Effectiveness of off-the shelf footwear in reducing foot pain in DVA recipients not eligible for medical grade footwear: a randomised controlled trial (ARP #1031)

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Background and rationale

Foot pain affects approximately one in three people over the age of 65 years[1-3] and has a significant impact on quality of life in this age-group. Studies of older people have demonstrated that foot pain is associated with decreased ability to undertake activities of daily living [4-9], problems with balance and gait[7, 10, 11] and an increased risk of falls.[12-16] Furthermore, several clinic-based studies assessing health-related quality of life across a range of age-groups have shown that people with foot disorders (such as generalised foot pain,[2, 17] nail infections,[18-20], hallux valgus[21, 22] hallux rigidus[23] and plantar heel pain[24]) demonstrate significantly lower scores than those without these conditions. A range of risk factors for foot problems have been identified, including increased age,[25-27] female sex,[7, 8, 26, 28] obesity,[8, 10, 28, 29] and chronic conditions such as osteoarthritis and diabetes.[8, 10, 29]

In addition to these risk factors, there is also strong evidence that many older people wear inappropriate or poor quality footwear, and that ill-fitting footwear may contribute to foot problems. A household survey of people aged over 80 years conducted in the United Kingdom found that most wore slippers all day, irrespective of whether they were housebound.[30] Similarly, a survey of indoor shoe-wearing habits of 128 older people in Australia indicated that more than half spent less than $30 Australian dollars on their indoor footwear (most commonly slippers), replaced them infrequently, and often wore their indoor shoes for outdoor activities.[31] More recently, a survey of sub-acute aged care hospital patients reported that only 14% wore “safe” footwear, with the most commonly observed detrimental features being a lack of fastening (86%), slippery soles (86%) and an excessively flexible heel counter (77%).[32]

By far the most commonly encountered problem with footwear in older people is the wearing of shoes that are too small. Burns *et al.*[33] compared the length and width of the feet and shoes of 65 people aged between 64 and 93 years attending a rehabilitation ward in the United Kingdom, and reported that 72% wore shoes of an incorrect size. Similarly, a study of 440 Veterans’ Affairs patients in the United States reported that only 26% were found to be wearing appropriately sized shoes,[34] and a recent study of 213 people aged 60 to 80 years in Thailand reported that 50% of women and 34% of men wore shoes that were too narrow.[35] Several factors may be responsible for this, including fashion influences (particularly in older women[36, 37]), not measuring foot dimensions when purchasing shoes,[31] or the absence of commercially-available, low-cost footwear that adequately caters for the altered morphology of the elderly foot.[38, 39] Irrespective of the underlying cause of poorly-fitting footwear, there is evidence that wearing shoes that are too small is associated with foot problems. In older people, wearing shoes substantially narrower than the foot is associated with corns on the toes, hallux valgus deformity and foot pain, whereas wearing shoes shorter than the foot is associated with lesser toe deformity.[40] Furthermore, a survey of 227 older women revealed that 61% reported foot pain when wearing shoes (most commonly in the forefoot and toes), and that those with foot pain exhibited a broader forefoot than those without pain.[41]

In Australia, the Department of Veterans’ Affairs (DVA), as part of the Rehabilitation Appliances Program, covers the costs of medical grade footwear for veterans who have severe foot deformity

(defined as feet that cannot be accommodated in regular “off-the-shelf” footwear). Footwear provision is one of the most common podiatry interventions. An analysis of 1996 to 1997 DVA data indicated that out of the total podiatry DVA population who had received a podiatry intervention (n=4,418), 3,227 (73%) received new medical grade footwear.[42] However, there is also a high demand for footwear by veterans who have foot pain but do not have severely deformed feet. In this context, it is likely that there are a substantial number of veterans who could benefit from the recommendation and use of more appropriate footwear. Such an intervention may have the potential, perhaps in the longer term, to reduce the need for frequent, on-going maintenance foot care provided by podiatrists under the DVA scheme, although this 16-week study did not provide direct evidence of a reduction in appointments.

In response to these observations, the Lower Extremity and Gait Studies Program, La Trobe University, was funded by the Department of Veterans’ Affairs to conduct a research study (ARP #1031). The aim of the study was to evaluate the effectiveness of relatively low-cost but good quality, custom-fitted footwear to DVA clients with foot pain who do not currently meet the structural deformity criteria for medical grade footwear.

Methods

Trial registration and ethical approval

The trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12612000322831). The Australian DVA Human Research Ethics Committee provided ethical approval (approval number E012/005[5.1]) and the La Trobe University Human Ethics Committee formally accepted this approval (E012/004). All participants provided written informed consent prior to enrolment. Ethical standards throughout the study adhered to the National Health and Medical Research Council (NHMRC) National Statement[43] and the World Medical Association's Declaration of Helsinki.[44]

Design

This study was a two-group randomised controlled trial with a 16 week prospective follow-up (Figure 1). Participants were randomly allocated to either a “usual care” control group or the intervention group.[45] Permuted block randomisation with random block sizes (stratified by sex[46]) was undertaken using an interactive voice response telephone service provided by the NHMRC Clinical Trials Centre at the University of Sydney, New South Wales, Australia to ensure allocation concealment. Due to the nature of the intervention, it was not possible to blind the participants or investigators. However, outcome measure data were entered into the database by an investigator blinded to group allocation.

Participant recruitment, screening and eligibility criteria

The geocoding feature of the DVA database was used to identify veterans currently receiving podiatry treatments who are residing in Melbourne, Victoria. From this group of veterans, the DVA

Departmental Management Information System was used to identify those who had not been issued with medical grade footwear within the last 5 years, by excluding veterans who had documented a footwear-related item number during this period (item numbers F604, F605, F606, F611, F612, F625, F660, F661 F670, F671, F615 or F616). The remaining veterans formed the primary recruitment source and were mailed an information package about the study, along with an invitation to contact the research team by either return mail or by telephone. Database recruitment was complemented by running advertisements in DVA newsletters and placing posters at Returned and Services Leagues Clubs in the surrounding suburbs.

During the initial telephone contact of participants, a member of the research team determined each veteran's eligibility by structured interview. To be included in the study, veterans needed to meet the following inclusion criteria:

(i) be aged 65 years or over;
(ii) be a current DVA Gold Card client not eligible for medical grade footwear;
(iii) had received podiatry treatment on at least three occasions in the past five years;
(iv) had disabling foot pain, using the case definition of the Manchester Foot Pain and Disability Index (MFPDI) [47] proposed by Roddy *et al.*[48] The MFPDI consists of 19 statements prefaced by the phrase "Because of pain in my feet", formalised under three constructs: functional limitation (10 items), pain intensity (five items), and personal appearance (two items), with three possible answers: "none of the time" (score= 0), "some days" (score = 1), and "most days/every day" (score = 2). The Roddy et al. definition requires at least one of the ten functional limitation items to be documented on most/every day(s) in the last month;
(v) had persistent foot pain, defined as foot pain present for at least 12 weeks, and;
(vi) were capable of understanding the English language in verbal and written form.

Veterans were not eligible for inclusion in the study if they:

(i) were currently residing in a residential aged care facility;
(ii) had diabetes and a history of foot ulceration (or current foot ulceration) or diabetic peripheral neuropathy (diagnosed with the 5.07 Semmes-Weinstein monofilament, using the International Working Group on the Diabetic Foot protocol[49]);
(iii) had a neurodegenerative disorder (e.g. Parkinson's disease);
(iv) had had a lower limb or partial foot amputation (although single toe amputations will be permitted);
(v) had been prescribed contoured foot orthoses within the past 3 months (although simple flat insoles will be permitted, as will contoured foot orthoses prescribed more than 3 months ago);
(vi) were currently wearing the intervention footwear, or;
(vii) had cognitive impairment (defined as a score of <7 on the Short Portable Mental Status Questionnaire[50]).

Intervention group

The intervention group continued to receive regular podiatry treatment as clinically required. This typically included toenail maintenance and scalpel debridement of hyperkeratotic lesions (corns and calluses). In addition, they were provided with good quality, off-the-shelf footwear (Dr Comfort®, Vasyli Medical, Labrador, Queensland, Australia). Men received the "Brian" style and women received the "Annie" style (see Figures 1 and 2). Both styles were available in three width fittings (medium, wide, extra-wide) and featured a stretchable Lycra® upper with Velcro® closure and a choice of two removable insoles (a flat, 4 mm foam insole or a cushioning insole with a contoured heel cup, 7 mm thick under the forefoot and 15 mm thick under the heel). The shoes were lightweight (ranging from approximately 200 to 500 gm, depending on size) and meet all commonly-used criteria for appropriate footwear (such as a low heel, appropriate fixation and adequate depth to accommodate toe deformities).[51-55] Due to sex differences in foot dimensions (and therefore the dimensions of the lasts the shoes are constructed from) the Brian style has a relatively broader fit than the Annie style. However, both the heel height and toe spring are the same for shoes of equivalent length across the two styles. The shoes are shown in Figures 1 and 2.

The research staff measured participants' feet using a Brannock Device® (Brannock Device Co, Inc., Liverpool, New York, USA) to ensure appropriate length and width, using the fitting protocol recommended by the footwear manufacturer.[56] Intervention group participants who wore flat insoles (or had been wearing contoured foot orthoses for more than 3 months) in their current footwear were permitted to wear them in their study footwear, provided that the fit of the shoes was considered to be appropriate.

Control group

The control group continue to receive regular podiatry treatment as clinically required. This typically involved regular (every 6 to 8 weeks) toenail maintenance and scalpel debridement of keratotic lesions (corns and calluses). Upon completion of the trial, they were provided with the same footwear used in the intervention group.

Baseline assessments

Participant characteristics were collected by structured interview at the baseline assessment and included age, sex, height, weight, waist circumference, hip circumference, country of birth, education, major medical conditions, medications, use of walking aids and cigarette smoking history. The following questionnaires and clinical tests were also administered:

(i) foot pain characteristics, including duration (in months) and location, using a standardised foot diagram;
(ii) presence and severity of hallux valgus, assessed using the *Manchester Scale*;[57]

(iii) foot structure and presence of hyperkeratotic lesions (corns and calluses), documented with three-dimensional clinical photographs using the FotoScan™ 3D Foot Scanner (Precision 3D Limited, Weston-super-Mare, UK);

(iv) the *Pain Catastrophizing Scale*, a questionnaire containing 13 items reflecting elevated negative cognitive responses to pain;[58]

(v) the short version of the *Geriatric Depression Scale*, a 15-item depression screening tool that has been specifically validated in older people;[59, 60]

(vi) footwear assessment, using selected components of the recently developed *Footwear Assessment Tool*,[55] and;

(vii) physical activity levels, using the *Incidental and Planned Activity Questionnaire*.[61]

Figure 1 – Dr Comfort® footwear used in the study for men (*Brian* style).

Figure 2 – Dr Comfort® footwear used in the study for women (*Annie* style).

In addition, participants allocated to the footwear intervention group were asked to complete six 100 mm visual analogue scales to ascertain their perceptions of: (i) the immediate level of comfort of the footwear (using the anchors “extremely uncomfortable” and “extremely comfortable”[62]); (ii) the attractiveness of the footwear (using the anchors “extremely unattractive” and “extremely attractive”); (iii) how attractive they think other people would find the footwear (using the anchors “extremely unattractive” and “extremely attractive”); (iv) how well the shoes fit (using the anchors “poorest fit possible” and “best fit possible”); (v) how easy it is to put the shoes on and take them off (using the anchors “most difficult as possible” and “as easy as imaginable”) and; (vi) how heavy the shoes are (using the anchors “extremely light” and “extremely heavy”).

The perceived therapeutic value of the shoes were assessed using responses to the statement “I believe that the shoes provided to me can reduce the severity of my foot pain”, with a 5-point Likert scale ranging from “strongly disagree” to “strongly agree”. In addition, two 100 mm visual analogue scales were used to ascertain expectations of pain reduction associated with the footwear, with the questions “With your shoes, do you expect to have less or more pain in the skin of your feet and / or ankles, during activities like standing and / or walking?” and “With your shoes, do you expect to have less or more pain to the muscles and joints of your feet and / or ankles, during activities like standing and / or walking?”, both using the anchors “much less” and “much more”. These questions were derived from the *Monitor Orthopaedic Shoes* questionnaire.[63]

Primary outcome measure

The primary outcome measure was the pain domain of the Foot Health Status Questionnaire (FHSQ). The FHSQ consists of 13 questions reflecting four foot health-related domains: foot pain, foot function, footwear, and general foot health.[64] The FHSQ pain domain comprises 4 questions, with higher scores representing better foot health (i.e. 100 = best foot health and 0 = worst foot health). The FHSQ pain domain demonstrates a high degree of content, criterion, and construct validity (Cronbach $\alpha = 0.88$), high retest reliability (intraclass correlation coefficient = 0.86) and has been used as an outcome measure in clinical trials for a range of foot disorders.[65] Previous research indicates that the minimal important difference for this measure is 12.5 points.[66] The FHSQ pain domain was measured at baseline and at 4, 8, 12 and 16 weeks, with the primary endpoint being the 16 week score.

Secondary outcome measures

Secondary outcome measures were documented at baseline and 16 weeks and included:

(i) the function domain of the FHSQ;[64]
(ii) the functional limitation, pain intensity and concern about appearance subscales of the MFPDI;[47]
(iii) the number of DVA podiatry treatments required during the study period;
(iv) general health-related quality of life, assessed with the Short Form 12® Version 2.0;[67]
(v) the number of falls experienced during the follow-up period;

(vi) functional mobility, using the Timed Up and Go Test;[68]
(vii) presence of hyperkeratotic lesions (corns and calluses);
(viii) number of participants using co-interventions to relieve foot pain (such as oral non-steroidal anti-inflammatory medications, topical medications and visits to other health-care practitioners), documented using a diary at 4, 8, 12 and 16 weeks, and;
(ix) participants' perception of overall treatment effect at week 16, assessed with the question "Overall, how has your foot pain changed since the start of the study?" with a 5-point Likert scale response ("marked worsening", "moderate worsening", "same", "moderate improvement", or "marked improvement"). For the purpose of analysis, this scale will then be dichotomised, where "success" is defined as marked or moderate improvement on this scale.

Sample size

The sample size for the study was calculated based on the pain domain of the FHSQ as the primary outcome measure.[64] Using a minimal important difference of 12.5 and a standard deviation of 23 obtained from a previous study,[66] and assuming a 10% drop-out rate, the required sample size was 60 per group (power = 80%). The extra precision provided by covariate analysis was conservatively ignored when performing this calculation.

Evaluation of adherence

Adherence to the intervention was documented at 4, 8, 12 and 16 weeks by asking participants on how many days (and for how many hours) they have worn their footwear, on average, in the past month.

Complications and adverse events

Participants were provided with an opportunity to report any difficulties they had with the footwear, and all adverse events were documented in the 4, 8, 12 and 16 week follow-up questionnaires.

Statistical analysis

Statistical analysis was undertaken using SPSS version 20.0 (IBM Corp, NY, USA). All analyses were conducted on an intention-to-treat principle using all randomised participants. Multiple imputation was used to replace any missing data using five iterations, with age, baseline scores, and group allocation as predictors.[69] Demographic characteristics and baseline data were summarised by descriptive statistics. Continuous data were explored for normality using standard tests to satisfy the assumptions of parametric statistics. Continuously-scored primary and secondary outcome measures with a normal distribution were compared between groups using a linear regression technique with baseline scores adjusted for by the analysis of covariance (ANCOVA) model.[70, 71] Nominal and ordinal scaled data were compared using chi-square analyses. An independent samples t-test was used to compare the number of podiatry

consultations between groups over the study period. Statistical significance for hypothesis tests were set at the conventional level of $\alpha = 0.05$.

Results

Participant recruitment and retention

From the total of 2,457 DVA clients invited to participate, 318 underwent telephone screening to reach our target of 121 participants. Permuted block randomisation with random block sizes of 6 and 8 participants (stratified by gender) was undertaken using an interactive voice response telephone service provided by the NHMRC Clinical Trials Centre at the University of Sydney, New South Wales, to ensure allocation concealment. Of the 121 participants, 61 were allocated to the control group and 60 to the intervention group.

One participant withdrew from the study shortly after being randomised as she did not like the appearance of the shoes. This participant subsequently withdrew consent, resulting in a total sample of 120 (the target sample size). A CONSORT flowchart of participant flow through the study is shown in Figure 3. As can be seen from this figure, 110 participants attended the 16 week follow-up appointment: 55 (93%) in the intervention group and 55 (90%) in the control group. In the intervention group, three participants dropped out before the 4 week follow-up (two had problems with the shoes and one had a fall and was admitted to respite care), and one was lost to follow-up at 16 weeks as they were on holiday and were unable to be contacted. In the control group, two participants did not complete the 8 week follow-up (one withdrew and one was unable to be contacted), one participant died prior to the 12 week follow-up, and three did not complete the 16 week follow-up (two were admitted to hospital and one was unable to be contacted). However, as specified in the original trial protocol, multiple imputation was used to deal with missing data, meaning that we had a full dataset for the 16 week follow-up outcome measures.

The final sample consisted of 120 participants (72 men, 48 women) aged 65 to 96 years, mean age 82 (SD 8) years. The participants in the two groups had similar baseline characteristics (Table 1). The mean duration of foot pain was 12.6 years and the regions most commonly affected were the forefoot (69%) and toes (63%).

Intervention adherence

Three participants in the intervention group did not wear the shoes at all. Of the remaining intervention group participants, the total number of hours the shoes were worn during the 16 week study period ranged from 16 to 896 (mean 526.7, SD 271.8). At the 16 week follow-up, nine participants had withdrawn or were lost to follow-up (four from the intervention group and five from the control group), giving completion rates of 93% and 92%, respectively. There was one confirmed death and two hospital admissions during the study unrelated to the intervention.

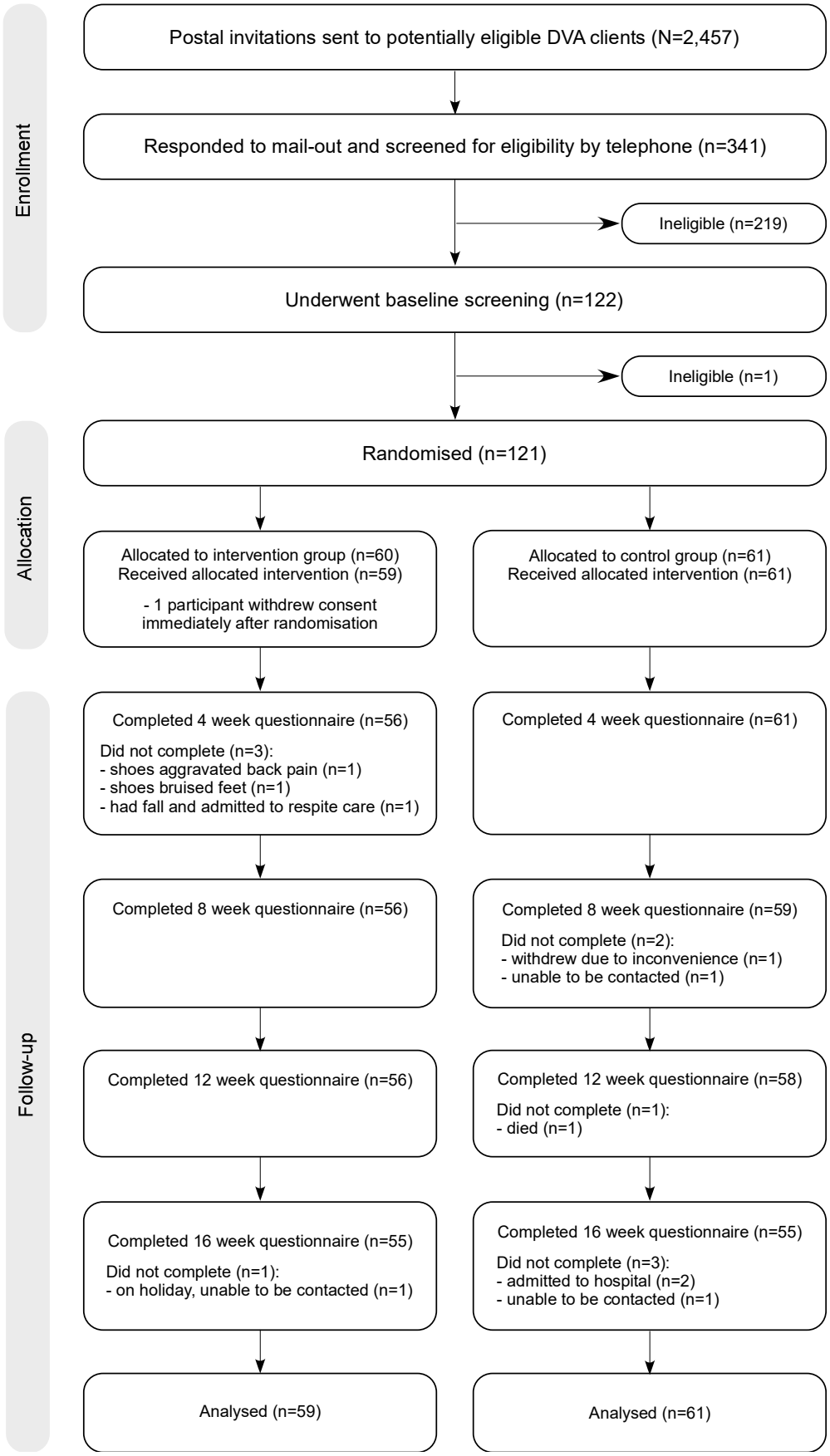

Figure 3. Flow chart of participants through study.

Table 1. Baseline characteristics of participants in intervention and control groups. Values are numbers (percentages) unless otherwise stated.

	Intervention group (n=59)	Control group (n=61)
Mean (SD) age (years)	82.3 (7.8)	82.8 (8.3)
Women	24 (40.7)	24 (39.3)
Mean (SD) body mass index	29.2 (5.4)	29.1 (4.9)
Medical history		
Diabetes	8 (13.6)	9 (14.8)
Stroke	8 (13.6)	11 (18.0)
Heart disease	19 (32.2)	31 (50.8)
Osteoarthritis	48 (81.4)	42 (68.9)
Rheumatoid arthritis	3 (5.1)	4 (6.6)
≥ 4 drugs	50 (84.7)	54 (88.5)
Physical activity		
Mean (SD) incidental activity (hrs/week)	23.1 (14.8)	22.2 (13.9)
Mean (SD) planned activity (hrs/week)	2.7 (3.1)	2.7 (3.1)
Mean (SD) duration of foot pain (years)	13.1 (14.6)	12.0 (14.5)
Location of foot pain		
Whole foot	7 (11.9)	2 (3.3)
Ankle	18 (30.5)	14 (23.0)
Heel	19 (32.2)	17 (27.9)
Arch	25 (42.4)	29 (47.5)
Forefoot	38 (64.4)	45 (73.8)
Toes	37 (62.7)	39 (63.9)
Current footwear style		
Walking shoe	20 (34.5)	28 (45.9)
Athletic shoe	10 (17.2)	10 (16.4)
Oxford shoe	10 (17.2)	10 (16.4)
Moccasin	8 (13.8)	3 (4.9)
Boot	3 (5.2)	1 (1.6)
Slipper	1 (1.7)	2 (3.3)
Court shoe	2 (3.4)	2 (3.3)
Other	2 (3.4)	1 (1.6)
Current footwear characteristics		
Too short	10 (16.9)	10 (16.4)
Too narrow	10 (17.2)	6 (9.8)
Fully worn or partly worn sole	26 (44.0)	39 (63.9)
Mean (SD) heel elevation (mm)	11.9 (4.9)	12.8 (5.1)
Mean (SD) age of shoes (months)	29.8 (36.5)	28.9 (29.7)
Mean (SD) weight of shoe (gm)	364.1 (111.4)	355.5 (95.7)
Foot problems		
Hallux valgus	20 (33.9)	30 (49.2)
Lesser toe deformity	52 (88.1)	48 (78.7)
Keratotic lesions – toes	13 (22.0)	16 (26.2)
Keratotic lesions – plantar forefoot	37 (62.7)	36 (59.0)

Footwear fitting and acceptability of footwear

Baseline testing (including all clinical assessments and footwear fitting) of 121 participants was completed on May 2, 2013. Footwear fitting of participants allocated to the intervention group was evaluated using a high resolution 3D foot scanner. Of the 60 participants allocated to the intervention group, two were unable to have their feet scanned due to mobility limitations, one participant's scan was unusable, and one participant withdrew consent, leaving 56 participants with foot scan data (aged 65 to 95 years, 22 women and 34 men).

The shoe sizes of these participants were determined using clinical assessment with the Brannock device®, and fully weightbearing foot scans were obtained with the FotoScan 3D foot scanner (Precision 3D Ltd, Weston-super-mare, UK). The dimensions (length, ball width and ball girth denoted by A, B, and C in Figure 4) of the allocated shoes were documented according to the corresponding last measurements provided by the manufacturer. Mean differences between last dimensions and corresponding foot dimensions obtained with the 3D scanner were calculated to provide an indication of shoe fitting accuracy.

Figure 4 below depicts the dimensions obtained from the 3D foot scanner and the corresponding dimensions obtained from the lasts.

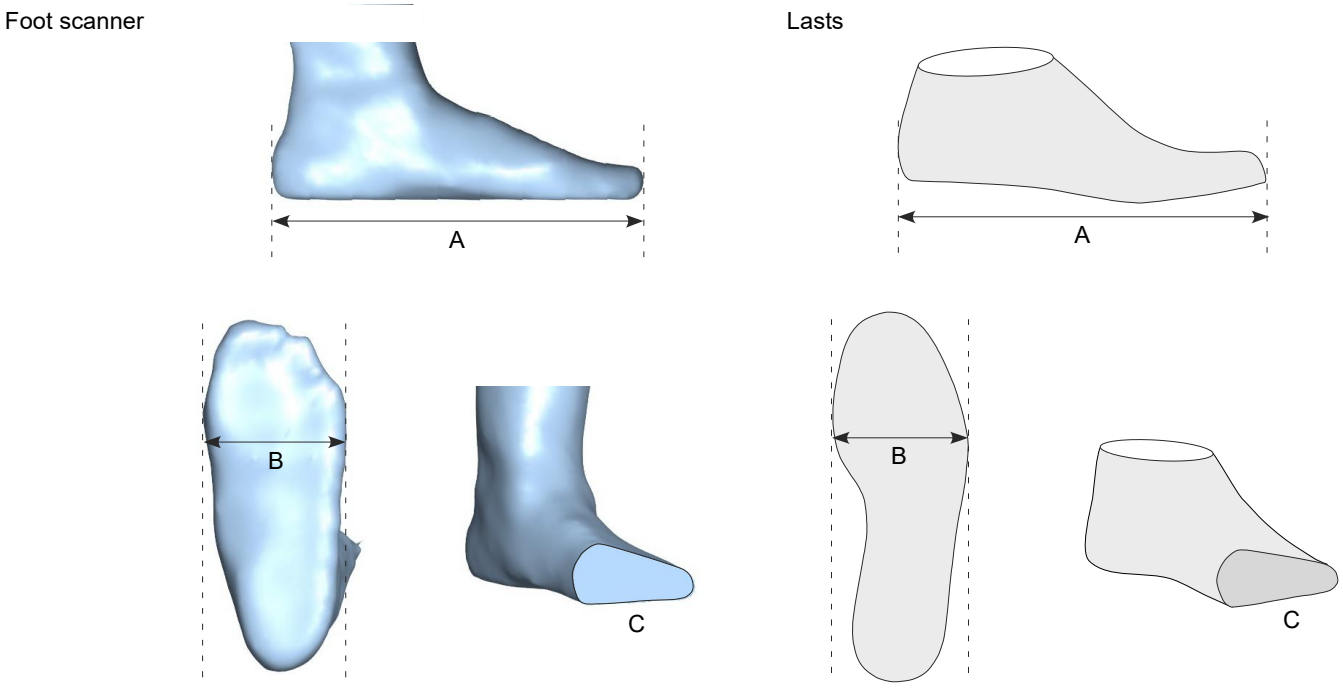

Figure 4. Dimensions obtained from the foot scanner and from the lasts. A: foot length, B: ball width, C: ball girth.

This analysis found that shoe size selection using the Brannock device® resulted in the allocation of Dr Comfort® shoes with last dimensions that were well matched to the dimensions of the foot determined by a high resolution 3D foot scanner. Table 2 below shows the differences between foot and shoe dimensions, and highlights that the shoes were slightly longer than the foot (23.6

mm) and of equivalent width and girth in the ball of the foot. Because the foot slightly elongates when walking, it is important that the shoes can accommodate for this, so the 23.6 mm difference between the length of the foot and the shoe is representative of good fitting.

Table 2. Differences between foot dimensions obtained with 3D foot scanner and corresponding shoe last dimensions.

	3D foot scanner mean (95% CI)	Shoe last mean (95% CI)	Mean difference (95% CI)*	*p* value
Length	255.0 (250.3 to 259.7)	278.7 (273.3 to 284.0)	23.6 (22.1 to 25.2)	<0.001
Ball width	93.8 (92.2 to 95.4)	95.6 (93.6 to 96.7)	1.4 (-0.1 to 2.9)	0.066
Ball girth	260.4 (254.4 to 266.3)	259.7 (255.1 to 264.3)	-0.7 (-6.1 to 4.8)	0.810

CI = confidence interval

Participants were also asked to complete six 100 mm visual analogue scales to ascertain their perceptions of: (i) how heavy the shoes are (using the anchors “extremely light” and “extremely heavy”), (ii) how easy it is to put the shoes on and take them off (using the anchors “most difficult as possible” and “as easy as imaginable”), (iii) how well the shoes fit (using the anchors “poorest fit possible” and “best fit possible”), (iv) the immediate level of comfort of the footwear (using the anchors “extremely uncomfortable” and “extremely comfortable”), (v) how attractive they think other people would find the footwear (using the anchors “extremely unattractive” and “extremely attractive”), and (iv) the attractiveness of the footwear to them (using the anchors “extremely unattractive” and “extremely attractive”). Figure 5 shows the results of this analysis, indicating that participants considered the footwear to be relatively lightweight, easy to put on and take off, well fitted and comfortable. Perceived attractiveness to others and themselves was modest (mean of 59 mm and 67 mm, respectively, from a total possible score of 100 mm).

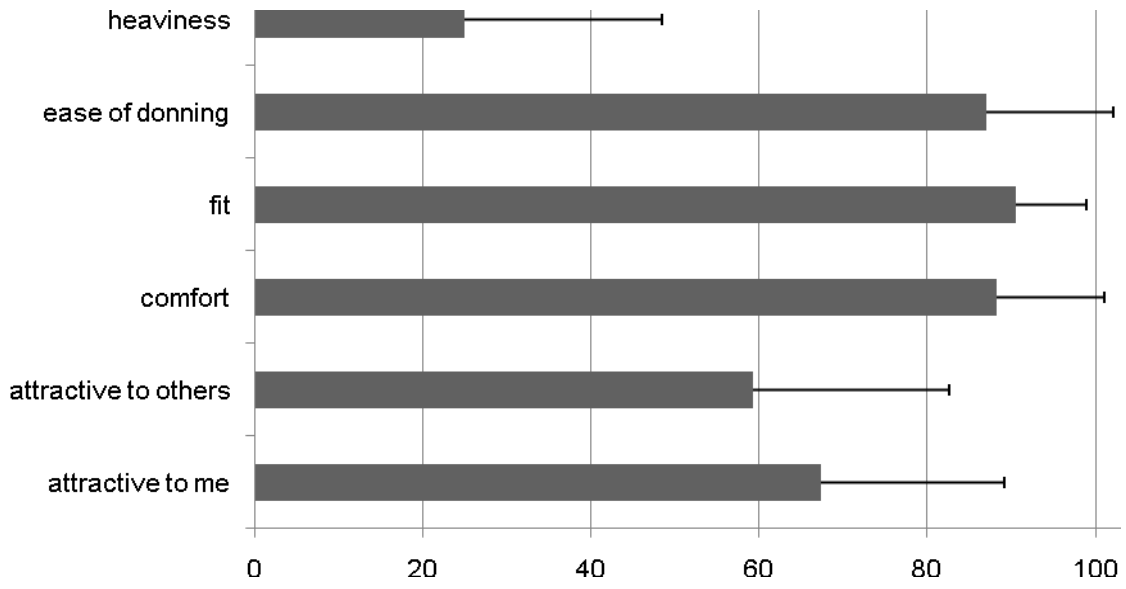

Figure 5. Perceptions of footwear on 100 mm visual analog scales. See text for explanation.

Adverse events

Problems with the shoes were reported by 12 (20%) participants, including that the shoes were too loose (n=6), too hot (n=2), had too much grip (n=2), were too tight (n=1) or too heavy (n=1). Shoe-related adverse events were reported by 7 (12%) participants. This included the shoes causing new foot or ankle pain (n=4), aggravation of back pain (n=1), bruising (n=1) or blisters (n=1). All adverse events were considered to be minor, with two exceptions: the participants who reported that the shoes aggravated their back pain or caused bruising withdrew from the study for these reasons prior to completing the 4 week questionnaire.

Primary outcome

Table 3 shows the mean (SD) scores and adjusted mean differences (95% CIs) between groups for the FHSQ pain subscale at baseline and at 16 week follow-up. As can be seen from the table, the scores were very similar at baseline. The control group experienced a small 0.5-point decrease in FHSQ from baseline to 16 weeks (indicative of slight worsening foot health), whereas the intervention group experienced a 12.6-point increase (indicative of improved foot health). A significant increase in the intervention group compared with the control group was found for the FHSQ pain subscale, indicating an improvement in foot health (ANCOVA-adjusted mean difference of 11.5 points, 4.2 to 18.8, *P*=0.002) at 16 weeks.

Secondary outcomes

Table 3 also shows the mean (SD) scores and adjusted mean differences (95% CIs) between groups for the FHSQ function subscale, MFPDI , SF-12, Timed Up and Go Test and number of keratotic lesions at baseline and 16 week follow-up. A significant increase in the intervention group compared with the control group was found for the FHSQ function subscale, indicating an improvement in foot health (ANCOVA-adjusted mean difference of 10.0 points, 0.9 to 19.1, *P*=0.032). In addition, the intervention group developed fewer keratotic lesions than the control group (ANCOVA-adjusted mean difference of -1.4, -2.5 to -0.2, *P*=0.021). There were no other differences between the groups for the remaining secondary outcome measures shown in Table 2.

There was no difference between the groups in relation to the number of podiatry consultations (intervention mean [SD] 1.9 [1.2], control group mean [SD] 1.9 [1.2], t_{118}=-0.14, *P*=0.887) or falls (intervention mean [SD] 1.5 [2.4], control group mean [SD] 0.9 [2.2], t_{118}=-1.25, *P*=0.215) recorded over the 16 week study period.

Use of co-interventions

The use of co-interventions was significantly lower in the intervention group compared to the control group (n=16 [27%] *versus* n=28 [46%]; relative risk = 0.74, 95%CI 0.56 to 0.98, *P*=0.026).

Table 3. Mean (SD) scores and adjusted mean differences (95% CIs) between groups at baseline and 16 week follow-up.

	Intervention group (n=59)	Control group (n=61)	Adjusted mean difference (95% CI)	P
FHSQ – pain subscale				
Baseline	54.8 (20.1)	58.0 (20.5)		
16 weeks	67.4 (23.1)	57.5 (22.3)	11.5 (4.2 to 18.8)	0.002
FHSQ – function subscale				
Baseline	54.1 (22.8)	56.7 (24.4)		
16 weeks	62.6 (27.9)	53.9 (27.8)	10.0 (0.9 to 19.1)	0.032
MFPDI – pain subscale				
Baseline	5.0 (1.6)	4.8 (2.0)		
16 weeks	4.6 (2.1)	4.7 (2.3)	-0.2 (-0.9 to 0.5)	0.606
MFPDI – function subscale				
Baseline	10.5 (2.3)	10.2 (3.6)		
16 weeks	9.4 (3.3)	9.8 (4.5)	-0.5 (-1.7 to 0.6)	0.364
MFPDI – appearance subscale				
Baseline	1.1 (1.2)	1.2 (1.5)		
16 weeks	1.0 (1.3)	1.0 (1.3)	0.0 (-0.4 to 0.4)	0.955
SF12 – physical component				
Baseline	33.9 (8.9)	35.9 (10.3)		
16 weeks	32.8 (9.0)	33.3 (10.2)	0.74 (-1.9 to 3.4)	0.582
SF12 – mental component				
Baseline	52.5 (11.8)	52.7 (11.7)		
16 weeks	52.4 (11.1)	51.2 (12.9)	1.3 (-2.1 to 4.7)	0.449
Timed up and go test (seconds)				
Baseline	16.5 (6.9)	15.5 (6.9)		
16 weeks	15.1 (6.5)	14.8 (5.9)	-0.4 (-1.6 to 0.8)	0.516
Number of keratotic lesions				
Baseline	3.5 (3.4)	3.8 (3.6)		
16 weeks	3.9 (3.4)	5.4 (4.4)	-1.4 (-2.5 to -0.2)	0.021

FHSQ: Foot Health Status Questionnaire (higher scores indicate better foot health)
MFPDI: Manchester Foot Pain and Disability Index (higher scores indicate worse foot health)
SF12: Short Form 12 (higher scores indicate better functioning)

Number of podiatry consultations during study period

The total number of DVA-funded standard podiatry consultations recorded over the study period per participant ranged from 0 to 6. There was no difference in the mean number of podiatry consultations between the groups (intervention mean [SD] 1.9 [1.2], control group mean [SD] 1.9 [1.2], t_{118}=-0.14, P=0.887).

Overall perception of treatment effectiveness

The intervention group were significantly more likely to report that their foot pain had moderately or markedly improved during the study compared to the control group (relative risk = 7.9, 95%CI 2.5 to 25.0, P<0.001). The number needed to treat was 3 (95% CI 2 to 5).

Discussion

Overview of major findings

Several studies have been undertaken to assess the effectiveness of footwear interventions in reducing foot pain in people with rheumatoid arthritis.[72-74] However, this is the first randomised controlled trial to evaluate the effectiveness of a footwear intervention in reducing foot pain in a veteran population. Our findings suggest that the provision of well-fitting, off-the-shelf, extra-depth footwear is both a safe and effective treatment. Participants allocated to the intervention group demonstrated a significant reduction in foot pain (as evidenced by an increase in the FHSQ pain subscale of 12.6 points) which exceeded the minimal important difference for this outcome measure.[66] In addition, the intervention group demonstrated a significant improvement in foot function, developed fewer keratotic lesions, were less likely to report the use of co-interventions, and were more likely to report that their foot pain had moderately or markedly improved at the 16 week follow-up compared to the usual care control group. Adverse events were reported by 7 (12%) of participants in the intervention group, however these were generally minor and only two participants stopped wearing their shoes for these reasons.

The shoes used in the study were selected as they meet all commonly-used criteria for appropriate footwear for older people with foot problems.[51-55] In particular, they provide greater depth than standard footwear and have a highly compliant upper manufactured from Lycra® (elastane) to accommodate forefoot deformity. It is likely that these features contributed to the reduction in foot pain, as the most common pain locations reported by our sample were the forefoot or the toes, the prevalence of hallux valgus and lesser toe deformities was high, and the intervention group developed fewer keratotic lesions over the study period compared to the control group. It has recently been demonstrated that dorsal and interdigital toe pressures are increased when wearing shoes with a narrow toe-box,[75] and previous studies of older people have reported associations between wearing shoes with insufficient length and width in the forefoot and toe deformity, the formation of keratotic lesions and foot pain.[35, 40, 41]

Low adherence is a well-recognised problem with therapeutic footwear intervention studies,[73, 76] which has been attributed to the unique role of footwear as both an item of clothing and a health-related intervention.[77] However, adherence to the intervention in our trial was generally high, with an average total wearing time of 527 hours (33 hours per week) over the 16 week study period. The relatively high adherence in our study compared to previous trials is likely due to the better cosmesis of off-the-shelf footwear compared to bespoke medical grade footwear, and the very favourable perceptions of fit and comfort reported by participants at the baseline assessment.[78] It is also likely that adherence would have been even higher had it not been for the fact that the data collection period encompassed the hottest Australian summer on record, with 31 days above 30ºC recorded in the study area between December 2012 and February 2013.[79] Participant adherence during this period was somewhat lower, as many participants understandably chose to wear open, slip-on footwear due to the hot weather.

Although we found that the intervention was effective in reducing foot pain, this did not translate to a reduction in the number of podiatry consultations during the study period. There are three likely explanations for this. First, it is possible that the 16 week follow-up period was of insufficient duration to detect any change in consultation behaviour. Second, all podiatry treatments provided to participants in the study were funded by the DVA, which reimburses private podiatrists on a per-consultation basis. Third-party funding systems such as these provide an incentive for clinicians to provide services as they deem appropriate without having to consider the client's capacity to pay. Similarly, clients do not have to consider the cost of treatment and may therefore request services on a more frequent basis than is clinically necessary. Indeed, we have previously found that the provision of footwear, orthoses or nail surgery does not reduce the number of on-going 'maintenance' treatments provided under this scheme.[42] Third, many veterans attend podiatry for routine management (such as nail cutting) which will not be influenced by footwear.

Strengths and limitations of the study

Key strengths of our study include the relatively long duration of follow-up (16 weeks) and the low, non-differential drop out rate. However, the findings of this study need to be interpreted in the context of several limitations. First, due to the nature of the intervention, it was not possible to blind participants or investigators to group allocation. Second, participants in this study were recruited from a veterans' affairs database, and were required to be ineligible for medical grade footwear. It is therefore possible that older people with more pronounced foot deformity were excluded, skewing our sample towards those with relatively 'normal' feet. However, the foot dimensions[38, 39] and prevalence of foot disorders[1, 7, 80] of participants in our study were very similar to previous studies of community-dwelling older people. This suggests that our findings may be broadly generalisable, with the exception of older people with marked foot deformity who are unable to be accommodated in regular footwear, and those with diabetic foot complications (an exclusion criteria). Third, this was a pragmatic trial, so we did not restrict the inclusion criteria in relation to the underlying *cause* of foot pain. It is therefore possible that our sample included some participants with conditions that may not have been amenable to treatment with footwear. However, off-the-shelf footwear is most often purchased without clinical assessment or diagnosis from health professionals, so our findings are likely to reflect the 'real world' context in which this intervention is most often administered.

Indications for further research

These findings indicate that off-the-shelf, extra-depth footwear is a safe and effective first-line treatment for foot pain in older veterans. However, it is worth noting that although there was a significant and clinically meaningful improvement in the intervention group, there remains some room for improvement to optimise foot health, as the mean FHSQ score in the intervention group at the completion of the study was 67.4 points (out of a total possible score of 100 points). The pragmatic design of the trial did not allow for any 'targeting' of the intervention beyond appropriate fitting of the shoes. Therefore, there could be some value in conducting a follow-up trial in which all participants receive the footwear, but the intervention group also receives foot orthoses designed to reduce the pressure under the region of the foot where they experience pain. In addition, it would be useful to determine whether more aesthetically appealing shoes would offer the same or greater benefits in terms of pain (due to greater adherence), as the perceived attractiveness of the Dr Comfort shoes we used was only moderate (see Figure 5).

Implications for the DVA

Footwear is an important component of foot health service provision by the DVA. Currently, veterans are able to receive subsidised medical grade footwear only if they meet the criterion of having foot deformity that cannot be accommodated in regular footwear. However, our findings indicate that there is a large population of veterans with foot pain who do not meet this criterion, yet can benefit greatly from relatively low cost, off-the-shelf footwear. Given that the criteria for receiving medical grade footwear are not well defined (and indeed, the criteria defining medical grade footwear is also somewhat vague), there is potential for the system of footwear provision to be more focused and potentially more cost-effective if the indications for off-the-shelf versus medical grade footwear are clarified.

Conclusion

This is the first randomised controlled trial to evaluate the effectiveness of footwear in reducing foot pain in older veterans. Our findings indicate that the recommendation and use of appropriately fitted, off-the-shelf, extra-depth footwear significantly reduces foot pain, improves foot function and is associated with the development of fewer keratotic lesions over a 16 week period compared to usual podiatry care.

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Contributors

Professor Hylton Menz and Nicoletta Frescos conceived the idea and obtained funding for the study. Professor Hylton Menz, Nicoletta Frescos and Dr Shannon Munteanu designed the trial protocol with assistance from Maria Auhl and Sonja Ristevski. Maria Auhl and Sonja Ristevski were responsible for recruitment, administration of the assessments and questionnaires, data entry and database management. Professor Hylton Menz conducted the statistical analysis and drafted all manuscripts and reports arising from the project.

Publications arising from project so far

Menz HB, Frescos N, Munteanu SE. Effectiveness of off-the-shelf footwear in reducing foot pain in Australian Department of Veterans' Affairs recipients not eligible for medical grade footwear: study protocol for a randomised controlled trial. *Trials* 2013;14:106.

Menz HB, Auhl M, Ristevski S, Frescos N, Munteanu SE. Evaluation of the accuracy of shoe fitting in older people using three-dimensional foot scanning. Submitted to *Journal of Foot and Ankle Research*.

Menz HB, Auhl M, Ristevski S, Frescos N, Munteanu SE. Effectiveness of off-the-shelf, extra-depth footwear in reducing foot pain in older people: randomised controlled trial. To be submitted to *BMJ*.

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