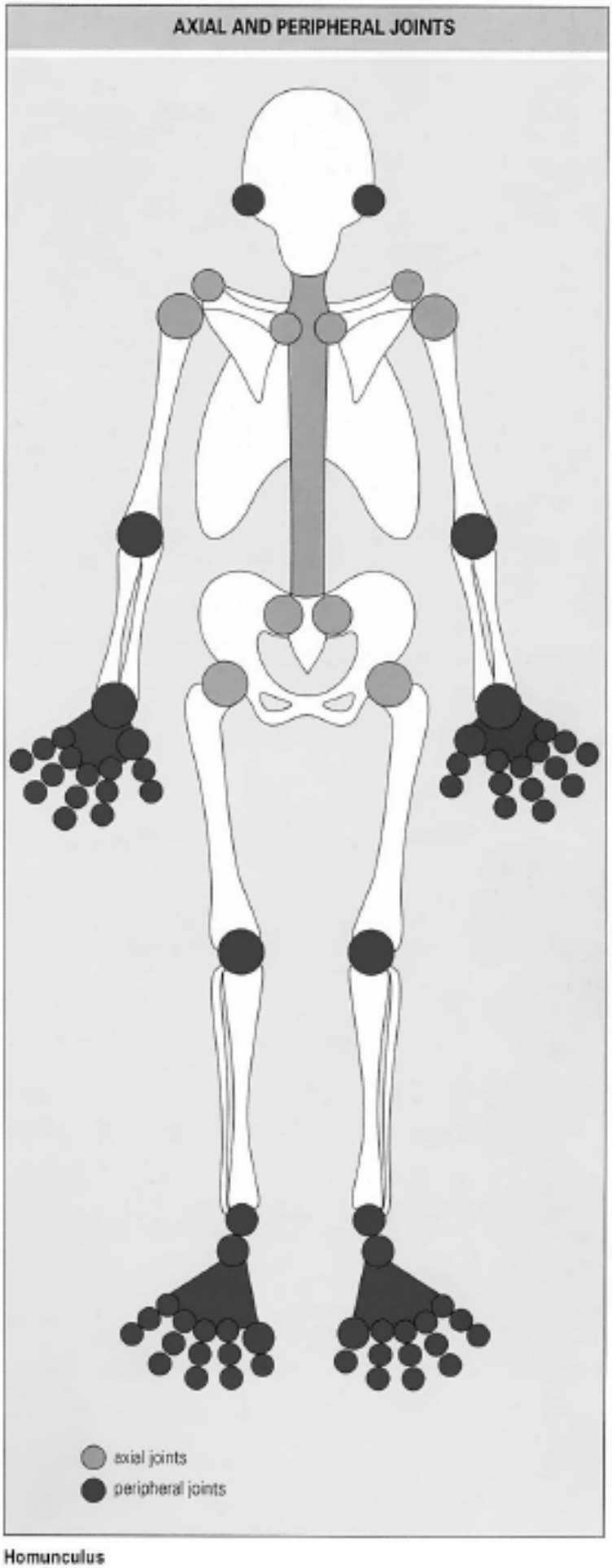
OR

B: Tophus proven to contain urate crystals by chemical means or polarised light microscopy: Y/N

OR

C: Presence of 6 or more of the following 12 clinical and radiographic phenomena: Y/N

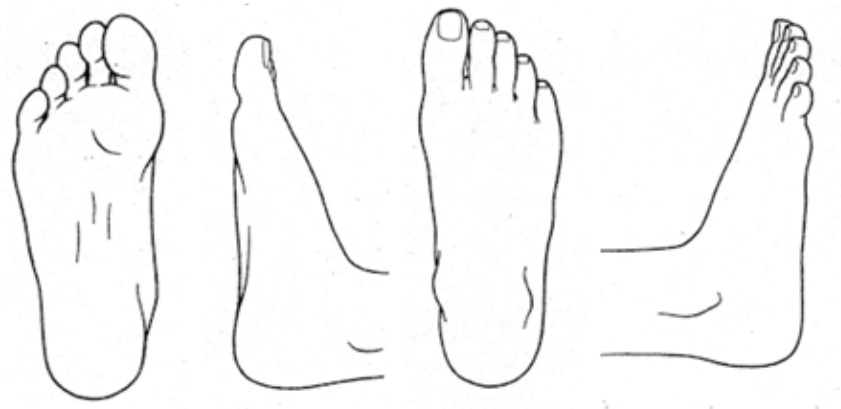
Diagnostic Criteria	**Present:**
1. More than one attack of acute arthritis	
2. Maximum inflammation developed within one day	
3. Monoarthritis attack	
4. Redness observed over joint(s)	
5. First metatarsophalangeal joint painful or swollen	
6. Unilateral first metatarsophalangeal joint attack	
7. Unilateral tarsal joint attack	
8. Tophus (proven or suspected)	
9. Hyperuricaemia	
10. Asymmetric swelling within a joint on x-ray	
11. Subcortical cysts without erosion on x-ray	
12. Joint fluid culture negative for organisms during attack	


AXIAL AND PERIPHERAL JOINTS
axial joints
peripheral joints

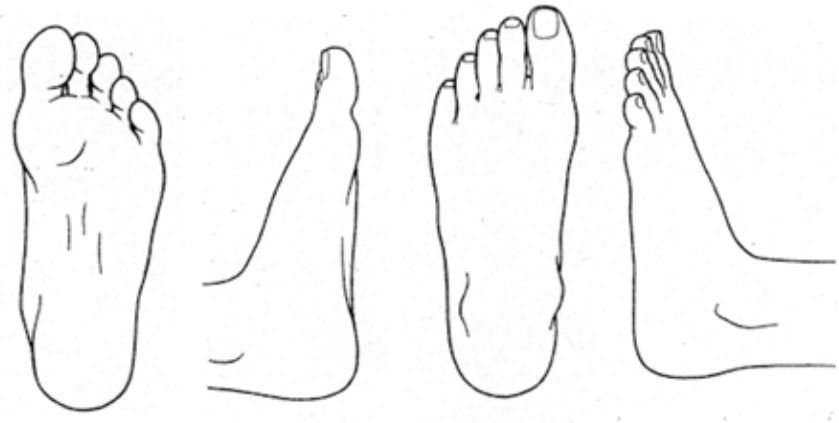
Homunculus

FOOT PROBLEMS

Right foot



Left foot



Total score:

Appendix 12. Foot posture index

FPI	*Talar head palpation*	*Malleolar Curves*	*Calcaneus Inv / Ev*	*Talonavic Congruence*	*Medial Arch Height*	*Forefoot Add/Abd*	***TOTAL***
LEFT							
RIGHT							
SCORE	***Description***	***Description***	***Description***	***Description***	***Description***	***Description***	***Comments***
-2	Palpable on lateral side, not on medial	Curve below either straight or convex	More than 5^{0} varus	Area markedly concave	High, angled towards posterior end	No lateral toes visible, Medial clearly visible	
-1	Palpable on lateral side, slightly on medial	Below concave but flatter /shallow than curve above	Between vertical and 5^{0} varus	Area slight but definitely concave	Moderately high and slightly posteriorly	Medial toes clearly more visible than lateral	
0	Equally palpable on both sides	Both infra/supra curves equal	Vertical	Area flat	Height normal, concentrically curved	Medial and lateral toes equally visible	
+1	Slightly on lateral side, palpable on medial	Curve below more concave then above curve	Between vertical and 5^{0} valgus	Area slightly bulging	Lowered with some flattening in centre	Lateral toes clearly more visible than medial	
+2	Not on lateral side, palpable on medial	Curve below markedly concave that above curve	More than 5^{0} valgus	Area markedly bulging	Very low, severe flattening, ground contact	No medial toes visible, Lateral toes clearly visible	

Appendix 13. Footwear assessment tool

Appendix 1: FOOTWEAR ASSESSMENT TOOL

1. FIT

Foot length ☐ *Thumb width* ☐

Fit of shoe (length) – rule of thumb (wearer's thumb)

Palpation:	good ☐	too short (< ½ thumb) ☐	too long (> 1 ½) ☐
Straw =	good ☐	too short (< ½ thumb) ☐	too long (> 1 ½) ☐

Fit of shoe (width) – grasp test	good ☐	too narrow ☐	too wide ☐
Fit of shoe (depth)	good ☐	too shallow ☐	

2. GENERAL

Age of shoe 0 – 6 months ☐ 6 – 12 months ☐ > 12 months ☐

Footwear style

walking shoe ☐	athletic shoe ☐	oxford shoe ☐	moccasin ☐
boot ☐	ugg-boot ☐	high heel ☐	Thong/flip-flop ☐
slipper ☐	backless slipper ☐	court shoe ☐	mule ☐
sandal ☐	surgical/bespoke ☐	other (specify) ☐	

Materials (upper)	leather ☐	synthetic ☐	mesh ☐	other ☐	
Materials (outsole	rubber ☐	plastic ☐	leather ☐	other ☐	

Weight ☐ *Length* ☐ *Weight/length* ☐

3. GENERAL STRUCTURE

Heel height =

0 – 2.5 cm ☐ 2.6 – 5.0 cm ☐ > 5.0 cm ☐

Forefoot height (measured at point of the 1st and MTPJs) =

0 – 0.9 cm ☐ 1.0 – 2.0 cm ☐ > 2.0 cm ☐

Longitudinal profile (heel – forefoot difference) =

flat (0 – 0.9 cm) ☐ small heel rise (1 – 3 cm) ☐ large heel rise (> 3 cm) ☐

Last (centre goniometer at 50% shoe length) =

straight (< 5°) ☐ semi-curved (5 – 15°) ☐ curved (> 15°) ☐

Fixation of upper to sole

board ☐ combination ☐ slip-lasted ☐

Forefoot sole flexion point

at level of MTPJs ☐ proximal to 1st MTPJ ☐ distal to 1st MTPJ ☐

4. MOTION CONTROL PROPERTIES

Density single ☐ dual ☐

Fixation none ☐ laces ☐ straps/buckles ☐ Velcro ☐ zips ☐
Number of eyelets ☐

Heel counter stiffness (20mm above bottom or upper)
no heel counter ☐ minimal (> 45°) ☐ moderate (< 45°) ☐ rigid (0-10°) ☐

Midfoot sole sagittal stability
minimal (> 45°) ☐ moderate (< 45°) ☐ rigid (0-10°) ☐

Midfoot sole frontal stability (torsional)
minimal (> 45°) ☐ moderate (< 45°) ☐ rigid (0-10°) ☐

5. CUSHIONING

Presence none ☐ heel ☐ heel/forefoot ☐

Lateral Midsole hardness	soft		firm		hard		
Durometer readings	1st		2nd		3rd		mean
Medial Midsole hardness	soft		firm		hard		
Durometer readings	1st		2nd		3rd		mean
Heel sole hardness (centre of inside heel shoe interface)	soft		firm		hard		
Durometer readings	1st		2nd		3rd		mean

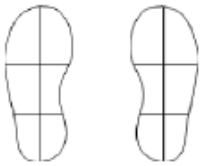
6. WEAR PATTERNS

Upper medial tilt (> 10°) ☐ neutral ☐ lateral tilt (> 10°) ☐

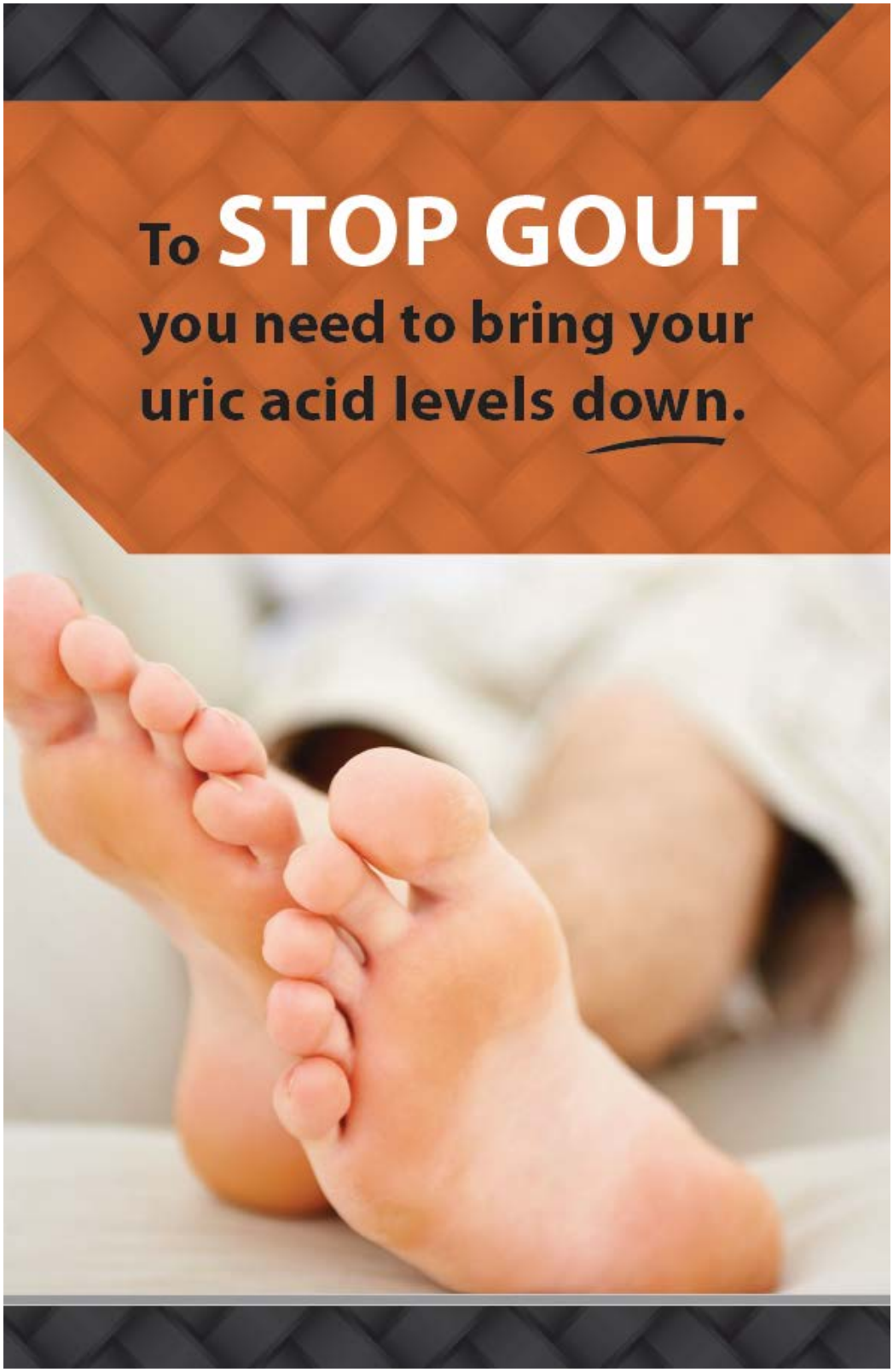
Midsole medial compression signs ☐ neutral ☐ lateral compression signs ☐

Tread pattern *A* textured ☐ smooth (i.e. no pattern) ☐
B not worn ☐ partly worn ☐ fully worn ☐

Outsole wear pattern none ☐ normal ☐ lateral ☐ medial ☐

R  L

Appendix 14. Stop gout booklet



Why do I get gout?

You might think that gout is caused by drinking too much beer and fizzy drinks and eating too much meat and shellfish. In fact, gout is caused by having too much of a chemical called uric acid in your blood.

Your body makes uric acid when you eat food. It is normal and healthy to have some uric acid in your body. Most people get rid of uric acid through their urine.

If you eat food, such as meat, seafood, beer, fizzy drinks and orange juice, your body can make too much uric acid.

How does gout affect you?

Gout can be a sign you could get diabetes, heart disease and kidney problems.

Gout can stop you doing all the things you enjoy. Gout can stop you playing sport and spending time with your family or whānau.

Gout can stop you feeling good about yourself and your life.

What causes your gout attacks?

If there is too much uric acid in your blood, the acid turns into crystals in your joints.

The crystals are very sharp, like needles, and your joint gets very sore and painful. This is called a gout attack.

Crystals can cause damage to your joints.

The crystals cause lumps which are called tophi (you say toe-fy). If tophi get too big they can make it hard for you to wear shoes, use a knife and fork, write and walk easily.

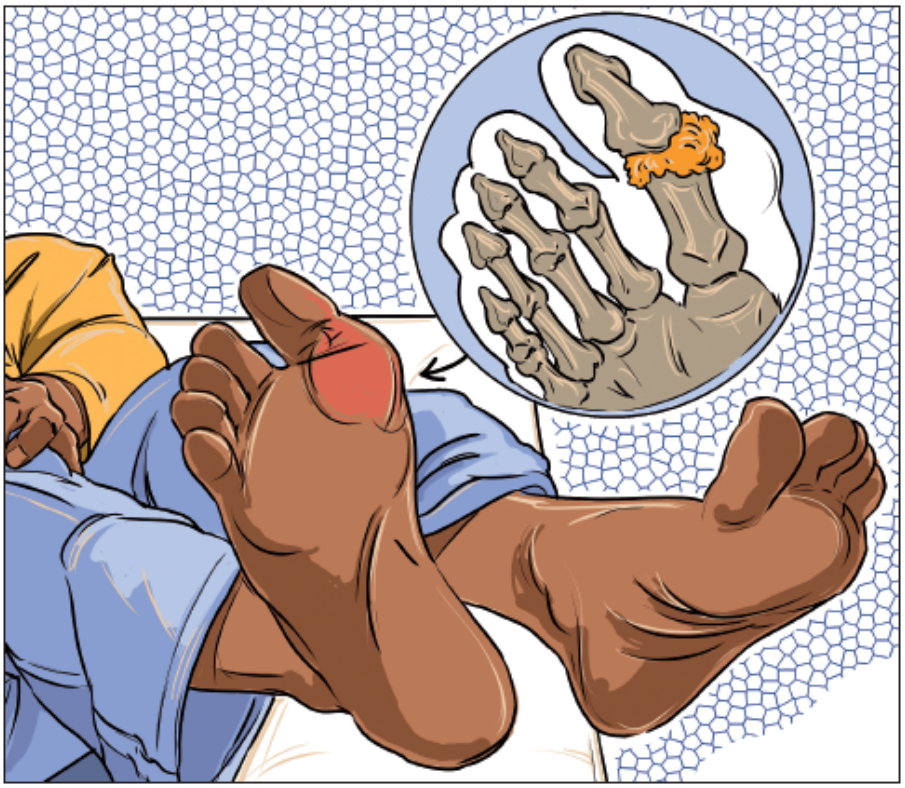
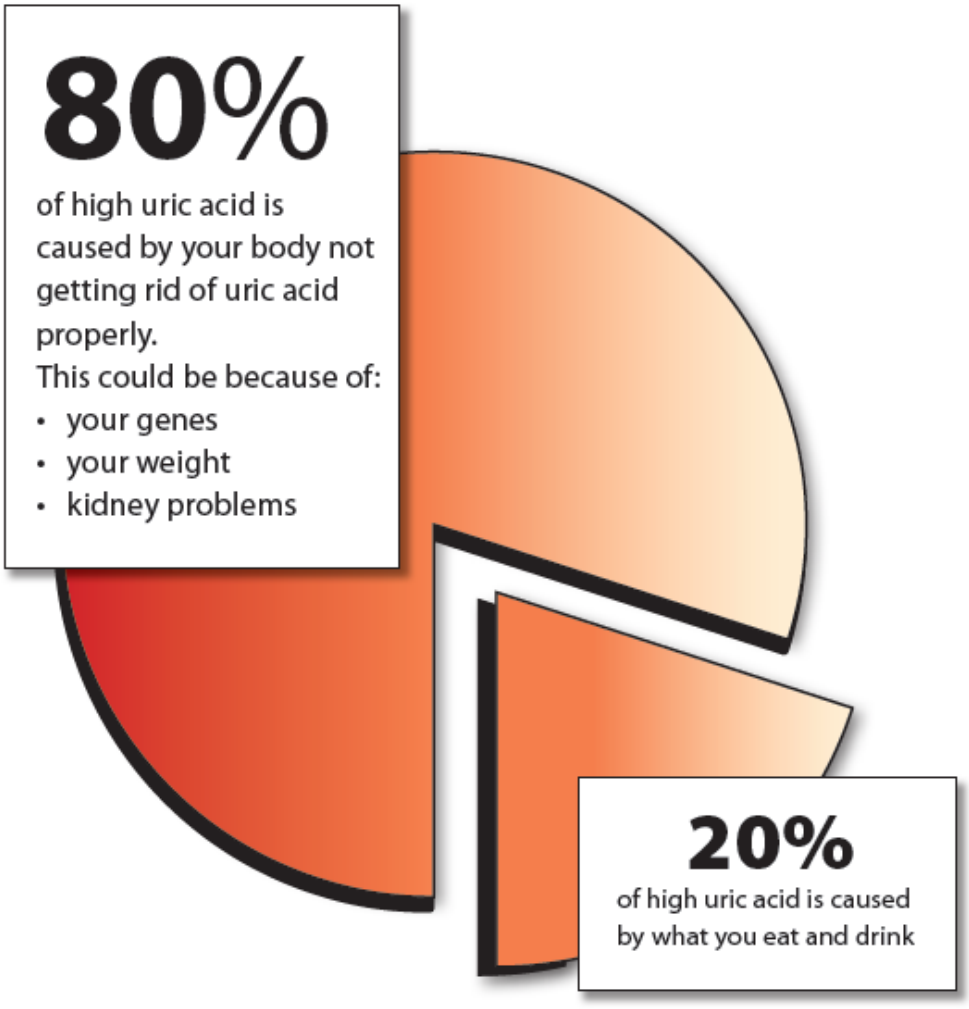


Image supplied by PHARMAC

What causes high uric acid in your body?

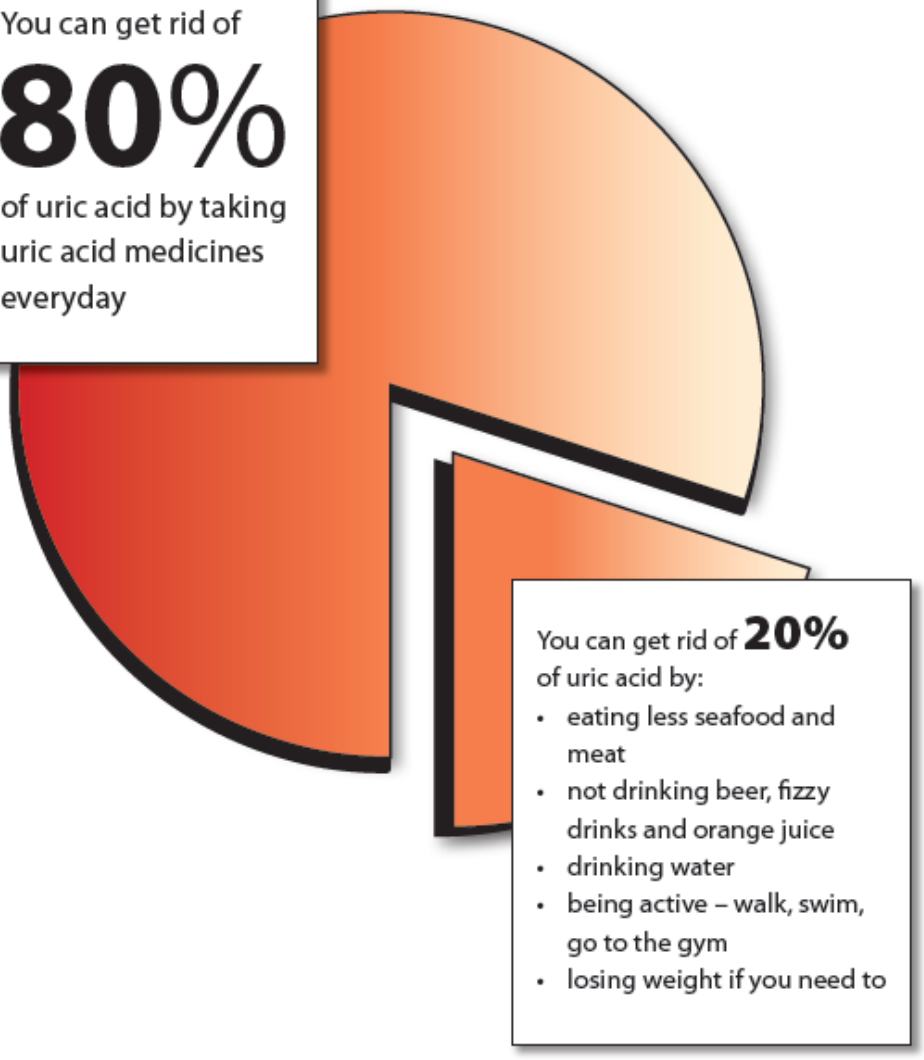


How can you get rid of uric acid in your body?

You can get rid of

80%

of uric acid by taking uric acid medicines everyday



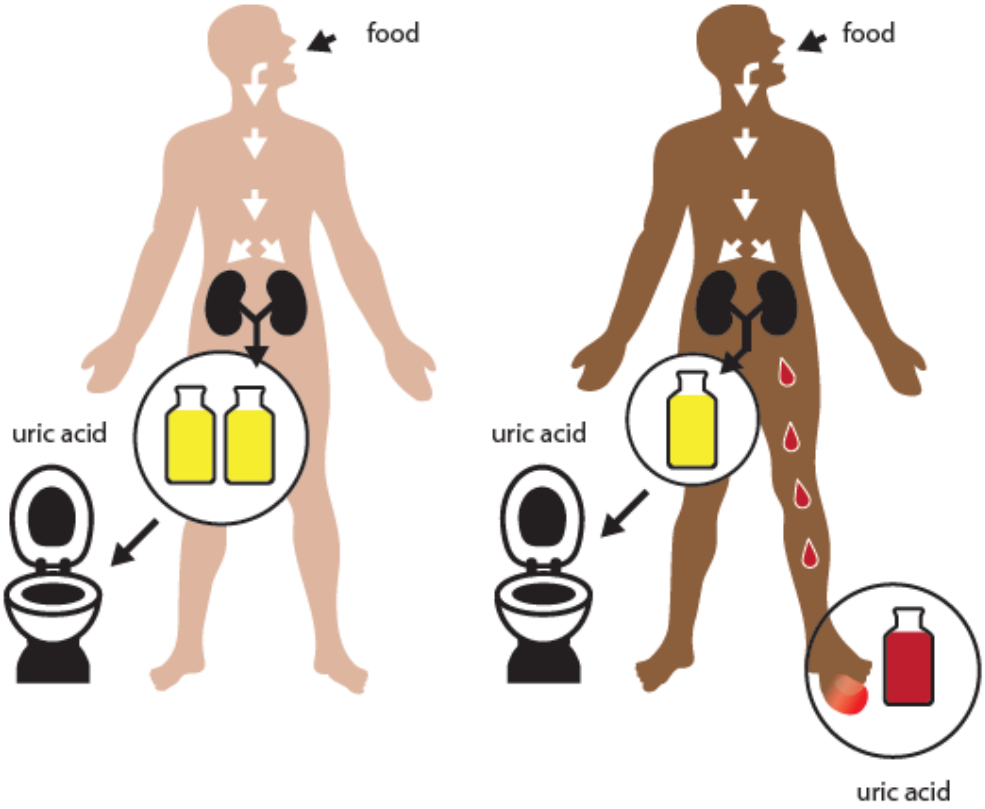
You can get rid of **20%** of uric acid by:

- eating less seafood and meat
- not drinking beer, fizzy drinks and orange juice
- drinking water
- being active – walk, swim, go to the gym
- losing weight if you need to

How you get rid of uric acid

Most people get rid of uric acid through their urine

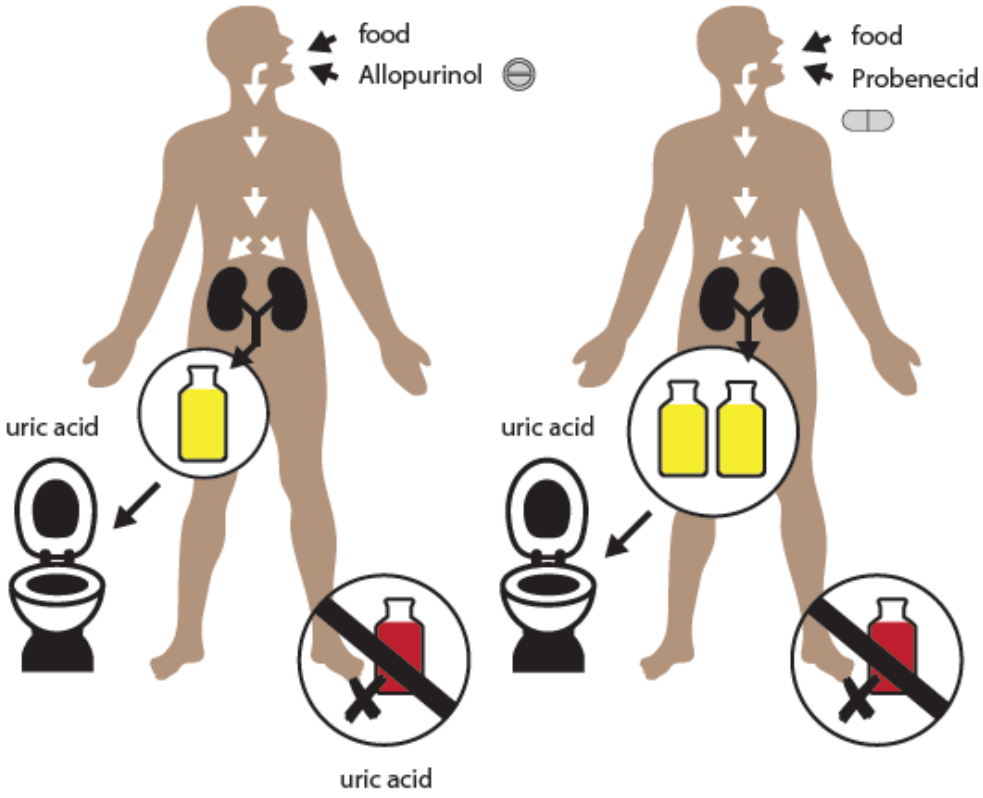
Some people, including many Māori and Pacific people, get rid of some of their uric acid, and the rest stays in their blood



How uric acid medicines help you

Some uric acid medicines stop your body making too much uric acid

Some uric acid medicines help your body get rid of uric acid through your urine



7

Medicines for gout

There are two types of medicines for gout:

1. Uric acid medicine

Uric acid medicines bring your uric acid levels down. You need to take them every day.

Common uric acid medicines are Allopurinol and Probenecid.

You need to take uric acid medicines every day, even if you are having a gout attack. When you start taking uric acid medicines, you might get a gout attack. So make sure your doctor also gives you medicine to treat the pain from a gout attack.

Side effects
Make sure you ask your doctor, nurse or pharmacist what the side effects of uric acid medicine could be and what you should do if you get side effects.

2. Gout attack medicines

Gout attack medicines treat gout attacks. You take these medicines when you feel a gout attack coming on or if you are in pain.

Common gout attack medicines are Colchicine, Prednisone, Naproxen, Diclofenac (Voltaren) and Ibuprofen.

Gout attack medicines only treat pain and swelling. Gout attack medicines do not stop gout because they do not bring your uric acid levels down.

Side effects
Most gout attack medicines should not be taken for a long time. People with tophi may need to take Colchicine for a long time.

Taking gout attack medicines all the time can cause side effects such as stomach problems.

Always ask your doctor, nurse or pharmacist how long you should take your gout attack medicine for.

Starting on uric acid medicine

Your doctor should start you on a low dose and slowly build up to a stronger dose. When you start on uric acid medicine you also need to take gout attack medicine. You will be taking two medicines.

1st medicine

Your uric acid medicine is called _____

You take:

_____ mg a day for _____

_____ mg a day for _____

_____ mg a day for _____

_____ mg a day for _____

Remember, keep taking your uric acid medicine every day even if you get an attack. Tell your doctor or nurse if you get an attack. Stop taking uric acid medicine immediately if you get a bad skin rash. Tell your doctor or nurse immediately if you get a bad skin rash.

Take your uric acid medicine every day even if you get a gout attack.

2nd medicine

Your gout attack medicine is _____

You take:

_____ mg a day for _____

_____ mg a day for _____

_____ mg a day for _____

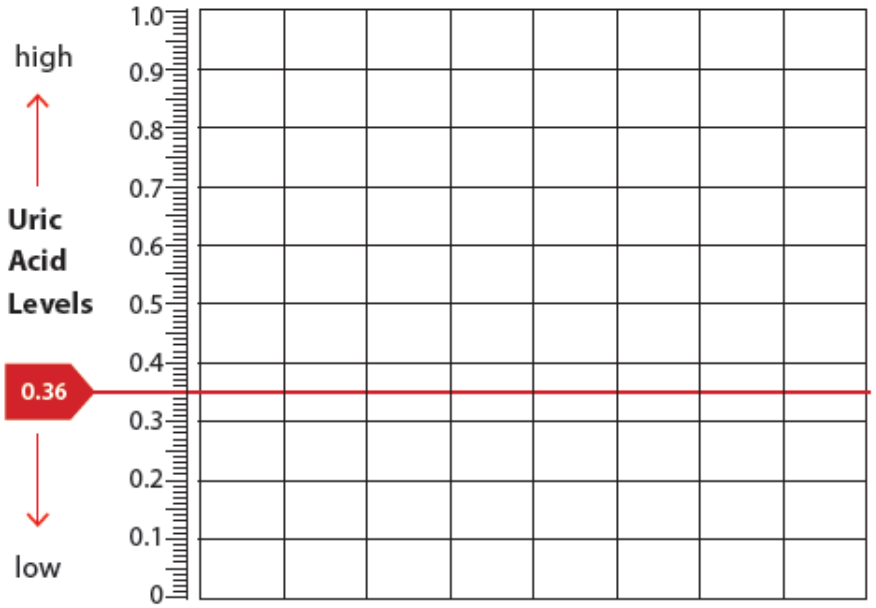
_____ mg a day for _____

Remember, you shouldn't take most gout attack medicines for a long time as they can cause stomach problems.

Checking your uric acid level

When you take uric acid medicine your target is to get your uric acid levels down to 0.36. You need to get your uric acid level checked regularly. You might need to take a stronger dose of your uric acid medicine if your levels don't come down. If you have tophi you might need to get your uric acid levels down to 0.30 to get rid of your tophi.

Fill in your uric acid levels on this graph



Choosing the right shoe

If you get gout in your foot, try not to wear:

sandals | jandals | slippers | old shoes

These shoes don't support your feet properly when you are walking or standing. This can affect your balance and make your pain worse.

People with gout in their feet need to wear shoes that:

1. are comfortable (not too tight), so there is room if your foot swells up
2. have a wide toe to leave room for your sore toe
3. have laces or velcro so you can tighten or loosen your shoe
4. have a cushioned insole that supports your foot
5. have a deep heel so your foot fits into your shoe properly
6. have a small heel because high heels can cause problems with your feet, knees and legs
7. have a firm sole that is not worn.

You need to buy a good quality shoe but your shoes don't have to be expensive.

If you are not sure about what shoes to buy, take this list with you and talk to the salesperson in the shop.

11

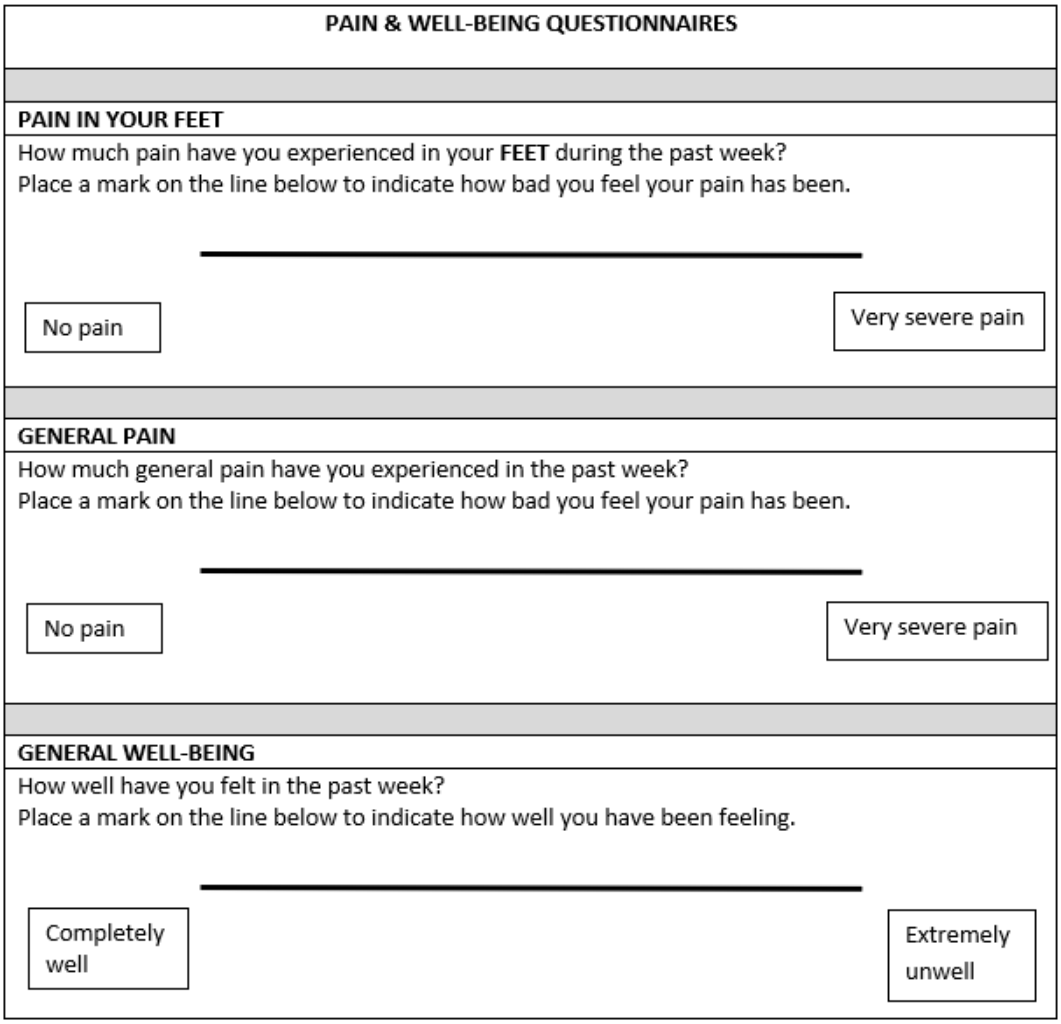

Ask your doctor, nurse or pharmacist
What is my uric acid level?
When do I need to get my uric acid level checked again?
What are the possible side effects from this new medicine?
When do I need to call you if I have any side effects?
What else can I do to bring my uric acid levels down?
Should I stop taking this medicine if I get side effects?
This medicine doesn't seem to be working for me – I am still getting gout attacks and my uric acid level isn't going down. Can you talk to a rheumatologist or specialist nurse and ask them what else we can do?
Do I need to get my heart and diabetes checked as well?
Do I need to take more uric acid medicine to get my uric acid level down?
What can I say to my family so they don't get gout?
Your question
Want to know more about gout:
Health Navigator:
http://www.healthnavigator.org.nz/health-topics/gout/
Arthritis NZ:
Phone: 0800 66 34 63
(freephone for cell phones and landlines)
http://www.arthritis.org.nz/what-is-arthritis/forms-of-arthritis/
This booklet was developed by Workbase Education Trust as part of a research project funded by the Ministry of Health.
Workbase would like to thank the Maaori Gout Action Group, Dr Peter Jones, Leanne Te Karu, Arthritis New Zealand and PHARMAC for feedback on this resource.

Appendix 15. Footwear diary

Week 1 Date: ___/___/___ to ___/___/___

	No. of hours shoes worn	Any gout flares?	Any pain or discomfort with the shoes?	Comments
M		Y / N	Y / N	
T		Y / N	Y / N	
W		Y / N	Y / N	
T		Y / N	Y / N	
F		Y / N	Y / N	
S		Y / N	Y / N	
S		Y / N	Y / N	

Appendix 16. Foot pain, overall pain and global visual analogue scales



PAIN & WELL-BEING QUESTIONNAIRES

PAIN IN YOUR FEET

How much pain have you experienced in your **FEET** during the past week?
Place a mark on the line below to indicate how bad you feel your pain has been.

No pain — Very severe pain

GENERAL PAIN

How much general pain have you experienced in the past week?
Place a mark on the line below to indicate how bad you feel your pain has been.

No pain — Very severe pain

GENERAL WELL-BEING

How well have you felt in the past week?
Place a mark on the line below to indicate how well you have been feeling.

Completely well — Extremely unwell

Appendix 17. Health assessment questionnaire-II

HAQ-II questionnaire

We are interested in learning how your illness affects your ability to function in daily life.
Place an x in the box which best describes your usual abilities over the past week.

Are you able to:	**Without any difficulty**	**With some difficulty**	**With much difficulty**	**Unable**
1. Get on and off the toilet?				
2. Open car doors?				
3. Stand up from a straight chair?				
4. Walk outdoors on flat ground?				
5. Wait in a line for 15 minutes?				
6. Reach and get down a 5-pound object (such as a bag of sugar) from just above your head?				
7. Go up 2 or more flights of stairs?				
8. Do outside work (such as yard work)?				
9. Lift heavy objects?				
10. Move heavy objects?				

Appendix 18. Lower limb tasks questionnaire

Health and Rehabilitation Research Institute
Auckland University of Technology

LOWER LIMB TASKS QUESTIONNAIRE
ACTIVITIES OF DAILY LIVING SECTION

Patient: _____ **Date:**_____

INSTRUCTIONS
Please rate your ability to do the following activities in the **past 24 hours** by circling the number below the appropriate response.

If you did not have the opportunity to perform an activity in the **past 24 hours**, please make your *best estimate* on which response would be the most accurate.

Please also rate how important each task is to you in your daily life according to the following scale:

1 = Not important
2 = Mildly important
3 = Moderately important
4 = Very important

Please answer all questions.

	UNABLE	SEVERE DIFFICULTY	MODERATE DIFFICULTY	MILD DIFFICULTY	NO DIFFICULTY	IMPORTANCE OF TASK
1. Walk for 10 minutes	0	1	2	3	4	1 2 3 4
2. Walk up or down 10 steps (1 flight)	0	1	2	3	4	1 2 3 4
3. Stand for 10 minutes	0	1	2	3	4	1 2 3 4
4. Stand for a typical work day	0	1	2	3	4	1 2 3 4
5. Get on and off a bus	0	1	2	3	4	1 2 3 4
6. Get up from a lounge chair	0	1	2	3	4	1 2 3 4
7. Push or pull a heavy shopping trolley	0	1	2	3	4	1 2 3 4
8. Get in and out of a car	0	1	2	3	4	1 2 3 4
9. Get out of bed in the morning	0	1	2	3	4	1 2 3 4
10. Walk across a slope/uneven ground	0	1	2	3	4	1 2 3 4

TOTAL (/40):_____

Enquiries concerning this questionnaire: Prof. Peter McNair, Health and Rehabilitation Research Institute, Auckland University of Technology, Private Bag 92006, Auckland, New Zealand. email: peter.mcnair@aut.ac.nz Phone: 921-9999 Ext 7143

Health and Rehabilitation Research Institute
Auckland University of Technology

LOWER LIMB TASKS QUESTIONNAIRE
RECREATIONAL ACTIVITIES SECTION

Patient: _____ **Date:**_____

INSTRUCTIONS
Please rate your ability to do the following activities in the **past 24 hours** by circling the number below the appropriate response.

If you did not have the opportunity to perform an activity in the **past 24 hours**, please make your *best estimate* on which response would be the most accurate.

Please also rate how important each task is to you in your daily life according to the following scale:

1. = Not important
2. = Mildly important
3. = Moderately important
4. = Very important

Please answer all questions.

	UNABLE	SEVERE DIFFICULTY	MODERATE DIFFICULTY	MILD DIFFICULTY	NO DIFFICULTY	IMPORTANCE OF TASK
1. Jog of 10 minutes	0	1	2	3	4	1 2 3 4
2. Pivot or twist quickly while walking	0	1	2	3	4	1 2 3 4
3. Jump for distance	0	1	2	3	4	1 2 3 4
4. Run fast/sprint	0	1	2	3	4	1 2 3 4
5. Stop and start moving quickly	0	1	2	3	4	1 2 3 4
6. Jump upwards and land	0	1	2	3	4	1 2 3 4
7. Kick a ball hard	0	1	2	3	4	1 2 3 4
8. Pivot or twist quickly while running	0	1	2	3	4	1 2 3 4
9. Kneel on both knees for 5 minutes	0	1	2	3	4	1 2 3 4
10. Squat to the ground/floor	0	1	2	3	4	1 2 3 4

TOTAL (/40):_____

Enquiries concerning this questionnaire: Prof. Peter McNair PhD, Health and Rehabilitation Research Institute, Auckland University of Technology, Private Bag 92006, Auckland; New Zealand. email: peter.mcnair@aut.ac.nz Phone: 921-9999 Ext 7143

Appendix 19. Leeds foot impact scale

LFIS-RA

Date:

Name:_____ Age:_____ Sex:_____

On the following pages you will find some statements which have been made by people who have Arthritis in their feet

Instructions: This questionnaire consists of 51 statements. Please read each statement carefully, and then pick out the **one statement** that best describes the way you have been feeling. Choose **True** if the statement applies to you and choose **Not True** if it does not apply to you **at the moment**. Circle the number beside the statement you have picked.

1. **My feet get painful when I'm standing**
   1 True
   0 Not True

2. **My feet hurt me**
   1 True
   0 Not True

3. **I find the pain in my feet frustrating**
   1 True
   0 Not True

4. **The pain is worse when I've been on my feet all day**
   1 True
   0 Not True

5. **At the end of the day there is pain and tension in my feet**
   1 True
   0 Not True

6. **I never get rid of the stiffness in the background**
   1 True
   0 Not True

7. **My feet throb at night**
   1 True
   0 Not True

8. **My feet wake me up at night**
   1 True
   0 Not True

9. **I feel as though I've got pebbles in my shoes**
   1 True
   0 Not True

10. **I get pain every time I put my foot down**
    1 True
    0 Not True

11. **I get a burning sensation all the time**
    1 True
    0 Not True

____ Subtotal Page 1

Continue on Back

12. **I cry with pain**
    1 True
    0 Not True

13. **I can only walk in certain shoes**
    1 True
    0 Not True

14. **I need shoes with plenty of room in them**
    1 True
    0 Not True

15. **I am limited in my choice of shoes**
    1 True
    0 Not True

16. **I need a wider fit of shoes**
    1 True
    0 Not True

17. **I feel I need a lot of padding under my feet**
    1 True
    0 Not True

18. **My footwear always feels heavy**
    1 True
    0 Not True

19. **I have to keep swapping and changing my shoes**
    1 True
    0 Not True

20. **I can't get any shoes on**
    1 True
    0 Not True

21. **I walk barefoot all the time**
    1 True
    0 Not True

22. **I feel unsafe on my feet**
    1. True
    2. Not True

23. **I have to walk for a bit and sit for a bit**
    1 True
    0 Not True

24. **I can't run**
    1 True
    0 Not True

25. **I find I shuffle around**
    1 True
    0 Not True

____ Subtotal Page 2

Continue on Page 3

26. **I am limping about all the time**
    1 True
    0 Not True

27. **I have to use a walking stick or walking frame**
    1 True
    0 Not True

28. **It takes me all my time to climb the stairs**
    1 True
    0 Not True

29. **I need help to climb stairs**
    1 True
    0 Not True

30. **I can't walk on cobbles**
    1 True
    0 Not True

31. **I am unsteady on uneven surfaces**
    1. True
    2. Not True

32. **I can't walk as far as I would like to**
    1 True
    0 Not True

33. **It takes me longer to do things**
    1 True
    0 Not True

34. **My whole life has been adapted**
    1 True
    0 Not True

35. **My feet restrict my movement**
    1 True
    0 Not True

36. **I get annoyed because I'm slower**
    1 True
    0 Not True

37. **I get frustrated because I can't do things So quickly**
    1 True
    0 Not True

38. **My whole life has slowed down**
    1 True
    0 Not True

39. **It's reduced the range of things I can do**
    1 True
    0 Not True

____ Subtotal Page 3

Continue on Back

40. **I have to plan everything out**
    1. True
    2. Not True

41. **I can't keep up like I used to**
    1 True
    0 Not True

42. **Socially it's affected my a lot**
    1 True
    0 Not True

43. **I am ashamed of how I walk**
    1 True
    0 Not True

44. **I'm nervous of missing a curb edge**
    1 True
    0 Not True

45. **I feel isolated because I can't go very far**
    1 True
    0 Not True

46. **I feel I slow other people down**
    1 True
    0 Not True

47. **I can't do some of the things I take for granted**
    1 True
    0 Not True

48. **I can't go for walks with the people close to me**
    1 True
    0 Not True

49. **I'm finding it difficult to be independent**
    1 True
    0 Not True

50. **I dread finishing up in a wheelchair**
    1 True
    0 Not True

51. **I get frustrated because I can't do things for myself**
    1 True
    0 Not True

Subtotal Page 4

Subtotal Page 3

Subtotal Page 2

Subtotal Page 1

Total Score

Appendix 20. Footwear visual analogue scales

FOOTWEAR COMFORT, FIT, EASE OF FIT AND WEIGHT OF SHOE

FOOTWEAR COMFORT

How much comfort have you experienced in the past week with your shoes?
Place a mark on the line below to indicate how comfortable your shoes have been.

Extremely Comfortable	Extremely Uncomfortable

SHOE-FIT

How well have your shoes fitted over the past week?
Place a mark on the line below to indicate how well your shoes have fitted.

Best fit possible	Poorest fit possible

EASE OF PUTTING SHOES ON AND OFF

How easy has it been putting your shoes on and taking them off over the past week?
Place a mark on the line below to indicate how easy it has been to take your shoes on and off.

Easy as imaginable	Most difficult as possible

WEIGHT OF SHOE

How heavy have your shoes been over the past week?
Place a mark on the line below to indicate how you feel about the weight of your shoes.

Extremely light	Extremely heavy

Appendix 21. Participant information sheet

Participant Information Sheet

AUT UNIVERSITY
TE WĀNANGA ARONUI O TAMAKI MAKAU RAU

Date Information Sheet Produced:

5th June 2015

Project Title

The clinical effectiveness of foot-care treatments in the reduction of foot pain and disability in people with gout

An Invitation

My name is Keith Rome, a Professor in Podiatry and I would like to extend a warm invitation to you to participate in my research project. This is also a part of a PhD being undertaken at AUT University. This project will contribute towards a good understanding of how foot-care treatments can reduce pain and disability in people with gout. The project is funded by the Auckland Medical Research Foundation (AMRF).

What is the purpose of this research?

Gout is a major cause of pain and disability in Aotearoa New Zealand. Foot pain occurs in most people with gout. We propose a long-term clinical trial examining the effects of foot-care treatments on foot pain and disability. The trial will assess the effect of two different foot care packages. The study findings will be used to make evidence-based recommendations regarding foot-care treatments for people with gout.

How was I identified and why am I being invited to participate in this research?

This project invites participants of any age above 20 years old who have gout. You are welcome to participate if you are over 20 years of age with a good grasp of the English language. However, if you have a medical history of foot or ankle surgery, neuromuscular problems or rheumatoid arthritis I will be unable to include you in this study regrettably. Your involvement in this project is voluntary and you are welcome to withdraw your participation at any time without reason.

What will happen in this research?

We will ask you to attend AUT School of Podiatry clinic over at the North Shore. We will then ask you questions about your general health and any other foot problems you have relating to your gout. We will then ask you to walk along a walkway wearing your current footwear. We will then ask you to repeat this again using a new pair of shoes. We will invite you back in 6-months and assess your new shoes. Food and beverages will be provided and you will have an opportunity to rest between each walk.

What are the discomforts and risks?

There are minimal risks. You may encounter a blister or rubbing.

How will these discomforts and risks be alleviated?

If blistering or rubbing does occur and prevents you undertaking everyday activities we will treat the foot complaint.

What are the benefits?

The aim of the proposal is to improve foot pain and impairment in people with gout. The study proposed will be immediately impact into clinical practice. All participants will receive a summary of findings. The research will also highlight the role that a health care professional can play in the assessment and management of patients with chronic gouty arthritis.

What compensation is available for injury or negligence?

In the unlikely event of a physical injury as a result of your participation in this study, rehabilitation and compensation for injury by accident may be available from the Accident Compensation Corporation, providing the incident details satisfy the requirements of the law and the Corporation's regulations.

How will my privacy be protected?

Your name, birthdate and any personal information that could identify you as an individual will not be used in this study or published in any medium. All the information that is provided by you will be treated as confidential and strict access will only be available to the researchers and yourself upon request.

What are the costs of participating in this research?

There will be no financial cost to you if you decide to participate in this research. We would like to offer you the costs of travelling from home to AUT North Shore and back to home.

What opportunity do I have to consider this invitation?

You have one-week to decide whether or not you would like to accept this invitation. I would like to arrange an appointment time with you at least two (2) weeks beforehand so that I can secure the equipment needed for this study. Please make sure you thoroughly read this Information Sheet and have any concerns answered before you participate.

How do I agree to participate in this research?

If you would like to participate in this study please contact Katie Hayden via the details given below. I will then give you a Consent Form (or send one if requested) to fill out and sign, to secure your place in the study.

Will I receive feedback on the results of this research?

If you are interested to see the outcomes of this research please indicate so on the applicable section of the consent form. The results will be sent to you in the form of a written summary and any papers that may be published as a result of this study can be accessed upon request.

What do I do if I have concerns about this research?

Any concerns regarding the nature of this project should be notified in the first instance to the Project Supervisor, Professor Keith Rome (contact details below)

Concerns regarding the conduct of the research should be notified to the Executive Secretary of AUTEC, Kate O'Connor, *ethics@aut.ac.nz* , 921 9999 ext 6038.

Whom do I contact for further information about this research?

Researcher Contact Details:

Katie Hayden

Phone: 0800 4688 288 or 022 164 3962

Email: khayden@aut.ac.nz

Project Supervisor Contact Details:

Professor Keith Rome

Phone: 921 9999 extension 7688

Email: k.rome@aut.ac.nz

Approved by the Auckland University of Technology Ethics Committee on *09/06/2015*, AUTEC Reference number *14/233*.

Appendix 22. Consent form

Consent Form

AUT UNIVERSITY
TE WĀNANGA ARONUI O TAMAKI MAKAU RAU

Project title: ***The clinical effectiveness of foot-care treatments in the reduction of foot pain and disability in people with gout***

Project Supervisor: ***Professor Keith Rome***

Researcher: ***Mike Frecklington***

- ○ I have read and understood the information provided about this research project in the Information Sheet dated 05 June 2015.
- ○ I have had an opportunity to ask questions and to have them answered.
- ○ I understand that I may withdraw myself or any information that I have provided for this project at any time prior to completion of data collection, without being disadvantaged in any way.
- ○ I understand that upon withdrawal, all personal information and individual data will be destroyed.
- ○ I agree to have foot measurements undertaken and understand that they will only be used for academic purposes. Publications outside of this project cannot eventuate without my written consent.
- ○ I understand that all personal information that could potentially identify myself will be strictly confidential and safeguarded in a password-protected file. This information will only be used for the requirements of this study.
- ○ I truthfully state that I have not received treatment with foot orthoses or footwear within the previous three (3) months, or had any history of foot and ankle surgery or rheumatoid arthritis
- ○ I henceforth agree to take part in this research.
- ○ I wish to receive a copy of the report from the research (please tick one): Yes○ No○

Participant's signature: .....

Participant's name: .....

Participant's Contact Details (if appropriate):

.....

.....

.....

.....

Date:

Approved by the Auckland University of Technology Ethics Committee on 09/06/2015 AUTEC Reference number 14/233

Note: The Participant should retain a copy of this form.

Appendix 23. The footwear experiences of people with gout: a qualitative study

Frecklington et al. Journal of Foot and Ankle Research (2019) 12:38
https://doi.org/10.1186/s13047-019-0349-7

Journal of Foot and Ankle Research

RESEARCH Open Access

The footwear experiences of people with gout: a qualitative study

Mike Frecklington[1*], Anita Williams[2], Nicola Dalbeth[3], Peter McNair[1], Peter Gow[4] and Keith Rome[1]

Abstract

Background: Footwear is an important concern for people with gout, who often describe difficulty finding suitable footwear. Previous studies have identified footwear as a major concern for people with gout. The aim of this study was to carry out an exploration of the footwear experiences of people with gout.

Methods: A qualitative descriptive methodological approach was used for both data collection and analysis. A purposive sampling strategy was adopted with semi-structured interviews conducted, involving 11 participants with gout. Thematic analysis was employed to identify key meanings and patterns within the data.

Results: Four key themes derived from interviews included; (1) comfort as a priority, (2) knowing what to buy, (3) knowing what to wear, and (4) challenges of different environments. Footwear comfort was of great importance and linked to characteristics of footwear, with uncomfortable footwear negatively influencing participation in daily activities. The balancing of comfort, appearance and cost, led to less options and reduced confidence when shoe shopping. Footwear use was further limited by the presence of foot tophi and flares, resulting in compromise of footwear choice. Environments such as formal settings and the workplace, led to different footwear requirements.

Conclusion: People with gout experience problems with footwear which can impact many aspects of life. Health care professionals should consider these footwear-related issues to help facilitate those with gout in finding appropriate footwear.

Keywords: Gout, Footwear, Qualitative research

Background

Gout is a common form of inflammatory arthritis characterised by deposition of monosodium urate (MSU) crystals, which form in people with high serum urate levels (hyperuricaemia). Gout can present as intermittent episodes of acute arthritis (gout flares) and/or subcutaneous nodules of MSU crystals (tophi) [1]. People with gout experience high levels of foot pain, impairment and disability [2]. To reduce the impact of gout related foot pain, appropriately designed footwear has been used [3]. However, it has been found that people with gout frequently wear footwear which is ill-fitting, lacks cushioning and lacks support. This may be due to inappropriate design at the point of purchase, or the wearing of the footwear over time resulting in effective design components becoming ineffective. Factors related to footwear may contribute to the high levels of foot pain, impairment and disability [4].

Footwear is an important concern for people with gout, with previous qualitative work highlighting footwear-related issues such as the inability to wear footwear during gout flares [5–7], uncertainty about what footwear type and design [8, 9], and difficulty finding footwear which accommodates for foot tophi [5, 9]. Further, in a previous mixed-methods study using an online survey with open-ended questions people with gout reported difficulty finding suitable shoes, revealed the impact of shoes on activity and identified what they preferred in relation to footwear features [10]. Although the impact of gout on footwear choice and use has been described, there is limited understanding of the experiences and perceptions of footwear of people living with gout. The aim of this study was to explore the personal experiences of footwear in people with gout.

* Correspondence: mike.frecklington@aut.ac.nz
[1]Health and Rehabilitation Research Institute, AUT University, Private Bag 92006, Auckland 1142, New Zealand
Full list of author information is available at the end of the article

Methods

Design

This qualitative study sought to gain insight into the subjective experiences of people living with gout in obtaining and wearing footwear [11]. Semi-structured interviews were conducted to explore the participants' individual perspectives. Inclusion criteria were: gout according to the 1977 preliminary American Rheumatism Association criteria [6], ≥20 years of age, and no history of other inflammatory arthritis or neuromuscular disease. Those who are unable to provide informed consent were excluded. Ethical approval was obtained from the Auckland University of Technology Ethics Committee (14/233) and all participants provided written informed consent.

Participants

Participants were recruited through public newspaper advertising in Auckland, New Zealand using purposeful sampling. Eligible participants were selected to achieve diversity across the following characteristics; gender, ethnicity, disease duration, presence of foot tophus, serum urate, frequency of gout flares.

Data collection

Face-to-face interviews were undertaken either at the Auckland University of Technology or their home. Interviews were conducted by MF, who is an experienced podiatrist and has previously been involved in footwear studies of people with gout. The interviews were audio-recorded. Initial discussions with the participant were held to determine a shared definition of footwear and direct them towards the area of interest. Participants were invited to bring pairs of their own footwear to further enhance discussion. Interview questions were developed based on previous studies in gout [3, 4]. An opening question of "… tell me about your experiences of footwear?" was asked, followed by additional trigger questions (open-ended and directed), and the opportunity for participants to express additional ideas they felt were important (Additional file 1). Questions were designed to promote two-way dialogue when exploring areas of interest, with regular summarises of the content discussed shared with the participant during interviews. The interviews lasted between 20 and 90 min.

Data analysis

Data collection and analysis occurred simultaneously and iteratively, and it emerged that this created new insights and additional dialogue, which influenced subsequent interviews and analyses. Interviews continued until the authors considered that sufficient information power was achieved by the clear research aim, diversity of participants across the sampling framework and the depth of discussions during interviews. Data was analysed using inductive thematic analysis [12] which aligns with qualitative description [13]. Audio recordings of the interviews were transcribed verbatim, anonymised to ensure confidentiality, and analysed after each interview. Transcripts were read and re-read to immerse the researcher in the data. Transcripts were then manually coded by MF, with initial codes and concepts reviewed by a second author (AW). Generated codes were then grouped into potential themes and sub-themes. These were then reviewed to determine a clear distinction between each theme. The final themes were defined, named and agreed upon by all authors. Illustrative quotes from transcripts were selected to provide evidence of each theme.

Results

Nine males and two females were interviewed. There was diversity across age, gender, ethnicity, and clinical features, consistent with the sampling framework (Table 1). Four central themes were derived from the

Table 1 Participant demographics

Participant	Gender	Age (years)	Ethnicity	Disease duration (years)	Tophus	Serum urate (mmol/L)	Flare frequency (past year)
1	F	61	South African	12	Y	0.27	3
2	M	54	Māori	25	N	0.40	3
3	M	83	Māori	10	N	0.27	2–3
4	M	40	NZ European	3	N	0.43	5
5	M	49	Pacific Island	3	N	0.45	2–3
6	M	40	Pacific Island	10	Y	0.59	6
7	F	53	Māori	2	N	0.41	1–2
8	M	72	NZ European	10	N	0.29	1–2
9	M	58	NZ European	5	N	0.54	0
10	M	48	Pacific Island	20	N	0.36	6
11	M	70	NZ European	15	Y	a	0

[a]serum urate not recently checked

data; (1) comfort as a priority, (2) knowing what to buy, (3) knowing what to wear, and (4) challenges of different environments. The thematic map showing the four central themes and sub-themes is displayed in Fig. 1.

Comfort as a priority

All participants stated the importance of comfort, supporting the idea that having comfortable footwear was a priority. The concept of striving for comfort was evident, with feelings of satisfaction upon finding comfortable footwear:

> *"I didn't realise that you can have comfortable shoes, cause I've never had comfortable shoes before" Participant 10, Male, 48 years old*

For some, feeling comfortable was more important than 'looking good':

> *"I've been wearing shoes in the past that don't look good, but they are comfortable. That's, and then, I mean I always get eyes and looks and weirds, but I didn't really care I was just like 'oh, I'm comfortable man'" Participant 6, Male, 40 years old*

Footwear characteristics such as having good fit, cushioning, being lightweight and having enough room to accommodate the foot, were identified as important influencers of footwear comfort:

> *"The fit of the shoe is important if it's too, if it's too tight then it's not comfortable" Participant 8, male, 72 years old*

Having uncomfortable footwear led to foot pain, which in turn could influence one's mood and ability to participate. This consequence was viewed with frustration:

> *"I'm the person who has to sit with a problem when I get home tonight because my feet are sore, and then I can't sleep, and then you don't sleep, and then you're miserable as H the next morning, and then you've got to work, and you're grumpy" Participant 1, Female, 61 years old*

Knowing what to buy

Barriers to shoe shopping were described including budgetary constraints, limited range, and a lack of confidence in knowing what the right shoe is to buy. Finding a balance between comfort and appearance was frequently described:

> *"The shoe looked really primo, but I knew straight away even with the bigger size fitting it was really*

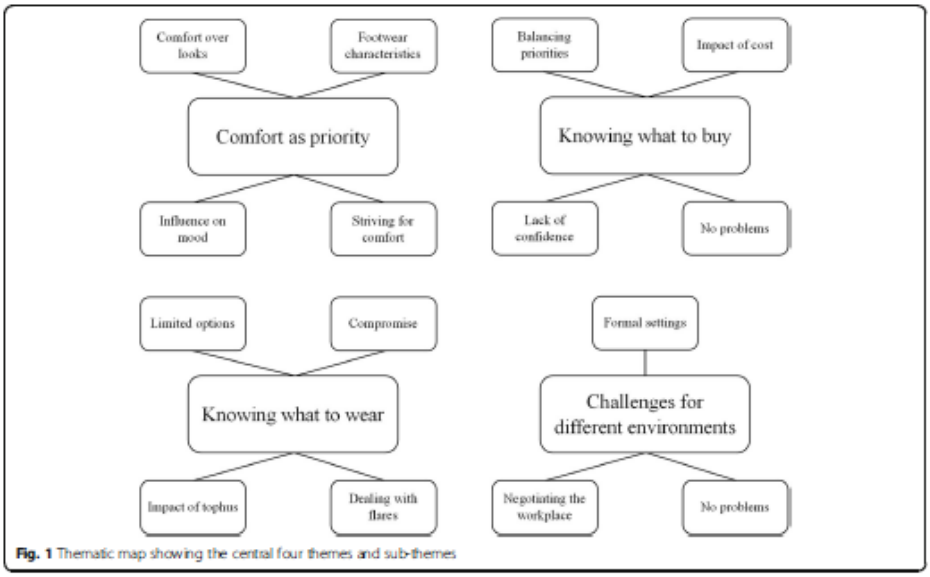


Fig. 1 Thematic map showing the central four themes and sub-themes

uncomfortable. I thought, no I can't put myself through this cause I'll end up with very sore feet you know and ah so I didn't buy them" Participant 10, Male, 48 years old

For others, this balance was strongly influenced by cost, placing further limitations on the footwear available forcing some to 'work with' what was left:

"I think it's just my um, my budget wise. What am I able to afford um, compared to what is out of my price range" Participant 6, Male, 40 years old

Obtaining advice was difficult creating uncertainty surrounding the right type of footwear to buy. This resulted in a lack of confidence with purchases based on negative past experiences, such as footwear becoming uncomfortable shortly after leaving the shop:

"I can try something on in the store and think 'oh my god this is so comfortable, fantastic, problem solved' and then, um it might not be for two or three wears then I'll be walking, and that pain will come back and it's like if I don't take these shoes off well it's just going to escalate" Participant 7, Female, 53 years old

In contrast, some found shoe shopping relatively straight-forward, with gout playing little role in the decision-making process when purchasing footwear:

"I haven't even really thought about buying shoes related to the gout" Participant 11, Male, 70 years old

Knowing what to wear

Despite owning multiple pairs of shoes, participants described a lack of suitable options with respect to the footwear in the cupboard. Having gout meant that footwear which was previously suitable, was no longer appropriate:

"In terms of shoes pre-gout, the only shoes I can still wear are these, that I had before I ever had gout" Participant 7, Female, 53 years old

Those with tophi described difficulties in accommodating for deformity, and how affected sites were irritated by certain footwear:

"If I go out I'll wear leather, proper leather shoes. Trouble is with that bump on my toe it's a bit of a pain aye. You know, um, very restrictive actually" Participant 6, Male, 40 years old

The unpredictable nature of not knowing whether footwear would remain comfortable or exacerbate their foot problems was described. For some, inappropriately fitting footwear could lead to a flare:

"I wore those, and it basically, again longer shoe but not enough width so that just aggravated it and kind of spoiled a day or two of the holiday, because my foot was flared up" Participant 4, Male, 40 years old

For some, there was resignation that finding footwear compatible with their foot and beliefs may not be possible, with others accepting that their current footwear may be as good as it gets. Compromise was evident:

"Having this gout there's not much, there's not much around. It's almost like here's what you've got to try and fit into, try to make it part of you, sort of um your footwear" Participant 6, Male, 40 years old

Challenges of different environments

Participants described that their footwear requirements were different depending on the situation. In formal settings, there was tension between having comfortable footwear and maintaining appearance. The trade-off of sacrificing footwear comfort was to put up with the pain during and after the occasion:

"You've got a formal or a fancy event to go to, you kind of, you just sacrifice as I've said earlier you deal with the consequence tomorrow because this looks right or this is more appropriate for that activity so you just basically suck it up and consequences come tomorrow" Participant 4, Male, 40 years old

Health and safety requirements dictated the footwear choices for several participants. Steel cap boots were viewed as limiting due to being heavy, inflexible and restrictive in the forefoot. Some would adapt their footwear habits to accommodate for their gout symptoms during a flare:

"When I got the gout, I still go to the work, one safety boot, one sneaker" Participant 2, Male, 54 years old

For others footwear discomfort resulted in a change in workplace practice:

"Even though I can work with the footwear I don't stay on my feet as long, so I'll try and stay on the hoist, I've changed my-my work structure to-to suit the ailment" Participant 5, Male, 49 years old

In contrast, some participants did not report any significant issues as they had found footwear which was comfortable and acceptable for the environments in which they interacted:

> *"I don't ah spend a lot of time thinking about my shoes I wear them and that's that. And once I, and once you've got a comfortable pair you don't need to think a lot about it" Participant 3, Male, 83 years old*

Discussion

This study offers unique insights into the footwear experiences and the footwear-related issues of people with gout, with four themes described. Factors contributing towards comfortable and acceptable footwear were readily identified, however, the practicalities of finding and choosing footwear which met these requirements was challenging. There was uncertainty in knowing what the best footwear was and whether footwear would exacerbate foot problems.

Participants placed footwear comfort as a priority, which aligns with previous research [4]. However, what was additionally revealed is that 'comfort' was linked to individual footwear characteristics, supporting the concept that particular footwear characteristics help to reduce the burden of foot pain and disability in those with gout [3, 10].

Our findings demonstrate that some people with gout struggle with finding appropriate footwear, aligning with previous research [9, 10]. When shopping, there was a desire to find footwear that met requirements for both comfort and appearance. Factors such as cost [4, 10] added further constraints on footwear choice. Participants described limited footwear options and reduced confidence with their footwear purchases, which may help to explain the high occurrence of poor-quality footwear worn by people with gout [4].

Prior studies have shown the impact of gout flares [6] and tophi [5, 9] on footwear choices. Participants in this study described similar narratives, and we also found that footwear could in turn exacerbate gout symptoms. Having gout meant that participants' footwear needed to meet their current foot health status rather than their previous footwear expectations.

The impact of footwear extended beyond foot symptoms. There was an inseparable link between the participant's footwear and their clothing outfit, meaning footwear decisions for social occasions were often made to the detriment of comfort. Where health and safety requirements determined choice, strategies such as not wearing a safety boot during flares demonstrates how footwear can be a limiting factor, resulting in potentially unsafe workplace behaviour. This is a particular challenge in gout, which frequently affects men of working age [14] adding another element to the difficulty that people with gout face when managing their gout symptoms and maintaining employment participation [7, 9].

We found some participants did not have any foot problems or difficulty with footwear and others who did not consider gout in their decision-making surrounding footwear, even if their gout is problematic. This appears to contrast previous studies highlighting the difficulties encountered by people with gout [5–8, 10], however, is similar to other work [9] reporting a diversity of experience with gout, and that not everyone with gout has foot problems or has the same foot problems. This suggests a need for more individualised approaches based on the patient experience.

The lack of suitable options both when purchasing footwear and lack of choice in those already owned was acknowledged by participants. Potential solutions to assist in finding appropriate footwear have been proposed for people with foot problems [15]. Health care practitioners involved in foot health and footwear can use this information to help those with gout reduce the disease burden on foot health. Footwear manufacturers and those in the retail setting should consider the challenges that people with gout face in finding suitable footwear.

Potential limitations of this study are that it was conducted in an urban region and may not represent the experiences of people in rural locations who have different footwear needs. The participants' occupation and socioeconomic status were not part of the sampling framework, however, we acknowledge that these may have an influence on footwear experiences and issues [15]. Another factor not captured is the possible influence of any previous footwear education on the results. However, it is clear that despite any previous education, these participants still experience difficulties. Hence, given the difficulties experienced by the participants of this study, future work is needed to develop footwear education for people with gout. Participants were aware at the time of recruitment that the study was about footwear experiences, and those with negative experiences may have been more interested in participating, therefore, the study findings may not be generalisable to all people with gout.

Conclusions

People with gout experience problems with footwear which can impact many aspects of life. Gout can limit a person's ability to find comfortable footwear which is acceptable and attainable. In addition, the environment in which people interact presents additional challenges to achieving comfortable footwear. Health care professionals should consider these footwear-related issues to help facilitate those with gout in finding appropriate footwear.

Additional file

Additional file 1: Interview guide. (DOCX 14 kb)

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Authors' contributions
MF, AW, ND, PM, PG and KR conceived the idea for the study. MF recruited participants and collected data. MF and AW analysed the data. All authors agreed on the interpretation of the results. All authors were involved in the drafting of the manuscript and approved the final version to be submitted for publication.

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Data and material available for this study would require further approval upon request from the corresponding author.

Ethics approval and consent to participate
The study was approved by the Auckland University of Technology Ethics Committee (14/233). All participants provided written informed consent.

Consent for publication
Not applicable.

Competing interests
ND has received personal fees, speaker fees or grants from Takeda, AstraZeneca/Ardea, Kowa, Horizon, Pfizer, Janssen, Abbvie; grants from AstraZeneca/Ironwood, Amgen, outside the submitted work. KR has received funding from ASICS, outside the submitted work. KR is Editor-In-Chief of the *Journal of Foot and Ankle Research*. It is journal policy that editors are removed from the editorial and peer reviewing process for manuscripts they have co-authored. The other authors declare no competing interest.

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Publisher's Note

Appendix 24. Effects of a footwear intervention on foot pain and disability in people with gout: a randomised controlled trial

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Effects of a footwear intervention on foot pain and disability in people with gout: a randomised controlled trial

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Abstract

Background: There is limited evidence supporting the long-term effect of a foot care package that includes footwear for people with gout. The aim of this study was to investigate the effectiveness of a footwear intervention on foot pain and disability in people with gout over 6 months.

Methods: Participants with gout ($n = 94$) were randomly allocated to either a control group (podiatric care and gout education) or footwear intervention group (podiatric care and gout education plus a commercially available athletic shoe). Measurements were undertaken at baseline and 2, 4, and 6 months. Primary outcome was foot pain severity. Secondary outcomes were overall pain, foot impairment/disability, footwear comfort, fit, ease and weight. Data were analysed using repeated measures models.

Results: Baseline foot pain scores were low, and no differences in foot pain scores were observed between groups over 6 months (adjusted effect estimate: −6.7, 95% CI −16.4 to 2.9, $P = 0.17$). Improvements between groups in overall pain scores (adjusted effect estimate: −13.2, 95% CI −22.2 to −4.3, $P < 0.01$) and foot impairment/disability scores (−4.7, 95% CI −9.1 to −0.3, $P = 0.04$) favouring the footwear intervention were observed at 2 months, but not at 4 or 6 months. Improvements between groups in footwear fit (adjusted effect estimate: −11.1, 95% CI −21.1 to −1.0, $P = 0.03$), ease (−13.2, 95% CI −23.8 to −2.7, $P = 0.01$) and weight (−10.3, 95% CI −19.8 to −0.8, $P = 0.03$) favouring the footwear intervention were also observed over 6 months. Similar improvements were observed for footwear comfort at 2 and 4 months. No other differences in secondary outcomes measured were observed at 6 months ($P > 0.05$).

Conclusions: Addition of footwear to a foot care package did not improve foot pain in people with gout. Short-term improvements in overall pain and foot impairment/disability and more durable improvements in footwear comfort and fit were observed with the footwear intervention.

Trial registration: ACTRN12614000209695. Registered 27 February 2014, http://www.anzctr.org.au/TrialSearch.aspx?searchTxt=ACTRN12614000209695&isBasic=True

Keywords: Gout, Foot, Footwear, Foot pain

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Background

Gout commonly affects the articular and soft tissue structures of the feet, especially the first metatarsophalangeal joint [1] and Achilles tendon [2]. Foot problems are commonly described by people with gout [3], and people with gout experience high levels of foot pain, impairment and disability [4].

Regular podiatric care is associated with a reduction in foot pain and disability in people with inflammatory arthritis, including those with gout [5]. Prescribing footwear may be part of a foot care package for people with arthritis affecting the foot and ankle. For example, footwear interventions can improve foot pain and function in people with rheumatoid arthritis and foot osteoarthritis [6]. In rheumatoid arthritis, footwear interventions can also improve plantar pressure measurements and walking speed [6].

A footwear intervention may also benefit people with gout. A substantial proportion of people with gout wear footwear lacking in cushioning, support, stability and motion control [7]. Furthermore, patients with gout wearing poor footwear report higher pain and disability scores [7]. We have reported the results of a feasibility study, showing that commercially available athletic footwear with heel and forefoot cushioning, a dual density midsole and rocker sole reduces foot pain and disability in people with gout at 2 months [8].

Currently, the evidence supporting the long-term effect of a foot care package that includes footwear for people with gout is limited. The aim of this study was to investigate whether addition of footwear to a foot care package has benefit on foot pain and disability in people with gout over 6 months.

Methods

Study design

The study was a 6-month, two-arm, parallel randomised controlled trial comparing two foot care packages for people with gout, registered as a clinical trial with the Australian New Zealand Clinical Trials Registry (ACTRN12614000209695).

Participants

Participants were recruited from public hospital rheumatology clinics and through public newspaper advertising throughout Auckland, New Zealand. Participants were recruited between October 2014 and June 2016. Inclusion criteria were gout according to the 1977 preliminary American Rheumatism Association classification criteria [9] and over 20 years of age. Exclusion criteria were history of other inflammatory arthritis or neuromuscular disease, experiencing a gout flare at time of screening visit, medication for foot pain in the past 4 weeks, prescription of footwear and/or foot orthoses in the past 3 months, previous foot and ankle surgery or unable to walk 10 m unaided. The trial was approved by the New Zealand Ministry of Health, Health and Disability Ethics Committees (14/CEN/117), and all participants provided written informed consent.

Randomisation and blinding

Participants were allocated 1:1 to the control group (podiatric care and gout education) or footwear intervention group (podiatric care and gout education plus a commercially available athletic shoe) using unstratified block randomisation with random block sizes. Centralised randomisation allowed the use of a sealed opaque envelope system. Randomisation of participants was undertaken by a research assistant with sole access to envelopes and not involved in data collection. Treating clinicians were not involved in the randomisation of participants. Participants could not be blinded to their study group. Participants invited into the study were informed they would receive a foot care package, without specific mention of footwear. Post-randomisation, participants were not informed of the intervention modalities in the other randomisation group.

Assessment

Participants attended study visits at the Auckland University of Technology Podiatry Clinic from November 2014 to February 2017. Baseline assessment included the recording of age, gender, ethnicity, body mass index (BMI), medical history and current medications. Disease-specific data included latest serum urate, disease duration, number of gout flares in the last 3 months and tophus count (total and at the foot).

Interventions

Participants attended two-monthly visits over a 6-month period. At each study visit, participants received standardised podiatric care comprising of palliative care of nails and skin, temporary padding, wound care, emollient use, footwear advice, foot care advice and gout education delivered by an experienced podiatrist (TM). Gout education was delivered using a pamphlet produced by the New Zealand Ministry of Health including information on the causes of gout, the role of urate in development of gout, pharmacological management, monitoring of serum urate levels and general footwear advice (https://www.health.govt.nz/system/files/documents/topic_sheets/stop_gout_booklet-dec2015.pdf). General footwear advice included information regarding footwear comfort, fit, cushioning, sole and heel height. In addition, participants in the footwear intervention group received a pair of ASICS Cardio Zip 3 shoes to wear during daily activities (Fig. 1). This footwear was chosen based on the findings of a previous feasibility study [8], and its characteristics including heel/forefoot cushioning, dual density midsole, wide-fitting option and

Fig. 1 ASICS Cardio Zip 3 shoes. **a** Men's and women's colour. **b** Women's colour only. Women had the option of choosing between the two colours

a zip for ease of fit. To determine the appropriate footwear size, the participant's foot length and width were measured by the podiatrist using a Brannock device. Women had the option of choosing between a black or white colour, with men having a black colour only. Footwear was then fitted by the podiatrist.

Outcomes

Outcome measures were measured at baseline and 2, 4, and 6 months. The primary outcome was participant-reported foot pain, measured using a 100-mm visual analogue scale (VAS) using the anchors of 'no pain' (0 mm) to 'very severe pain' (100 mm) [4, 8]. Secondary outcome measures included participant-reported overall pain (global representation of pain) using 100-mm VAS, with lower scores indicating less pain, patient global assessment using 100-mm VAS, with lower scores indicating better wellbeing, and activity limitation using the Health Assessment Questionnaire (HAQ-II) [10]. Overall pain, patient global assessment and HAQ-II measures have been endorsed by Outcome Measures in Rheumatology (OMERACT) for use in gout studies [11]. Lower limb function was assessed using the activities of daily living and recreational activities subscales of the Lower Limb Tasks Questionnaire (LLTQ), with higher scores indicating better function [12]. Foot impairment and disability was measured using the Leeds Foot Impact Scale (LFIS), with lower scores indicating less impairment and disability [13]. The LLTQ and LFIS have been used in previous gout studies [8, 14]. Participant perceptions of footwear comfort, fit, ease and weight were each evaluated using 100 mm VAS, with lower scores indicating better comfort, fit, ease and weight. Self-reported footwear daily diaries were used to record footwear use and adverse events measured over the 6 months in the footwear intervention group, returned at each study visit [8]. The characteristics of the footwear worn by the control group were measured at each study visit. Participants were also asked at each visit about whether they had experienced a gout flare since the last study visit.

Sample size

Initial sample size calculations were based on a previous feasibility study [8]. To detect the minimally important difference of − 15 mm in the foot pain VAS (− 17.2 mm detected in feasibility study, $p = 0.003$) with power 0.80, using the repeated measures model detailed below with a baseline to 6-month correlation of 0.30 would require 52 participants in each group (correlation extrapolated from feasibility study). Using a conservatively estimated loss to follow-up rate of 25% at 6 months, the initial aim was to recruit 140 participants. A protocol amendment containing a revised sample size computation was submitted to and approved by an independent data monitoring committee, due to a decline in recruitment and lower than estimated withdrawal rates. The revision used a new estimated baseline to 6-month correlation of 0.49 in the primary outcome and a new dropout rate, based on the first 38 completions. A revised sample size of 39 completions per group was determined. At an estimated loss to follow-up rate of 15%, the target recruitment was 92 participants (46 per group).

Statistical analysis

Primary and secondary analyses were based on an intention-to-treat (ITT) analysis set, from which only participants with no baseline nor post-randomisation data were excluded. Primary and other outcomes were compared across the treatment groups using repeated measures models of outcome data at 2, 4, and 6 months adjusted for baseline. A blind review of the data was undertaken at the end of the trial to consider the specific regression models to use, inclusion of covariates, the appropriateness of multiple imputations for any missing covariate and any necessary data transformation. Continuous outcomes were fitted using linear mixed models except for footwear-related visual analogue scale outcomes, fitted with a scaled zero-inflated beta regression model (generalised additive model for location, scale and shape) due to an increased proportion of zero scores recorded for these outcomes. Age, gender, ethnicity, BMI, colchicine use, non-steroidal anti-inflammatory drug use, prednisone

use and the presence of subcutaneous tophi at baseline were considered for inclusion in the regression models during a blind review, absent all knowledge of allocation. Partial R^2 was used as the main selection criterion. Ten multiply imputed data sets were produced, using all observed data, under an assumption of Missingness at Random. No data transformation was found to be needed. No correction for multiple testing was applied. All tests were carried out at a significance level of 0.05 against two-sided alternatives. Data were analysed using SAS version 9.4 and R version 3.2.

Results

Participant flow and characteristics

Figure 2 shows the flow of participants through the study. There were 187 potential participants screened and 94 randomised. Participants were predominantly male of New Zealand European ethnicity, with over 10 year's disease duration and on urate-lowering therapy (Table 1). High rates of obesity and comorbidities such as hypertension and cardiovascular disease were observed. Notable differences between groups included the higher number of tophi reported in the control group. Poor footwear was common at baseline, with the majority of participants wearing footwear which was worn and over 12 months old (Table 2).

Recorded protocol violations included randomisation of three participants who consented but did not complete the initial study visit (excluded from the ITT set), and the withdrawal of one participant who consented but was later found to have had foot surgery with a toe amputation, post-randomisation (included in the ITT set).

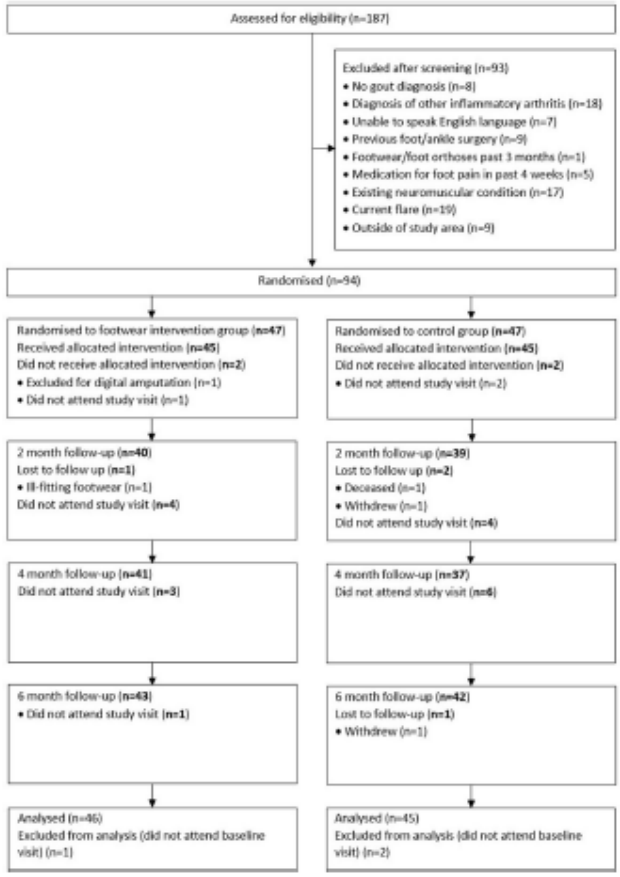

Fig. 2 Flow of participants through the study

Table 1 Baseline descriptive statistics

Variable	Footwear intervention group ($n = 47$)	Control group ($n = 47$)
Sex, male, *n* (%)	40 (85%)	43 (91%)
Age, years	62.6 (17.0)	62.4 (13.7)
BMI, kg/m^2	30.2 (6.4)	32.0 (7.0)
Ethnicity, *n* (%)		
NZ European	28 (62%)	26 (57%)
Pacific	6 (13%)	11 (23%)
Asian	7 (16%)	5 (11%)
Māori	4 (9%)	4 (9%)
Gout history, mean (SD)		
Disease duration (years)	12.2 (11.2)	13.6 (12.3)
Flares prior 3 months	0.7 (0.9)	0.4 (0.7)
Foot tophus, *n* (%)	9 (19%)	17 (36%)
Any tophus, *n* (%)	13 (28%)	24 (51%)
Serum urate, mmol/L	0.39 (0.13)	0.38 (0.11)
Medications, *n* (%)		
Urate-lowering therapy	33 (72%)	30 (64%)
Colchicine	15 (33%)	17 (36%)
Prednisone	9 (20%)	10 (21%)
NSAID	12 (27%)	13 (29%)
Diuretic	8 (18%)	5 (11%)
Medical History, *n* (%)		
Hypertension	22 (48%)	22 (54%)
Cardiovascular disease	13 (28%)	11 (24%)
Type 2 diabetes	7 (15%)	3 (7%)
Peripheral vascular disease	4 (9%)	3 (7%)
Peripheral neuropathy	3 (7%)	5 (11%)

BMI body mass index, *NSAID* non-steroidal anti-inflammatory drug

Four participants in the footwear intervention group were unable to wear their allocated footwear due to discomfort. Of these participants, three remained enrolled in the trial and continued to receive the other facets of their allocated intervention with one participant withdrawal. Participants in the footwear intervention group reported wearing their allocated footwear on average 24 h per week during the study period. Participants in the control group continued to wear footwear of similar type, age and wear during the study period (Additional file 1). At the 6-month follow-up, 89% of the control group and 91% of the footwear intervention group completed the study.

Primary outcome

All efficacy endpoints and covariate adjustments are shown in Table 3. Baseline foot pain scores were low. There was no difference in foot pain at any time-point over the 6-month study period between the two groups (adjusted effect estimate: −6.7, 95% CI −16.4 to 2.9, $P = 0.17$).

Secondary outcomes

Improvements between groups in overall pain scores (adjusted effect estimate: −13.2, 95% CI −22.2 to −4.3, $P < 0.01$) favouring the footwear intervention were observed at 2 months, but there was no difference between the groups at 4 or 6 months (adjusted effect estimate at 6 months: −4.0, 95% CI −13.6 to 5.7, $P = 0.42$). Foot-related impairment and disability was reduced at 2 months in the footwear intervention group (adjusted effect estimate: −4.7, 95% CI −9.7 to −0.3, $P = 0.04$), but there was no difference between groups at 4 or 6 months (adjusted effect estimate at 6 months: −3.0, 95% CI 0.2 to −1.8, $P = 0.21$). No between-group differences in patient global assessment, HAQ-II and LLTQ were observed (Table 2).

Between-group differences favouring the footwear intervention were observed in footwear comfort at

Table 2 Baseline footwear characteristics

Variable	Footwear intervention group (*n* = 47)	Control group (*n* = 47)
Footwear type, *n* (%)		
Good	23 (51%)	23 (51%)
Athletic	5	11
Oxford	10	5
Therapeutic	2	0
Walking	6	7
Moderate	3 (7%)	2 (4%)
Boot	3	2
Poor	19 (42%)	20 (44%)
Sandal	8	4
Moccasin	4	7
Flip-flop	4	4
Slipper	2	4
Court	1	0
Mule	0	1
Footwear age, *n* (%)		
< 6 months	8 (18%)	12 (27%)
6–12 months	5 (11%)	9 (20%)
> 12 months	31 (70%)	24 (53%)
Upper wear, *n* (%)		
Neutral	34 (77%)	26 (58%)
Medial	9 (20%)	17 (38%)
Lateral	1 (2%)	2 (4%)
Midsole wear, *n* (%)		
Neutral	38 (86%)	31 (69%)
Medial	9 (20%)	9 (20%)
Lateral	1 (2%)	5 (11%)
Outsole wear, *n* (%)		
None	2 (4%)	7 (16%)
Partly worn	35 (78%)	29 (64%)
Fully worn	8 (18%)	9 (20%)
Outsole wear pattern, *n* (%)		
None	1 (2%)	6 (13%)
Normal	17 (38%)	19 (42%)
Medial	0 (0%)	0 (0%)
Lateral	27 (60%)	20 (44%)

2 months (adjusted effect estimate: − 10.4, 95% CI − 19.9 to − 0.9, $P = 0.03$) and 4 months (adjusted effect estimate: − 11.3, 95% CI − 21.4 to − 1.3, $P = 0.03$), but not at 6 months (adjusted effect estimate: − 8.0, 95% CI − 19.2 to 3.3, $P = 0.16$). Similarly, between-group differences favouring the footwear intervention were observed in footwear fit (adjusted effect estimate: − 11.1, 95% CI − 23.0 to − 1.0, $P = 0.03$), footwear ease (adjusted effect estimate: − 13.2, 95% CI − 23.8 to − 2.7, $P = 0.01$) and footwear weight (adjusted effect estimate: − 10.3, 95% CI − 19.8 to − 0.8, $P = 0.03$) at all time-points over the 6-month study period.

Adverse events

Two participants (4%) in the footwear intervention group developed foot blisters and one participant (1%) in the footwear intervention group withdrew from the study due to footwear discomfort. During the trial period, 16 participants (34%) in the control group and

Table 3 Outcome measure scores and effect estimates adjusted from baseline

	Footwear intervention group mean (SD)	Control group mean (SD)	Adjusted effect estimate	*P*
Foot pain VAS				
Baseline	14.8 (18.7)	17.5 (22.4)		
2 months	10.7 (13.0)	16.8 (21.8)	− 5.0 (− 12.9 to 2.8)	0.21
4 months	13.8 (23.0)	16.1 (22.3)	− 1.8 (− 10.1 to 6.4)	0.66
6 months	13.1 (20.8)	20.5 (26.1)	− 6.7 (− 16.4 to 2.9)	0.17
Overall pain VAS[a]				
Baseline	18.7 (19.6)	17.7 (23.9)		
2 months	9.7 (13.6)	23.3 (27.5)	− 13.2 (− 22.2 to − 4.3)	*< 0.01*
4 months	16.2 (19.4)	17.9 (22.8)	− 2.3 (− 0.5 to 0.6)	0.65
6 months	16.3 (19.2)	20.7 (26.8)	− 4.0 (− 13.6 to 5.7)	0.42
Patient Global Assessment VAS[a]				
Baseline	22.7 (24.5)	21.5 (25.8)		
2 months	17.7 (24.2)	16.4 (21.6)	1.2 (− 7.4 to 9.9)	0.78
4 months	14.6 (16.6)	16.6 (20.2)	− 2.8 (− 11.9 to 6.3)	0.55
6 months	15.3 (19.4)	18.8 (21.9)	− 3.4 (− 12.6 to 5.7)	0.46
Health Assessment Questionnaire II				
Baseline	0.5 (0.6)	0.4 (0.5)		
2 months	0.5 (0.6)	0.4 (0.4)	− 0.1 (− 0.3 to 0.1)	0.36
4 months	0.6 (0.6)	0.3 (0.5)	0.0 (−0.2 to 0.2)	0.84
6 months	0.5 (0.5)	0.4 (0.6)	− 0.1 (− 0.3 to 0.1)	0.28
LFIS total score				
Baseline	15.5 (11.5)	15.4 (12.5)		
2 months	13.8 (13.0)	16.4 (14.1)	− 4.7 (− 9.1 to − 0.3)	*0.04*
4 months	14.9 (14.2)	14.2 (12.3)	− 1.3 (− 6.1 to 3.5)	0.59
6 months	14.4 (13.6)	16.9 (14.2)	− 3.0 (0.2 to 1.8)	0.21
LLTQ activities of daily l				
Baseline	32.7 (8.2)	33.8 (6.8)		
2 months	34.8 (7.2)	32.9 (8.0)	2.2 (− 0.2 to 4.6)	0.07
4 months	32.9 (8.1)	35.4 (6.7)	− 0.4 (− 3.1 to 2.3)	0.77
6 months	34.0 (6.9)	33.8 (7.7)	1.1 (− 1.2 to 3.4)	0.35
LLTQ recreational activities[b]				
Baseline	22.7 (11.8)	21.1 (11.6)		
2 months	23.5 (14.2)	22.8 (11.5)	0.8 (− 2.8 to 4.4)	0.66
4 months	20.8 (12.8)	25.1 (9.9)	− 3.4 (− 7.5 to 0.8)	0.11
6 months	21.7 (12.6)	22.2 (12.0)	− 0.9 (− 4.8 to 3.0)	0.66
Footwear comfort VAS[c]				
Baseline	24.0 (21.9)	27.6 (28.0)		
2 months	10.3 (13.1)	26.2 (26.5)	− 10.4 (− 19.9 to − 0.9)	*0.03*
4 months	9.1 (9.8)	24.0 (21.0)	− 11.3 (− 21.4 to − 1.3)	*0.03*
6 months	17.5 (23.5)	27.9 (28.4)	− 8.0 (− 19.2 to 3.3)	0.16
Footwear fit VAS[d]				
Baseline	20.6 (20.1)	24.0 (27.2)		
2 months	9.8 (16.0)	22.2 (21.3)	− 9.5 (− 17.2 to − 1.8)	*0.02*
4 months	10.3 (13.6)	22.2 (20.4)	− 11.1 (− 19.9 to − 2.4)	*0.01*

Table 3 Outcome measure scores and effect estimates adjusted from baseline *(Continued)*

	Footwear intervention group mean (SD)	Control group mean (SD)	Adjusted effect estimate	*P*
6 months	11.9 (20.0)	27.9 (28.4)	− 11.1 (− 21.1 to − 1.0)	*0.03*
Footwear ease VAS[e]				
Baseline	20.9 (23.0)	19.3 (23.8)		
2 months	12.7 (19.1)	26.8 (28.2)	− 9.8 (− 19.4 to − 0.3)	*0.04*
4 months	10.2 (16.6)	23.8 (25.2)	− 12.3 (− 23.0 to − 1.6)	*0.02*
6 months	11.3 (19.7)	27.9 (28.4)	− 13.2 (− 23.8 to − 2.7)	*0.01*
Footwear weight VAS[d]				
Baseline	21.9 (21.9)	22.7 (24.6)		
2 months	12.7 (17.8)	27.0 (26.6)	− 9.7 (− 19.5 to 0.0)	*0.05*
4 months	13.6 (20.3)	24.6 (20.4)	− 10.8 (− 20.6 to − 0.9)	*0.03*
6 months	11.4 (19.7)	27.9 (28.4)	− 10.3 (− 19.8 to − 0.8)	*0.03*

VAS visual analogue scale, *LRS* Leeds Foot Impact Scale, *LLTQ* Lower Limb Tasks Questionnaire
[a]BMI adjusted
[b]Age adjusted
[c]BMI and prednisone adjusted
[d]Sex and BMI adjusted
[e]Ethnicity and BMI adjusted
Data in italics indicates statistical significance

14 participants (30%) in the footwear intervention group experienced a gout flare.

Discussion

This is the first randomised controlled trial of a podiatric intervention in gout. Although improvements in footwear comfort, fit and ease were observed in the footwear intervention group throughout the study period, no significant difference in foot pain was observed between groups. Short-term improvements in both overall pain and foot-related impairment and disability favouring the footwear intervention group were observed at the two-month time-point, consistent with the previous feasibility study [8].

The low levels of foot pain at the time of the baseline visit may have contributed to a floor effect, suggesting that clinical meaningful changes in foot pain could not be detected. Foot pain was not part of the inclusion criteria based on the previous feasibility study [8], which may have also contributed to the baseline foot pain levels observed. This highlights the challenge of studying pain as an outcome in gout which is an intermittently flaring condition. We observed baseline serum urate levels were close to target guidelines [15] and participants reported a low number of flares in the 3 months prior to the trial, which suggests generally well-controlled disease. Our findings for baseline foot pain levels were lower than the previous feasibility study [8], however, were consistent with previous studies measuring foot pain in people with longstanding gout during an intercritical period [4, 15].

Comfort and fit have been identified as important factors in footwear selection for people with gout [7]. Footwear is an important concern for people with gout, who often describe difficulty finding suitable footwear [16]. Improvements in footwear comfort, fit, weight and ease were observed in the footwear intervention group. The footwear received by the footwear intervention group had a number of characteristics which have been identified as beneficial for people with gout when compared to participants own footwear [8]. Footwear characteristics including correct footwear fit, the presence of cushioning and good torsional stiffness have previously been identified as influencers of subjective footwear comfort [17]. In the footwear intervention group, the fitting of footwear by a clinician may also be a factor. The footwear habits of the control group did alter during the trial, despite the footwear advice delivered. This furthers highlight the challenges that people with gout have finding appropriate footwear [16, 18]. These findings suggest that helping people with gout find footwear with good characteristics is important; however, this may not involve the need for expensive footwear prescription.

Strengths of this study include the use of OMERACT-endorsed patient-reported outcomes for gout [11], high retention rates in both groups, and novelty as the first randomised controlled trial of a podiatric intervention in people with gout. The key study limitation was that participants could not be blinded to the footwear intervention, which may have biased the study outcomes, as all endpoints were patient-reported. We did attempt to reduce this bias by informing participants that they would be receiving a foot care package without the specific mention of receiving footwear and ensuring that all participants received a comprehensive foot care intervention. The study was undertaken in an urban New Zealand city and the findings may lack generalisability to other settings. The footwear

used in this study had distinct characteristics, so it is unclear whether these findings can be generalised to other types of footwear such as open-toed footwear.

This study has focused on a commercially available athletic shoe. The podiatric care package was limited to standardised care and foot health advice, with or without the footwear intervention, and the role of other interventions such as foot orthoses is unknown. Further investigation into other footwear interventions for people with gout, including cost-effectiveness, is warranted. Changes to structural properties of the footwear through use may have also been a potential reason that long-term benefits were not observed. The effects of wear on the structural properties of footwear over time, and its relationship with biomechanical parameters such as plantar pressure and patient-reported outcomes such as foot pain, impairment and disability, are unknown. Future work might also explore factors which influence foot care and footwear use, and the willingness to pay for appropriate footwear.

Conclusions

The footwear intervention did not significantly improve foot pain in people without high baseline levels of foot pain. However, short-term improvements in overall pain and foot impairment/disability, and more durable improvements in footwear comfort and fit were observed with the footwear intervention.

Additional file

Additional file 1: Control group footwear characteristics. (DOCX 16 kb)

Abbreviations

BMI: Body mass index; HAQ-II: Health Assessment Questionnaire; ITT: Intention-to-treat; LFIS: Leeds Foot Impact Scale; LLTQ: Lower Limb Tasks Questionnaire; OMERACT: Outcome Measures in Rheumatology; VAS: visual analogue scale

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Availability of data and materials

Data and material available for this study would require further approval upon request from the corresponding author.

Authors' contributions

MF had full access to all of the study data and takes responsibility for the integrity and accuracy of the statistical analysis. MF, ND, PMcN, AV, PG and KR contributed to the study design, data analyses, data interpretation and manuscript preparation. TM contributed to acquisition of data and manuscript preparation. All authors were involved in the drafting of the manuscript, with all authors approving the final version to be submitted for publication.

Ethics approval and consent to participate

The trial was approved by the New Zealand Ministry of Health, Health and Disability Ethics Committees (14/CEN/117) and all participants provided written informed consent.

Consent for publication

Not applicable.

Competing interests

N. D. has received consulting fees, speaker fees or grants from Takeda, Teijin, Menarini, Amgen, Ardea Biosciences, AstraZeneca, Horizon, Cymabay and Kowa, outside the submitted work. K. R has received funding from ASICS, outside the submitted work. ASICS had no role in the design of the study. The footwear used in the study was purchased at retail price. The other authors declare that they have no competing interests.

Publisher's Note

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