



Deposited via The University of Leeds.

White Rose Research Online URL for this paper:

<https://eprints.whiterose.ac.uk/id/eprint/133953/>

Version: Accepted Version

Article:

Corbacho, B, Cockayne, S, Fairhurst, C et al. (2018) Cost-Effectiveness of a Multifaceted Podiatry Intervention for the Prevention of Falls in Older People: The REducing Falls with Orthoses and a Multifaceted Podiatry Intervention Trial Findings. *Gerontology*, 64 (5). pp. 503-512. ISSN: 0304-324X

<https://doi.org/10.1159/000489171>

Reuse

Items deposited in White Rose Research Online are protected by copyright, with all rights reserved unless indicated otherwise. They may be downloaded and/or printed for private study, or other acts as permitted by national copyright laws. The publisher or other rights holders may allow further reproduction and re-use of the full text version. This is indicated by the licence information on the White Rose Research Online record for the item.

Takedown

If you consider content in White Rose Research Online to be in breach of UK law, please notify us by emailing eprints@whiterose.ac.uk including the URL of the record and the reason for the withdrawal request.

1 **Title page**

2

3 **Cost-effectiveness of a multifaceted podiatry intervention for the prevention of falls in older people: The**
4 **REFORM trial findings**

5

6 **Short title:** REFORM trial cost-effectiveness findings

7

8 **Byline**

9 Belen Corbacho¹§, Sarah Cockayne¹, Arabella Scantlebury¹, Caroline Fairhurst¹, Catherine E Hewitt¹, Kate
10 Hicks¹, Anne-Maree Kenan², Sarah E Lamb³, Caroline McIntosh⁴, Hylton B Menz⁵, Anthony C Redmond², Sara
11 Rodgers¹, Judith Watson¹, David J Torgerson¹ on behalf of the REFORM study*

12

13 **Department(s) and institution(s) to which the work should be attributed**

14 ¹ York Trials Unit, Department of Health Sciences, University of York, York, United Kingdom

15 ² NIHR Leeds Musculoskeletal Biomedical Research Unit, Chapel Allerton Hospital, Leeds, United Kingdom

16 ³ Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, Kadoorie Critical Care
17 Research Centre, John Radcliffe Hospital, University of Oxford, Oxford, United Kingdom

18 ⁴ National University of Ireland, Galway, Republic of Ireland

19 ⁵ School of Allied Health, College of Science, Health and Engineering,, La Trobe University, Bundoora,
20 Victoria, Australia

21 § Corresponding author

22

23 **Details of corresponding author**

24 Belen Corbacho

25 ARRC Building, Department of Health Sciences, University of York, York, YO10 5DD, UK

26 Email: belen.corbacho@york.ac.uk

27 Tel: +44 (0) 1904 321852 / Fax: +44 (0) 1904 321387

28

29 **Key words:** elderly, falls, footwear, quality of life, shoes, podiatry intervention, decision making, cost-
30 effectiveness

31

32

33

34

35

36

37

38

39

40

41

42

43

44

45 **Abstract**

46

47 **Background:** Falls are a major cause of morbidity among older people. Multifaceted interventions may be
48 effective in preventing falls and related fractures.

49

50 **Objective:** To evaluate the cost-effectiveness alongside the REFORM (REducing Falls with Orthoses and a
51 Multifaceted podiatry intervention) trial.

52

53 **Methods:** REFORM was a pragmatic multicentre cohort randomised controlled trial in England and Ireland; 1010
54 participants (>65 years) were randomised to receive either a podiatry intervention (n= 493), including foot and
55 ankle strengthening exercises, foot orthoses, new footwear if required, and a falls prevention leaflet, or usual
56 podiatry treatment plus a falls prevention leaflet (n=517). Primary outcome: incidence of falls per participant in
57 the 12 months following randomisation. Secondary outcomes: proportion of fallers and quality of life (EQ-5D-
58 3L) which was converted into quality-adjusted life years (QALYs) for each participant. Differences in mean costs
59 and QALYs at 12 months were used to assess the cost-effectiveness of the intervention relative to usual care.
60 Cost-effectiveness analyses were conducted in accordance with National Institute for Health and Clinical
61 Excellence reference case standards, using a regression based approach with costs expressed in GBP (2015 price).
62 The base case analysis used an intention to treat approach on the imputed data set using multiple imputation (MI).

63

64 **Results:** There was a small, non-statistically significant reduction in the incidence rate of falls in the intervention
65 group (adjusted incidence rate ratio 0.88, 95% CI 0.73 to 1.05, p = 0.16). Participants allocated to the intervention
66 group accumulated on average marginally higher QALYs than usual care participants (mean difference 0.0129,
67 95% CI -0.0050 to 0.0314). The intervention costs on average £252 more per participant compared to usual care
68 (95% CI -£69 to £589). Incremental cost-effectiveness ratios ranged between £19,494 and £20,593 per QALY
69 gained, below the conventional NHS cost-effectiveness thresholds of £20,000 to £30,000 per additional QALY.
70 The probability that the podiatry intervention is cost-effective at a threshold of £30,000 per QALY gained is 0.65.
71 The results were robust to sensitivity analyses.

72

73 **Conclusion:** The benefits of the intervention justified the moderate cost. The intervention could be a cost-effective
74 option for falls prevention when compared with usual care in the UK.

75

76

77

78

79

80

81 **Trial registration number:** ISRCTN68240461

82

83

84 **INTRODUCTION**

85

86 Falls are common among older people with a high cost to health care systems and society [1-3]. The cost burden
87 of falls to the UK National Health Service (NHS) is estimated of more than £2 billion per year [4]. Given that the
88 number of people over the age of 65 is predicted to increase, we might expect the cost of falls to the NHS to rise
89 further every year. It has been suggested that podiatry care play a role in falls prevention, as cohort studies have
90 indicated a relationship between risk of falling and both foot and ankle problems [5, 6] and inappropriate footwear
91 [7]. There is evidence that a multifaceted podiatry intervention –which combines foot and ankle exercise, foot
92 orthoses, foot advise and a falls prevention booklet combined with routine podiatry care - is effective at reducing
93 the incidence of falls among older people in an Australian setting [8]. This trial did not include an economic
94 evaluation.

95

96 The REFORM (REducing Falls with Orthoses and a Multifaceted podiatry intervention) trial evaluated the clinical
97 and cost-effectiveness of a multifaceted podiatric intervention aimed at reducing the incidence of falls among
98 people at high risk of falling within the UK setting [9]. There was a non-statistically significant reduction in the
99 incidence rate of falls in the intervention group [adjusted incidence ratio 0.88; 95% confidence interval (CI) 0.73
100 to 1.05; $p=0.16$]. However, the proportion of participants experiencing a fall was reduced (50 vs 55%, adjusted
101 odds ratio 0.78; 95% CI 0.60 to 1.00; $p=0.05$). Hence, there is a potential to improve health related quality of life
102 (HRQOL) by preventing falls and to reduce health care costs. From an economic perspective, the recommendation
103 is that estimation, and not hypothesis testing, be used to inform decision making for resource allocation in health
104 care [10]. Therefore it remains important to assess whether the benefits of the intervention justify the extra costs
105 of providing the multifaceted programme; addressing this will be important in order to deliver improved services
106 to this population that offer good value for money to the NHS. This paper reports on the economic evaluation
107 conducted alongside the REFORM trial.

108

109 **METHODS**

110

111 **Overview**

112 We conducted a pragmatic open two-arm, cohort randomised controlled trial [11] with an economic evaluation.
113 The REFORM protocol has been published elsewhere [12]. In summary, participants were recruited to an
114 observational cohort study from podiatric clinic lists in the UK and the Republic of Ireland and followed up for
115 falls data. Participants, who fulfilled the REFORM trial eligibility criteria, were then randomised into the trial,
116 when podiatrists had capacity to deliver the trial intervention. All participants received routine podiatry care
117 which typically aimed to reduce painful conditions such as corns, callouses and pathological nails, which have
118 been found to be associated with an increased risk of falls. In addition to this, all participants received a falls
119 prevention leaflet produced by Age UK (Staying Steady June 2010) along with a group specific trial newsletter
120 informing them about the progress of the trial. Participants allocated to the intervention group additionally
121 received footwear advice, provision of new footwear if current footwear was judged to be inappropriate (supplied
122 by Hotter Footwear® and DB Shoes Ltd); foot orthoses (x-line®, Healthystep, Mossley, UK); and a 30 minutes
123 a day, three times a week home-based foot and ankle exercise programme supplemented with a DVD and

124 explanatory booklet [8]. Intervention participants were invited to attend two podiatry appointments, with further
125 appointments offered if required.

126

127 A cost-utility analysis with health outcomes expressed in terms of quality-adjusted life years (QALYs) in
128 accordance with the NICE (National Institute for Health and Clinical Excellence) reference case [13] was
129 undertaken. Cost-effectiveness in terms of cost per fall averted was assessed for comparison. The evaluation took
130 the perspective of the NHS and personal social services for a time horizon of 12 months; with costs presented in
131 UK pounds sterling at 2015 prices. A regression approach on an intention-to-treat basis was used. The base-case
132 analysis was conducted on the dataset generated by multiple imputation (MI) methods [14]. Sensitivity analysis
133 included complete-case (CC) analysis to test the impact of excluding participants with missing data on the final
134 results. All analyses and modelling were conducted in Stata 13.1 (StataCorp 2011, TX, USA).

135

136 **Health outcomes**

137 The primary outcome measure was QALYs. Therefore, in addition to the participant-reported outcomes described
138 in the clinical paper [9], participants also completed the EQ-5D-3L (EuroQoL Group Rotterdam, The Netherlands)
139 at baseline, six and 12 months post-randomisation. The EQ-5D-3L is comprised of five dimensions of health status
140 (mobility, self-care, usual activities, pain or discomfort, and anxiety or depression) with three severity levels (no,
141 some, extreme problems/unable to) for each dimension. The EQ-5D has been recommended by The Prevention
142 of Falls Network Europe Consensus as a measure of health related quality of life (HRQoL) in trials [15] and has
143 been used before in UK settings assessing HRQoL implications of falls in older people [2]. The EQ-5D-3L health
144 states were converted into utilities using a UK-based social tariff [16]. A utility of one indicates perfect health, a
145 utility of zero indicates “as bad as death”, and negative utilities identify states considered worse than death. These
146 utilities were used to weight duration of survival and estimate QALYs, that were calculated using the area under
147 the curve method [17] and were adjusted for baseline utility [18].

148

149 **Resource use and costs**

150 Resource use associated with falls was collected prospectively using participant-reported questionnaires at
151 baseline, six and 12 months. We collected information on resource use that we considered could potentially relate
152 to the intervention, to allow us to assess the possibility that the provision of the multifaceted intervention prevents
153 costs that would otherwise be incurred. Hence we asked participants to report visits to primary care professionals
154 (General Practitioner (GP) and GP nurse), community care (occupational therapist), hospitalisations (inpatient,
155 day-case, outpatient and A&E) and visits to podiatry clinics. The cost of the podiatry intervention was assessed
156 based on the data collected as part of a baseline appointment questionnaire and the podiatrist database, which
157 included information directly related to the podiatrist assessments and the intervention package received by the
158 participant (e.g. orthosis prescription, exercise programme and exercise equipment). Participants allocated to the
159 intervention would receive at least one baseline visit to the podiatrist plus at least one follow-up appointment. The
160 first appointment was assumed to last for 1 hour; the second appointment for 30 minutes and all the rest were
161 assumed to be the same duration as a GP clinic consultation (11.7 minutes). The cost for the visits was estimated
162 according to NHS pay scales on the Agenda for Change for NHS podiatrist staff in England, Wales, Scotland and
163 Northern Ireland (https://healthcareers.nhs.uk/glossary#Agenda_for_Change). Podiatrists delivering the

164 intervention ranged from band 6 to band 8. The base-case analysis includes only costs falling within the NHS and,
165 hence, the cost of the provision of new footwear was not considered in the analysis. The total cost per each
166 participant was estimated by multiplying each resource use item by their associated unit costs (**Table 1**).

167

168 **Handling missing data**

169 Complete case (CC) assessment excludes all participants with any missing or incomplete data. To avoid biases
170 associated with CC analysis [19] incomplete data on cost and QALYs were handled using multiple imputation
171 analysis assuming the data were missing at random (MAR), via chained equations and predictive mean matching
172 [20, 21]. The same set of covariates as in the clinical effectiveness analysis was selected for the analysis (age, sex,
173 history of falls, centre, costs and utilities). Rubin's rules were used to combine point and variance estimates across
174 imputed datasets, allowing the estimation of the difference in costs and QALYs between both groups. Five
175 imputed data sets were generated as this has been deemed sufficient to obtain valid responses [22, 23]. Despite
176 MI being the most robust method to handle missing data in economic evaluation, we analysed the pattern of
177 missing data following economic guidelines [24] to ensure that the pattern of REFORM data reflects the
178 assumption made for the base-case analysis (e.g. data are MAR). The association between missingness and
179 baseline variables was explored by means of logistic regression.

180

181 **Base case analysis**

182 The base-case analysis was conducted on the imputed dataset on an intention to treat (ITT) basis, and included
183 only fall-related health care visits. Since the NHS will not cover the cost of the provision of new footwear this
184 was not considered for the base-case analysis.

185

186 The cost-effectiveness of the intervention was calculated by comparing the mean differences in expected costs
187 and QALYs between the two groups [25]. If the intervention (or usual care) is less costly and more effective, it
188 would 'dominate' the alternative and hence be considered cost-effective. If not, the incremental cost-effectiveness
189 ratio (ICER) would be estimated as the difference in mean total costs at one year divided by the difference in
190 mean total QALYs for the intervention compared to usual care. The mean estimates and their 95% confidence
191 intervals (CI) were generated by means of seemingly unrelated regression (SUR) using bias corrected and
192 accelerated (BCA) bootstrap methods. According to NICE, the cost-effectiveness threshold (e.g. quantity that the
193 NHS is willing to pay (WTP) per person for an additional QALY ranges from £20,000 to £30,000 per QALY
194 gained. The ICER was also arranged in terms of net monetary benefit (NMB), which translate the health benefits
195 into monetary value using the cost-effectiveness thresholds (e.g. incremental QALYs multiplied by the WTP
196 threshold) [26]. The intervention would be considered cost-effective if the NMB were positive. Non-parametric
197 bootstrapping was used to determine the level of sample uncertainty associated with the mean ICER by generating
198 5,000 estimates of incremental costs and benefits, represented graphically
199 in a cost-effectiveness plane and a cost-effectiveness acceptability curve that shows the probability that the
200 intervention is more cost-effective than usual care for a range of cost-effectiveness thresholds.

201

202 **Cost per fall averted**

203 Cost-effectiveness was also estimated in terms of falls prevented following guidelines for economic evaluation of
204 fall prevention strategies [27]. This other form of analysis has the potential to strengthen the case for the
205 multifaceted intervention by exploring the cost per fall averted and how this links to health care saving. The
206 number of falls averted was estimated as the difference in mean reduction in the fall rate between the two groups
207 in the trial estimated as per the adjusted negative binomial model.

208

209 **Sensitivity analysis**

210 Several sensitivity analysis were undertaken to assess the impact of uncertainty on the economic evaluation. These
211 were conducted to test the robustness of the results using four scenarios: (i) restricting the analysis to CC, assuming
212 the data were missing completely at random (MCAR); (ii) MI by imputing HRQoL at an aggregated level (e.g.,
213 at QALYs level); (iii) MI recalculating the average costs including both fall and non-fall resource use; and (iv)
214 MI from a wider societal perspective that included costs incurred by the patients (e.g., cost of the shoes as a
215 personal expense for the patient).

216

217 **HRQoL beyond the trial**

218 HRQoL was extrapolated to 5 years to explore how the differences in HRQoL evolve beyond the duration of the
219 trial. We used a decision-model approach –using evidence from REFORM trial - assuming (i) two health states
220 (alive and dead); and (ii) the initial podiatry intervention, when displacing usual care, is expected to continue to
221 bring gains of 0.0129 QALYs per patient per year and incur costs of £251 more per year when alive (e.g.
222 incremental cost estimates in the trial are considered fixed over the five years).

223

224 **RESULTS**

225

226 **Patient population and missing data**

227 The analysis was based on the 1010 trial participants (493 intervention vs 517 usual care). Twenty four participants
228 died during the trial [9 (1.8%) intervention vs 15 (2.9%) usual care]. The proportion of participants with complete
229 data decreased with follow-up: from 72.0% (baseline) to 54.4% (12 months) for the intervention group; and from
230 71.8% (baseline) to 61.3% (12 months) for the usual care group. The missing data followed non monotonic pattern
231 (i.e. there were participants with missing six month data but complete data at 12 months); showing that complete
232 case assessment would be, as a minimum, inefficient as it would discard observed data from individuals with
233 some missing outcomes. The results of a logistic analysis regression showed that participants that were older (OR
234 1.04; 95% CI 1.02 to 1.06), with lower EQ-5D at baseline (OR 0.68; 95% CI 0.35 to 1.32), and those with a history
235 of falling (OR 1.26; 95% CI 0.89 to 1.77) were more likely to have missing QALY data. This suggests that data
236 are unlikely to be MCAR.

237

238 **Resource use and costs**

239 In total, 413 out of 493 (83.8%) participants allocated to the intervention had at least one visit to the podiatry
240 clinic and 183 (37.1%) had at least two. A total of 260 participants received a new pair of shoes. Moreover a total
241 of 241 participants also received a pair of insoles: X-Line red (n = 23), X-Line blue (n = 209) or Formthotics
242 insoles (n = 9). They also received resistive therapy bands and therapy balls for the exercises. The intervention

243 cost on average £115.50 (SD £33.06), and £155.79 (SD £55.02) when the price of the shoes (societal perspective)
244 was included (Table 2). On average intervention participants had more hospital admissions, outpatient visits and
245 A&E attendances related to falls than usual care participants over the trial duration, but had on average fewer
246 falls-related visits to the GP (Table 3). In total, 413/493 (83.8%) participants allocated to the intervention group
247 had at least one visit to the podiatry clinic, and 183/493 (37.1%) had at least two. Costs associated with falls-
248 related hospital inpatient stay and the intervention itself were the major cost drivers for the analysis.

249

250 **Effectiveness**

251 At baseline, participants reported problems in mobility (59.7% intervention vs 56.9% usual care) and pain (78.4%
252 intervention vs 56.6% usual care) more than in other dimensions. The intervention showed a reduction in the
253 number of participants reporting problems from baseline to 12 months both for mobility (11% intervention vs 1%
254 usual care) and pain (15% intervention vs 10% usual care). The likelihood of remaining in perfect health decreased
255 over time; however the reduction in the number of participants in perfect health in the intervention group (7.4%)
256 was lower than for the usual care group (17.7%). The data also showed that improvement in anxiety/depression
257 was proportionally greater than the other dimensions, especially in the intervention group: 19% reduction in
258 number of participants reporting anxiety problems compared to 1.5% reduction in the usual care group.
259 Participants in the intervention group started from a lower baseline utility on average (0.67 intervention vs 0.70
260 usual care); differences in HRQoL were very small across the 12 month follow-up and the 95% CIs overlap at
261 each time point (Figure 1). At the end of the trial, the difference in QALYs (intervention – usual care) when
262 controlling for baseline utility (for available cases: n=377 intervention vs n=415 usual care) showed a marginally
263 higher QALY gain for the intervention group (0.008 QALY gain; 95% CI -0.009 to 0.026).

264

265 **Cost-effectiveness and uncertainty**

266 The incremental analysis (Table 3) shows that on average, the intervention cost £252.17 more per participant
267 when compared to usual care (95% CI £-69.48 to £589.38); but yields slightly greater benefits, namely 0.012 of
268 a QALY (95% CI -0.00 to 0.03) when adjusted for all covariates (including baseline utility). Therefore, the ICER
269 for the base case analysis was estimated at £19,494 per additional QALY. In order to take uncertainty into account,
270 the paired bootstrapped costs and QALYs were plotted on the cost-effectiveness plane and the corresponding
271 probability that the intervention is more cost-effective than usual care in a cost-effectiveness acceptability curve
272 was presented graphically (Figure 1). The probability of the intervention being cost-effective is 65% at the £30,000
273 NICE WTP threshold. Several sensitivity analyses were undertaken to test the impact of different assumptions
274 about costs and imputation (Table 4). None of these analyses markedly changed the ICER or the probability of
275 cost-effectiveness, except the complete-case which indicated that the Intervention was dominated by usual care.

276

277 **Cost per fall averted**

278 The intervention was both more costly and more effective (mean incremental effect 0.19 falls averted per person
279 year; 95% CI -0.05 to 0.44) than usual care, with an incremental cost per fall averted of £1,253.82 (ICER).

280

281 **HRQoL beyond the trial**

282 At year five the difference in HRQoL between the intervention and usual-care groups observed in the trial was
283 predicted to remain higher for patients allocated to the intervention group (0.0117 QALYs) than the usual care
284 group. The expected incremental cost-effectiveness of the podiatry intervention was £21,460 per QALY gained.

285

286 **DISCUSSION**

287

288 REFORM is the largest study to evaluate the cost-effectiveness of a multifaceted podiatric programme to reduce
289 the risk of falling. Over the 12 month follow up, the podiatric programme cost £252.17 more per participant than
290 usual care, but led to an average improvement of 0.012 QALYs. These findings suggest that the podiatric
291 programme costs £19,494 for every additional QALY gained. Therefore, given the NICE WTP threshold, our
292 base-case results suggest that, on average, the podiatric programme could represent a cost-effective use of NHS
293 resources. However, the uncertainty around the trial estimates means that the probability of the intervention being
294 cost-effective is 65% for a threshold of £30,000 per QALY gained.

295

296 REFORM was a pragmatic trial conducted across ten sites that adhered closely to its novel design (a cohort
297 randomised trial), which aimed to reduce the incidence of attrition, and provided a robust design to evaluate this
298 podiatric intervention. The engagement of participants with the intervention was high, with 84% of intervention
299 participants attending at least one trial podiatry appointment. Intervention participants were asked at 3, 6 and 12
300 months post-randomisation how many times a week they typically undertook the prescribed foot and ankle
301 exercises. At 12 months, compliance with the exercise component was reasonable (29% reported performing the
302 exercises at least three times a week, and 75% at least once a week). An instrumental variable CACE analysis
303 approach was used for the primary trial analysis to account for non-compliance with the intervention (defined as
304 not attending a trial podiatry appointment). In this analysis, the intervention was seen to have a marginally greater
305 effect than in the ITT analysis (incidence rate ratio 0.86, 95% CI 0.69 to 1.06; p=0.16).

306

307 There are a number of potential limitations with our analysis to note. The first caveat relates to the problem of
308 missing data. This is a common problem in trial-based economic evaluations that is amplified where there are
309 frequent assessments, as here. The difficulties in dealing with missing data are driven by the fact that the true
310 mechanism is usually unknown given the observed data. The pattern of missing data was analysed according to
311 economic guidelines to ensure that REFORM data support the main assumption that drives the MI mechanism
312 assumed for our base case analysis. This analysis shows that data is unlikely to be MCAR, which in turn suggest
313 that CC analysis might lead to biased estimates. The analysis also showed that missing data followed a non-
314 monotonic pattern, indicating that even if complete case analysis was unbiased, it would be inefficient as it
315 discards observed data from patients with some missing outcomes. Finally the fact that outcome can be predicted
316 by baseline variables suggest that MI is the best approach for the analysis, as it can handle non-monotonic missing
317 data while incorporating the uncertainty around the unobserved data and maintaining the correlation structure. It
318 is therefore very unlikely that assumptions regarding missing data will change the conclusions of the base case
319 analysis.

320

321 The second limitation relates to the duration of the study, as one year might be considered too short to account for
322 any differences in costs and HRQoL that might be expected with such an intervention. The analysis shows that
323 the podiatry intervention has a positive impact on HRQoL as measured by the EQ-5D, providing improved levels
324 of mobility and anxiety and depression in the intervention group. Furthermore the improvement in anxiety and
325 depression was proportionally greater than the other dimensions. This might be a chance finding but it is possible
326 that the added reassurance of contact with a health professional, or a decreased likelihood of experiencing at least
327 one fall, together with the improved levels of mobility, may have led to a decrease in anxiety in the intervention
328 group. Although cost-effectiveness was demonstrated based on QALYs gained and not necessarily on reducing
329 falls, falls could potentially have a negative effect on patients' HRQoL, and any intervention to improve this is
330 worthy of consideration. In order to account for the limitation related to the duration of the trial we explored how
331 the differences in HRQoL observed in REFORM may evolve beyond the trial. The extrapolation of the within
332 trial HRQoL estimates indicates that the podiatry intervention remains cost-effective at five years. Nonetheless,
333 the value for money of the intervention decreases with time, as this was only a conservative projection that
334 excludes potential costs savings associated with the intervention. It is notable, however, that a large proportion of
335 the intervention costs are incurred during the first year. Furthermore, the mean incremental effect of the
336 intervention (e.g. 0.19 falls averted per person year) observed in the study, which might be interpreted as only
337 slight clinical significance, was obtained with an incremental cost per fall averted of £1,253.82. In terms of value
338 for money, this spending on the care of falls may account for approximately 26 visits to a podiatrist based on
339 current NHS reference costs. This also shows that there are other potential cost savings that can emerge from the
340 trial that make it more likely that the intervention would yield long-term cost savings for the NHS.

341
342 REFORM findings to some extent support those of Spink and colleagues [5], however this study did not include
343 an economic evaluation. To the best of our knowledge there is no evidence that specifically focusses on the cost-
344 effectiveness of podiatry-related programmes in relation to falls prevention. Previously reported economic
345 evaluations have mostly looked at exercise programs founded on the home-based "Otago Exercise Programme"
346 [28-32] which has been proven to be cost-effective in people aged over 80 years. Similarly there is a firm basis
347 to consider exercise programmes as a cost-effective intervention in reducing fall-related injuries among
348 community-dwelling older women [33]. These evaluations have reported cost-effectiveness in terms of cost per
349 fall averted. However there are concerns about the lack of ability of cost-effectiveness analysis to inform decision
350 makers on whether the strategy for fall prevention represents good value for money compared to other health care
351 programmes. Cost-utility analysis, based on QALYs – which capture the value of improvements in morbidity and
352 mobility - can facilitate the comparison of different health care interventions and therefore are the preferred
353 method to guide resource allocation within the health care systems. The results of previous cost-utility analyses
354 have found group-based exercise programmes to be cost-effective for fall prevention for patients at high risk of
355 falling (e.g. previously fallen) [34] and for older women [35]. It is difficult to assess how these economic analyses
356 compare with our analysis as there are essential differences in the methods, interventions and comparators, and
357 populations across studies. However, a Cochrane review looking at falls prevention strategies (none of which
358 were similar to the multifaceted podiatry intervention investigated in REFORM) concluded that, similar to
359 REFORM, there was some evidence that these were cost-saving during the trial period and could be cost-effective
360 over the participants' remaining lifetime [36].

361

362 There is a need to identify cost-effective means for preventing falls to guide appropriate use of limited NHS
363 resources. From this analysis, we conclude that the podiatry programme could represent a cost-effective option
364 within the NHS to reduce the risk of falling among older people. In terms of clinical practice, there is also potential
365 for the cost of the intervention to be further reduced if podiatry assistants rather than the podiatrist undertook the
366 assessment of participant's footwear, and measuring, ordering and fitting of new footwear. However, the
367 differences in benefits between the podiatry intervention and usual care are small and although the intervention is
368 more cost-effective than usual care, decision makers should be aware of the uncertainty associated with our results.
369 Despite the promising results, future research on long term impact of the intervention on HRQoL and costs would
370 strength the results of the current economic evaluation.

371

372 **Acknowledgments**

373 The research team would like to thank the independent members of the Trial Steering/Data Monitoring and Ethics
374 Committee Professor Roger Francis, Dr Sara Brookes, Dr Margaret May, Professor Chris Nester and Dr Ian
375 Mathieson for their advice, overseeing the study and reviewing adverse event data. The research was supported
376 by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research
377 and Care Oxford at Oxford Health NHS Foundation Trust, and supported by the NIHR Biomedical Research
378 Centre, Oxford. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR
379 or the Department of Health.

380

381 **Funding**

382 This project was funded by the NIHR Health Technology Assessment Programme (project number 09/77/01) and
383 will be published in full in the [insert journal title, volume and issue number, if known]. Further information
384 available at: [<http://www.nets.nihr.ac.uk/projects/hta/097701>]. This report presents independent research
385 commissioned by the National Institute for Health Research (NIHR). The views and opinions expressed by authors
386 in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR HTA
387 programme or the Department of Health.

388

389 **Contributors**

390 BC was the trial economist and was responsible for conducting the economic evaluation and produced the first
391 draft of the paper. SC was a co-investigator (co-I) and trial manager. AS contributed to the process evaluation.
392 CF was the trial statistician. CEH was a co-I and lead statistician. KH was a trial coordinator. AMK was a co-I
393 and provided podiatric expertise. SEL was a co-I and falls expert; CM was a co-I and led the Irish centre; HBM
394 was a co-I and Chief investigator from previous trial; ACR was a co-I and podiatry expert; SR was a trial co-
395 ordinator; JW was co-I; DJT was chief investigator and oversaw the conduct of the economic analysis. All authors
396 contributed to the writing of the paper and read and approved the final manuscript.

397

397 **References**

- 398 1. Gill, T., A.W. Taylor, and A. Pengelly, *A population-based survey of factors relating to the*
399 *prevalence of falls in older people*. *Gerontology*, 2005. **51**(5): p. 340-345.
- 400 2. Iglesias, C., A. Manca, and D. Torgerson, *The health-related quality of life and cost implications*
401 *of falls in elderly women*. *Osteoporosis international*, 2009. **20**(6): p. 869-878.

- 402 3. Prudham, D. and J.G. Evans, *Factors associated with falls in the elderly: a community study.* Age and ageing, 1981. **10**(3): p. 141-146.
- 403
- 404 4. Tian, Y., J. Thompson, D. Buck, and L. Sonola, *Exploring the system-wide costs of falls in older*
- 405 *people in Torbay.* London: The King's Fund, 2013.
- 406 5. Menz, H.B., M.E. Morris, and S.R. Lord, *Foot and ankle risk factors for falls in older people: a*
- 407 *prospective study.* The Journals of Gerontology Series A: Biological Sciences and Medical
- 408 Sciences, 2006. **61**(8): p. 866-870.
- 409 6. Mickle, K.J., B.J. Munro, S.R. Lord, H.B. Menz, and J.R. Steele, *Foot pain, plantar pressures, and*
- 410 *falls in older people: a prospective study.* Journal of the American Geriatrics Society, 2010.
- 411 **58**(10): p. 1936-1940.
- 412 7. Hatton, A.L., K. Rome, J. Dixon, D.J. Martin, and P.O. McKeon, *Footwear interventions: a review*
- 413 *of their sensorimotor and mechanical effects on balance performance and gait in older adults.*
- 414 Journal of the American Podiatric Medical Association, 2013. **103**(6): p. 516-533.
- 415 8. Spink, M.J., H.B. Menz, M.R. Fotoohabadi, E. Wee, K.B. Landorf, K.D. Hill, and S.R. Lord,
- 416 *Effectiveness of a multifaceted podiatry intervention to prevent falls in community dwelling*
- 417 *older people with disabling foot pain: randomised controlled trial.* Bmj, 2011. **342**: p. d3411.
- 418 9. Cockayne, S., J. Adamson, A. Clarke, B. Corbacho, C. Fairhurst, L. Green, C.E. Hewitt, K. Hicks,
- 419 A.-M. Kenan, and S.E. Lamb, *Cohort randomised controlled trial of a multifaceted podiatry*
- 420 *intervention for the prevention of falls in older people (the REFORM Trial).* PLoS one, 2017.
- 421 **12**(1): p. e0168712.
- 422 10. Claxton, K., *The irrelevance of inference: a decision-making approach to the stochastic*
- 423 *evaluation of health care technologies.* Journal of health economics, 1999. **18**(3): p. 341-364.
- 424 11. Relton, C., D. Torgerson, A. O'Cathain, and J. Nicholl, *Rethinking pragmatic randomised*
- 425 *controlled trials: introducing the "cohort multiple randomised controlled trial" design.* Bmj,
- 426 2010. **340**: p. c1066.
- 427 12. Cockayne, S., J. Adamson, B.C. Martin, C. Fairhurst, C. Hewitt, K. Hicks, R. Hull, A.M. Keenan,
- 428 S.E. Lamb, and L. Loughrey, *The REFORM study protocol: a cohort randomised controlled trial*
- 429 *of a multifaceted podiatry intervention for the prevention of falls in older people.* BMJ open,
- 430 2014. **4**(12): p. e006977.
- 431 13. National Institute for Health and Care Excellence, *Guide to the methods of technology*
- 432 *appraisal.* 2013: London: NICE.
- 433 14. Manca, A. and S. Palmer, *Handling missing data in patient-level cost-effectiveness analysis*
- 434 *alongside randomised clinical trials.* Applied health economics and health policy, 2005. **4**(2):
- 435 p. 65-75.
- 436 15. Lamb, S.E., E.C. Jørstad-Stein, K. Hauer, and C. Becker, *Development of a common outcome*
- 437 *data set for fall injury prevention trials: the Prevention of Falls Network Europe consensus.*
- 438 Journal of the American Geriatrics Society, 2005. **53**(9): p. 1618-1622.
- 439 16. Dolan, P., C. Gudex, P. Kind, and A. Williams, *A social tariff for EuroQol: results from a UK*
- 440 *general population survey.* 1995: Centre for Health Economics University of York, UK.
- 441 17. Billingham, L., K.R. Abrams, and D.R. Jones, *Methods for the analysis of quality-of-life and*
- 442 *survival data in health technology assessment.* Health technology assessment (Winchester,
- 443 England), 1998. **3**(10): p. 1-152.
- 444 18. Manca, A., N. Hawkins, and M.J. Sculpher, *Estimating mean QALYs in trial-based cost-*
- 445 *effectiveness analysis: the importance of controlling for baseline utility.* Health economics,
- 446 2005. **14**(5): p. 487-496.
- 447 19. Little, R.J. and D.B. Rubin, *The analysis of social science data with missing values.* Sociological
- 448 Methods & Research, 1989. **18**(2-3): p. 292-326.
- 449 20. Carlin, J.B., J.C. Galati, and P. Royston, *A new framework for managing and analyzing multiply*
- 450 *imputed data in Stata.* Stata Journal, 2008. **8**(1): p. 49-67.
- 451 21. White, I.R., P. Royston, and A.M. Wood, *Multiple imputation using chained equations: issues*
- 452 *and guidance for practice.* Statistics in medicine, 2011. **30**(4): p. 377-399.

- 453 22. Rubin, D.B., *Multiple imputation for nonresponse in surveys*. Vol. 81. 2004: John Wiley & Sons.
- 454 23. Van Buuren, S., H.C. Boshuizen, and D.L. Knook, *Multiple imputation of missing blood pressure*
455 *covariates in survival analysis*. *Statistics in medicine*, 1999. **18**(6): p. 681-694.
- 456 24. Faria, R., M. Gomes, D. Epstein, and I.R. White, *A guide to handling missing data in cost-*
457 *effectiveness analysis conducted within randomised controlled trials*. *PharmacoEconomics*,
458 2014. **32**(12): p. 1157-1170.
- 459 25. Johannesson, M. and M.C. Weinstein, *On the decision rules of cost-effectiveness analysis*.
460 *Journal of health economics*, 1993. **12**(4): p. 459-467.
- 461 26. Claxton, K., *Exploring uncertainty in cost-effectiveness analysis*. *Pharmacoeconomics*, 2008.
462 **26**(9): p. 781-798.
- 463 27. Davis, J., M.C. Robertson, T. Comans, and P.A. Scuffham, *Guidelines for conducting and*
464 *reporting economic evaluation of fall prevention strategies*. *Osteoporosis international*, 2011.
465 **22**(9): p. 2449-2459.
- 466 28. Frick, K.D., J.Y. Kung, J.M. Parrish, and M.J. Narrett, *Evaluating the Cost-Effectiveness of Fall*
467 *Prevention Programs that Reduce Fall-Related Hip Fractures in Older Adults*. *Journal of the*
468 *American Geriatrics Society*, 2010. **58**(1): p. 136-141.
- 469 29. Hektoen, L.F., E. Aas, and H. Lurås, *Cost-effectiveness in fall prevention for older women*.
470 *Scandinavian Journal of Social Medicine*, 2009. **37**(6): p. 584-589.
- 471 30. Ontario, H.Q., *The Falls/fractures economic model in ontario residents aged 65 years and over*
472 *(FEMOR)*. *Ontario health technology assessment series*, 2008. **8**(6): p. 1.
- 473 31. Robertson, M.C., N. Devlin, M.M. Gardner, and A.J. Campbell, *Effectiveness and economic*
474 *evaluation of a nurse delivered home exercise programme to prevent falls. 1: Randomised*
475 *controlled trial*. *Bmj*, 2001. **322**(7288): p. 697.
- 476 32. Robertson, M.C., N. Devlin, P. Scuffham, M.M. Gardner, D.M. Buchner, and A.J. Campbell,
477 *Economic evaluation of a community based exercise programme to prevent falls*. *Journal of*
478 *epidemiology and community health*, 2001. **55**(8): p. 600-606.
- 479 33. Patil, R., P. Kolu, J. Raitanen, J. Valvanne, P. Kannus, S. Karinkanta, H. Sievänen, and K. Uusi-
480 Rasi, *Cost-effectiveness of vitamin D supplementation and exercise in preventing injurious falls*
481 *among older home-dwelling women: findings from an RCT*. *Osteoporosis International*, 2016.
482 **27**(1): p. 193-201.
- 483 34. Church, J., S. Goodall, R. Norman, and M. Haas, *The cost-effectiveness of falls prevention*
484 *interventions for older community-dwelling Australians*. *Australian and New Zealand journal*
485 *of public health*, 2012. **36**(3): p. 241-248.
- 486 35. McLean, K., L. Day, and A. Dalton, *Economic evaluation of a group-based exercise program for*
487 *falls prevention among the older community-dwelling population*. *BMC geriatrics*, 2015. **15**(1):
488 p. 33.
- 489 36. Gillespie, L.D., M.C. Robertson, W.J. Gillespie, C. Sherrington, S. Gates, L.M. Clemson, and S.E.
490 Lamb, *Interventions for preventing falls in older people living in the community*. *Cochrane*
491 *Database Syst Rev*, 2012. **9**(11).