Effectiveness of Off-the-Shelf, Extra-Depth Footwear in Reducing Foot Pain in Older People: A Randomized Controlled Trial

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Background. Foot pain is highly prevalent in older people and in many cases is associated with inappropriate footwear. This study evaluated the effectiveness of off-the-shelf, extra-depth footwear in reducing foot pain.

Methods. Community-dwelling older people with disabling foot pain (72 men and 48 women aged 65 to 96 years; mean age 82 (SD 8)) were randomly allocated to an intervention group (n = 59) or control group (n = 61). The intervention group was provided with off-the-shelf, extra-depth footwear. Participants in the control group received their footwear at the completion of the study. Both groups continued to receive usual podiatry care for the study period. The primary outcome measure was the Foot Health Status Questionnaire (FHSQ), measured at baseline and 16 weeks.

Results. There was a significant improvement in the FHSQ pain domain (ANCOVA-adjusted mean difference 11.5 points, 95% confidence interval 4.2 to 18.8, p = .002) and FHSQ function domain (10.0 points, 0.9 to 19.1, p = .032) in the intervention group compared to the control group. The intervention group also developed fewer keratotic lesions (mean difference −1.4, −2.5 to −0.2, p = .021), were less likely to report the use of co-interventions (relative risk [RR] 0.74, 0.56 to 0.98, p = .026) and were more likely to report that their foot pain had moderately or markedly improved during the study (RR = 7.93, 2.51 to 25.00, p < .001; number needed to treat = 3, 2 to 5).

Conclusions. Off-the-shelf, extra-depth footwear significantly reduces foot pain, improves foot function and is associated with the development of fewer keratotic lesions in older people.

Key Words: Foot—Footwear—Pain—Randomized trial.

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Foot pain affects approximately one in four people over the age of 65 years (1,2) and has a significant impact on quality of life. Several studies have demonstrated that foot pain is associated with decreased ability to undertake activities of daily living (3,4), problems with balance and gait (3,5) and an increased risk of falls (6,7). As a consequence, older people account for a substantial number of consultations to primary care physicians (8), podiatrists (9), and orthopedic surgeons (10).

One potentially modifiable risk factor for the development of foot pain in older people is wearing ill-fitting footwear. It has been estimated that between 26% and 50% of older people wear shoes that are either too short or too narrow (11–14), and several studies have reported associations between ill-fitting shoes and foot problems (12,15). A retirement village study involving 176 residents aged 62 to 96 years found that wearing shoes substantially narrower than the foot was associated with corns on the toes, hallux valgus deformity, and foot pain, whereas wearing shoes shorter than the foot was associated with hammertoes and clawtoes (15). Similarly, a study of 213 community-dwelling people aged 60 to 80 years reported that those who wore shoes that were too narrow were twice as likely to report foot pain (12).

The use of appropriately fitted footwear with sufficient depth and width to cater for the altered morphology of the older foot could potentially be a simple and effective primary care intervention for foot pain in this age-group. Although several trials have been undertaken to assess the effectiveness of footwear interventions in people with rheumatoid arthritis (16,17) and diabetes (18,19), no such trials have been conducted in a general older population. Therefore, the objective of this study was to evaluate the effectiveness of off-the-shelf, extra-depth footwear in reducing foot pain in ambulatory, community-dwelling older people over a 16 week period.

Methods

Participants

Between October 2012 and May 2013 we recruited participants by post using a database of older people currently...
receiving podiatry treatment funded by the AustralianDepartment of Veterans’ Affairs (DVA). The DVA database was used to identify veterans residing in Melbourne, Victoria who had not been issued with medical grade footwear within the last 5 years. Participants were eligible if they were aged 65 years or over, were a current DVA Gold Card client not eligible for medical grade footwear, had received podiatry treatment on at least three occasions in the past 5 years, had disabling foot pain (using the Roddy et al (20), case definition of the Manchester Foot Pain and Disability Index [MFPDI]) (21), had foot pain present for at least 12 weeks, and were capable of understanding the English language. Exclusion criteria included residing in a residential aged care facility, diabetes and current or previous foot ulceration, diabetic peripheral neuropathy, neurodegenerative disorders, lower limb or partial foot amputation, having been prescribed contoured foot orthoses within the past 3 months, currently wearing the intervention footwear, or cognitive impairment (defined as a score of <7 on the Short Portable Mental Status Questionnaire) (22).

**Trial Design**

We carried out a parallel group randomized controlled trial with 16 weeks’ follow-up. An *a priori* sample size calculation, based on a minimal important difference of 12.5 and a standard deviation of 23 (23) of our primary outcome measure (the pain domain of the Foot Health Status Questionnaire) (24), a 10% drop-out rate, 80% power and a significance level of 5%, indicated that we needed 120 participants. Participants were initially screened by phone for eligibility, and then assessed at baseline and at 16 weeks. Between the baseline and 16 week appointments, participants completed postal questionnaires at 4, 8, and 12 weeks. Group allocation (randomization) was then undertaken during a single session at the University Health Sciences Clinic. Due to the nature of the intervention, it was not possible to blind the participants or assessors. However, data entry was performed by an assessor blinded to group allocation by ensuring that each assessor entered data for participants they did not assess at baseline. Further details of the methods are reported in the trial protocol paper (25). The Australian DVA Human Research Ethics Committee provided ethical approval (E012/005[5.1]) and the La Trobe University Human Ethics Committee accepted this approval (E012/004). All participants provided written informed consent prior to enrolment.

**Randomization**

The assessors used an interactive voice response telephone service provided by the National Health and Medical Research Council Clinical Trials Centre at the University of Sydney to carry out permuted block randomization (stratified by sex, with mixed block lengths of six, and eight participants) to ensure allocation concealment.

**Interventions**

Both groups continued to receive regular podiatry treatment funded by the DVA. The intervention group was provided with off-the-shelf, extra-depth footwear (Dr Comfort, Vasyli Medical, Queensland, Australia), available in three width fittings and featuring a stretchable Lycra upper with Velcro closure and a choice of two removable insoles (a flat, foam insole or a cushioning insole with a contoured heel cup). See Figure 1. Participants’ feet were measured with a Brannock Device (Brannock Device Co, Inc., Liverpool, New York), using the protocol recommended by the footwear manufacturer. Intervention group participants who wore flat insoles (or had been wearing contoured foot orthoses for more than 3 months) were permitted to wear them in their study footwear, provided that the fit of the shoes was appropriate. The accuracy of the shoe fitting procedure was evaluated by comparing measurements of the foot to the corresponding last measurements of the allocated shoes (26). The control group was provided with the footwear at the completion of the study.

**Outcomes**

The primary outcome measure was the pain domain of the FHSQ. The FHSQ consists of 13 questions reflecting four domains: foot pain, foot function, footwear, and general foot

![Figure 1. Dr Comfort footwear used in the study. Top: Brian style for men; Bottom: Annie style for women. From 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 randomized controlled trial. Trials 2013;14:106.](https://academic.oup.com/biomedgerontology/article-abstract/70/4/511/571326)
health (24). The FHSQ pain domain comprises four questions, with higher scores representing better foot health (i.e., 100 = best foot health and 0 = worst foot health). The FHSQ is well validated and has been used as an outcome measure in several clinical trials of foot disorders (27). Previous research indicates that the minimal important difference for this measure is 12.5 points (23). The FHSQ pain domain was measured at baseline and at 4, 8, 12, and 16 weeks to provide insight into the trajectory of any improvements in foot pain. However, to address the issue of multiple testing of serial measurements (28) we pre-specified 16 weeks as the single primary end-point and no statistical comparisons of the 4, 8, and 12 week scores were undertaken.

Secondary outcome measures were documented at baseline and 16 weeks and included the function domain of the FHSQ, the functional limitation, pain intensity and concern about appearance subscales of the MFPDI (21), the number of DVA-funded podiatry consultations documented during the study period, general health status, assessed with the Short Form 12 Version 2.0 (29), the number of falls experienced during the follow-up period, the Timed Up and Go Test (30), presence of keratotic lesions (corns and calluses), the number of participants using co-interventions to relieve foot pain (documented with a diary that was returned at 4, 8, 12, and 16 weeks), and 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”). This scale was then dichotomized, with a positive outcome defined as moderate or marked improvement.

Adherence and Adverse Events

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 for each of these days) they had worn their footwear, on average, in the past month. Adverse events were also collected with the questionnaires at 4, 8, 12, and 16 weeks using an open-ended response option.

Statistical Analysis

All analyses were carried out using the intention-to-treat principle. We used multiple imputation to replace any missing data using five iterations, with age, baseline scores, and group allocation as predictors (31). We explored continuous data for normality using standard tests to satisfy the assumptions of parametric statistics. Continuous primary and secondary outcome measures were compared between groups using a linear regression technique with baseline scores adjusted for by the analysis of covariance model (ANCOVA) (32). Nominal data were compared using relative risks (RRs). Global improvement was calculated using the dichotomized perception of overall treatment effect and expressed as a RR and number needed to treat. An independent samples t-test was used to compare the number of podiatry consultations between groups over the study period. Statistical analysis was undertaken using SPSS version 20.0 (IBM Corp, NY).

Results

Baseline testing commenced in October 2012 and all follow-up assessments were completed by August 2013. Figure 2 shows the flow of participants through the study. One participant randomized to the intervention group did not like the appearance of the shoes and immediately withdrew consent; otherwise all randomized participants received their allocated intervention. The 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).

Intervention Adherence and Participant Retention

Three participants in the intervention group (5%) did not wear the shoes. Of the remaining intervention group participants, the total number of hours the shoes were worn 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.

Adverse Events

Problems with the shoes were reported by 12 (20%) participants, specifically 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, including 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 mild, 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 2 shows the mean (SD) scores and adjusted mean differences (95% CIs) between groups for the FHSQ pain domain at baseline and at 16 week follow-up. A significant increase in the intervention group compared with the control group was found for the FHSQ pain domain, indicating an improvement in foot health (ANCOVA-adjusted mean difference of 11.5 points, 4.2 to 18.8, p = .002) at 16 weeks.
Secondary Outcomes

Table 2 shows the mean (SD) scores and adjusted mean differences (95% CIs) between groups for the secondary outcomes 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 domain, indicating an improvement in foot health (ANCOVA-adjusted mean difference of 10.0 points, 0.9 to 19.1, \( p = .032 \)). 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, \( p = .021 \)). There were no other differences between the groups for the remaining secondary outcome measures shown in Table 2.

There were 95 falls recorded during the study: 40 in the control group and 55 in the intervention group. There
was no significant difference between the groups with regard to the proportion of fallers (control group n = 14 [23%], intervention group n = 19 [32%], RR = 1.27, 0.82 to 2.98, p = .256) or the median number of falls per person (control group median [range] = 0 [0 to 11]; intervention group median [range] = 0 [0 to 9], Mann-Whitney U test p = .352).

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 = .887) or falls (intervention mean [SD] 1.5 [2.4], control group mean [SD] 0.9 [2.2], t_{118} = −1.25, p = .215) recorded over the study period.

**Table 2. Mean (SD) Scores and Adjusted Mean Differences (95% CIs) Between Groups at Baseline and 16 Week Follow-up.**

<table>
<thead>
<tr>
<th></th>
<th>Intervention Group (n = 59)</th>
<th>Control Group (n = 61)</th>
<th>Adjusted Mean Difference (95% CI)</th>
<th>p</th>
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<tr>
<td>FHSQ – pain domain</td>
<td></td>
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<tr>
<td>Baseline</td>
<td>54.8 (20.1)</td>
<td>58.0 (20.5)</td>
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<td>16 wk</td>
<td>67.4 (23.1)</td>
<td>57.5 (22.3)</td>
<td>11.5 (4.2 to 18.8)</td>
<td>.002</td>
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<tr>
<td>FHSQ – function domain</td>
<td></td>
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<tr>
<td>Baseline</td>
<td>54.1 (22.8)</td>
<td>56.7 (24.4)</td>
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<tr>
<td>16 wk</td>
<td>62.6 (27.9)</td>
<td>55.9 (27.8)</td>
<td>10.0 (0.9 to 19.1)</td>
<td>.032</td>
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<td>MFPDI – pain subscale</td>
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<tr>
<td>Baseline</td>
<td>5.0 (1.6)</td>
<td>4.8 (2.0)</td>
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<tr>
<td>16 wk</td>
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<td>4.7 (2.3)</td>
<td>−0.2 (−0.9 to 0.5)</td>
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<td>MFPDI – function subscale</td>
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<td>10.2 (3.6)</td>
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<td>16 wk</td>
<td>9.4 (3.3)</td>
<td>9.8 (4.5)</td>
<td>−0.5 (−1.7 to 0.6)</td>
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<td>SF12 – physical component</td>
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<tr>
<td>16 wk</td>
<td>32.8 (9.0)</td>
<td>33.3 (10.2)</td>
<td>0.74 (−1.9 to 3.4)</td>
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<td>SF12 – mental component</td>
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<td>52.5 (11.8)</td>
<td>52.7 (11.7)</td>
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<tr>
<td>16 wk</td>
<td>52.4 (11.1)</td>
<td>51.2 (12.9)</td>
<td>−1.3 (−2.1 to 4.7)</td>
<td>.449</td>
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<td>Timed up and go test (s)</td>
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<tr>
<td>Baseline</td>
<td>16.5 (6.9)</td>
<td>15.5 (6.9)</td>
<td>−0.4 (−1.6 to 0.8)</td>
<td>.516</td>
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<tr>
<td>16 wk</td>
<td>15.1 (6.5)</td>
<td>14.8 (5.9)</td>
<td>0.3 (−0.4 to 1.0)</td>
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<tr>
<td>Number of keratotic lesions</td>
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<tr>
<td>Baseline</td>
<td>3.5 (3.4)</td>
<td>3.8 (3.6)</td>
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<tr>
<td>16 wk</td>
<td>3.9 (3.4)</td>
<td>5.4 (4.4)</td>
<td>−1.4 (−2.5 to −0.2)</td>
<td>.021</td>
</tr>
</tbody>
</table>

FHSQ = Foot Health Status Questionnaire (higher scores indicate better foot health); MFPDI = Manchester Foot Pain and Disability Index (higher scores indicate worse foot health); SF-12 = Short Form 12 (higher scores indicate better functioning).

**Use of Co-interventions**

The use of co-interventions throughout the duration of the study period (which included anti-inflammatory medications, padding, strapping, and massage) was significantly lower in the intervention group compared to the control group (n = 16 [27%] versus n = 28 [46%]; RR = 0.74, 0.56 to 0.98, p = .026).

**Overall Perception of Treatment Effectiveness**

The intervention group were significantly more likely to report that their foot pain had moderately or markedly improved compared to the control group (RR = 7.93, 2.51 to 25.00, p < .001). The number needed to treat was 3 (2 to 5).

**DISCUSSION**

This is the first randomized controlled trial to evaluate the effectiveness of a footwear intervention in reducing foot pain in a general older population. Our findings suggest that appropriately-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...
subsclae of 12.6 points) which exceeds the minimal important difference for this outcome measure (23). 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 compared to the 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 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 (33), 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 (12,15,34).

Low adherence is a well-recognized problem with therapeutic footwear intervention studies (17), which has been attributed to the unique role of footwear as both an item of clothing and a health-related intervention (35). However, adherence to the intervention in our trial was generally high, with an average total wearing time of 527 hours (33 hours per week). 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 favorable perceptions of fit and comfort reported by participants at the baseline assessment (26). 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 30°C (86°F) recorded in the study area between December 2012 and February 2013 (36). 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 two likely explanations for this. Firstly, it is possible that the 16 week follow-up period was of insufficient duration to detect any change in consultation behavior. Secondly, 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 (37).

Key strengths of our study include the inclusion of a usual care control group 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, it was not possible to blind participants or investigators to group allocation. Second, participants in this study 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 (1,3,40) of participants in our study were very similar to previous studies of community-dwelling older people. This suggests that our findings may be broadly generalizable, 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 criterion). 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. Finally, although the duration of follow-up (16 weeks) was longer than most footwear trials, changing footwear is a long-term intervention so we are unable to determine the extent to which the benefits observed in the study would persist over a longer period.

In summary, this is the first randomized controlled trial to evaluate the effectiveness of footwear in reducing foot pain in older people. Our findings indicate that wearing appropriately-fitting, 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. The high adherence and acceptability of the intervention suggests that this may be a useful first-line treatment for foot pain in primary care.

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