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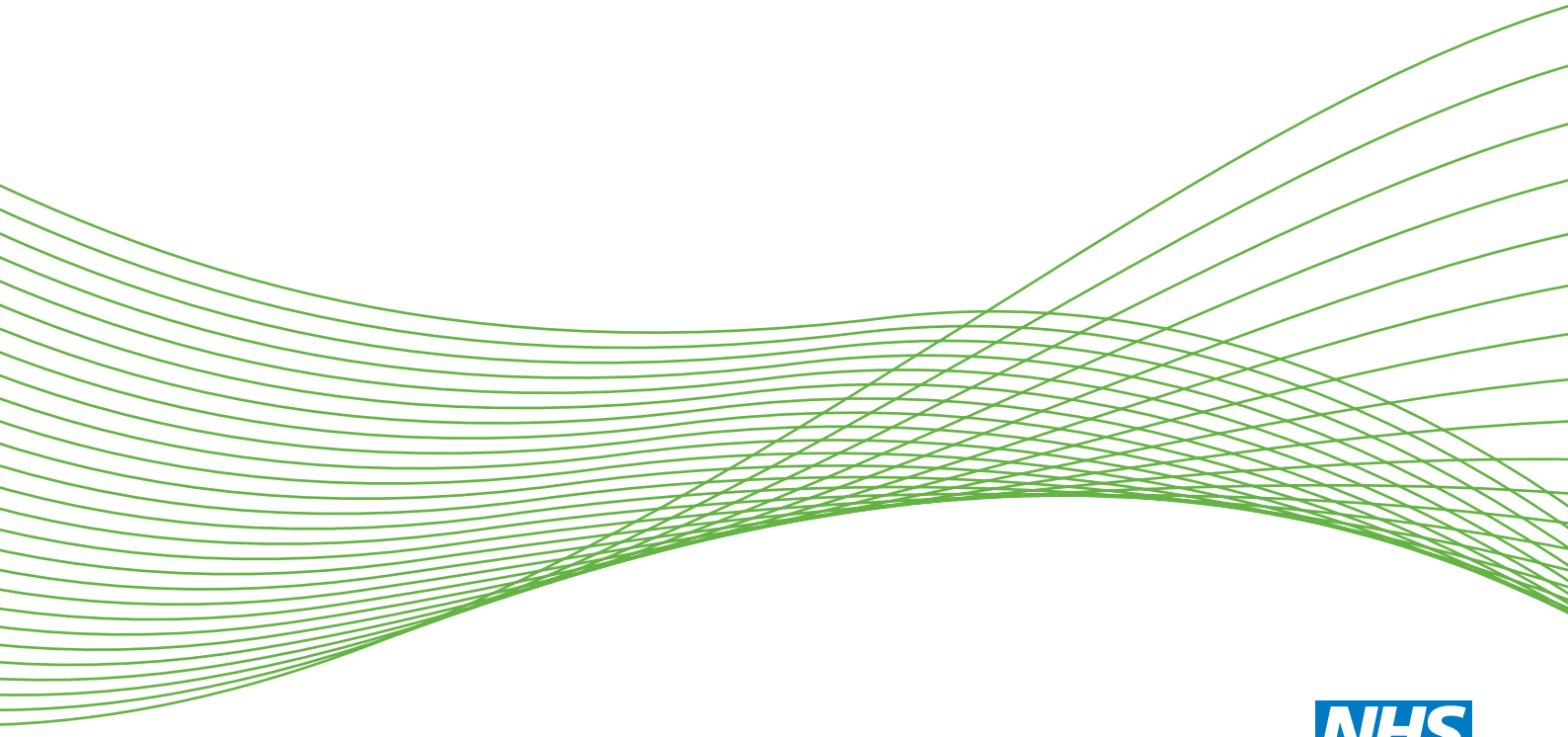

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Abstract

Clinical effectiveness and cost-effectiveness of a multifaceted podiatry intervention for falls prevention in older people: a multicentre cohort randomised controlled trial (the REducing Falls with ORthoses and a Multifaceted podiatry intervention trial)

Sarah Cockayne,[1]* Sara Rodgers,[1] Lorraine Green,[2,3] Caroline Fairhurst,[1] Joy Adamson,[1] Arabella Scantlebury,[1] Belen Corbacho,[1] Catherine E Hewitt,[1] Kate Hicks,[1] Robin Hull,[4] Anne-Maree Keenan,[2,3] Sarah E Lamb,[5] Caroline McIntosh,[6] Hylton B Menz,[7] Anthony Redmond,[2,3] Zoe Richardson,[1] Wesley Vernon,[8] Judith Watson[1] and David J Torgerson[1]

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Background: Falls are a serious cause of morbidity and cost to individuals and society. Evidence suggests that foot problems and inappropriate footwear may increase the risk of falling. Podiatric interventions could help reduce falls; however, there is limited evidence regarding their clinical effectiveness and cost-effectiveness.

Objectives: To determine the clinical effectiveness and cost-effectiveness of a multifaceted podiatry intervention for preventing falls in community-dwelling older people at risk of falling, relative to usual care.

Design: A pragmatic, multicentred, cohort randomised controlled trial with an economic evaluation and qualitative study.

Setting: Nine NHS trusts in the UK and one site in Ireland.

Participants: In total, 1010 participants aged ≥ 65 years were randomised (intervention, $n = 493$; usual care, $n = 517$) via a secure, remote service. Blinding was not possible.

Interventions: All participants received a falls prevention leaflet and routine care from their podiatrist and general practitioner. The intervention also consisted of footwear advice, footwear provision if required, foot orthoses and foot- and ankle-strengthening exercises.

Main outcome measures: The primary outcome was the incidence rate of falls per participant in the 12 months following randomisation. The secondary outcomes included the proportion of fallers and multiple fallers, time to first fall, fear of falling, fracture rate, health-related quality of life (HRQoL) and cost-effectiveness.

Results: The primary analysis consisted of 484 (98.2%) intervention and 507 (98.1%) usual-care participants. There was a non-statistically significant reduction in the incidence rate of falls in the intervention group [adjusted incidence rate ratio 0.88, 95% confidence interval (CI) 0.73 to 1.05; $p = 0.16$]. The proportion of participants experiencing a fall was lower (50% vs. 55%, adjusted odds ratio 0.78, 95% CI 0.60 to 1.00; $p = 0.05$). No differences were observed in key secondary outcomes. No serious, unexpected and related adverse events were reported. The intervention costs £252.17 more per participant (95% CI –£69.48 to £589.38) than usual care, was marginally more beneficial in terms of HRQoL measured via the EuroQoL-5 Dimensions [mean quality-adjusted life-year (QALY) difference 0.0129, 95% CI –0.0050 to 0.0314 QALYs] and had a 65% probability of being cost-effective at the National Institute for Health and Care Excellence threshold of £30,000 per QALY gained. The intervention was generally acceptable to podiatrists and trial participants.

Limitations: Owing to the difficulty in calculating a sample size for a count outcome, the sample size was based on detecting a difference in the proportion of participants experiencing at least one fall, and not the primary outcome. We are therefore unable to confirm if the trial was sufficiently powered for the primary outcome. The findings are not generalisable to patients who are not receiving podiatry care.

Conclusions: The intervention was safe and potentially effective. Although the primary outcome measure did not reach significance, a lower fall rate was observed in the intervention group. The reduction in the proportion of older adults who experienced a fall was of borderline statistical significance. The economic evaluation suggests that the intervention could be cost-effective.

Future work: Further research could examine whether or not the intervention could be delivered in group sessions, by physiotherapists, or in high-risk patients.

Trial registration: Current Controlled Trials ISRCTN68240461.

Funding: This project was funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 21, No. 24. See the NIHR Journals Library website for further project information.

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List of abbreviations

A&E	accident and emergency
CACE	complier average causal effect
CD-RISC2	2-item abbreviated version of the Connor-Davidson Resilience Scale
CEA	cost-effectiveness analysis
CEAC	cost-effectiveness acceptability curve
CI	confidence interval
DVD	digital versatile disc
EQ-5D	EuroQoL-5 Dimensions
EQ-5D-3L	EuroQoL-5 Dimensions, 3 Level
FAI	Frenchay Activities Index
FES-I	Falls Efficacy Scale – International
GDS	Geriatric Depression Scale
GP	general practitioner
HRQoL	health-related quality of life
HTA	Health Technology Assessment
ICER	incremental cost-effectiveness ratio
IRR	incidence rate ratio
ITT	intention to treat
MAR	missing at random
MCAR	missing completely at random
MI	multiple imputation
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NMB	net monetary benefit
OLS	ordinary least squares
OR	odds ratio
PI	principal investigator
QALY	quality-adjusted life-year
RCT	randomised controlled trial
REC	research ethics committee
REFORM	REducing Falls with ORthoses and a Multifaceted podiatry intervention
SAE	serious adverse event
SD	standard deviation
SUR	seemingly unrelated regression
TSC	Trial Steering Committee
WTP	willingness to pay
YTU	York Trials Unit

Plain English summary

Each year, many older people suffer serious injuries from falling. Foot problems and unsuitable footwear increase the risk of falling.

The REducing Falls with ORthoses and a Multifaceted podiatry intervention (REFORM) study aimed to find out if a package of care provided by a podiatrist could reduce the number of falls experienced by people ≥ 65 years old. All 1010 participants were sent a leaflet about how to prevent falls, and 493 participants were also offered the package of care, which consisted of three parts. Participants were given footwear advice and new footwear if their current footwear was thought to be unsuitable. They were also given an orthotic insole or, if they were already wearing an insole, their current insole was reviewed to ensure that it met their clinical needs. Finally, they were given a programme of foot and ankle balance exercises to do at home.

We found a small, but not statistically significant, reduction in the number of falls experienced by participants offered the podiatry package. A lower proportion of participants suffered at least one fall over 12 months in the group offered the podiatry package. The podiatry package is relatively inexpensive and we found that it was reasonable value for money. On the whole, participants liked the podiatry package and the majority of podiatrists thought that it was acceptable and straightforward to deliver but also found some of the programme elements to be time-consuming, such as explaining the foot and ankle exercises and the provision of footwear.

Scientific summary

Background

Falls and fall-related fractures are a serious cause of morbidity and cost to individuals and society. Approximately 30% of people aged ≥ 65 years and 50% of those aged ≥ 80 years living in the community fall each year. The financial cost of injurious falls has been estimated at £2B per annum, which is mainly attributed to hip fractures.

It has been suggested that podiatry care could play a role in falls prevention, as cohort studies have indicated a relationship between risk of falling and both foot and ankle problems and inappropriate footwear. At the time of designing the REducing Falls with ORthoses and a Multifaceted podiatry intervention (REFORM) study, two Cochrane reviews on falls prevention were identified; however, neither included any randomised controlled trials (RCTs) of podiatry interventions. A subsequent update found one Australian RCT that showed a statistically significant reduction in falls in community-dwelling older people with foot pain who had received a multifaceted podiatry intervention (foot and ankle exercises, foot orthoses, footwear advice, subsidy for new footwear and a falls prevention booklet with routine podiatry care) compared with those who received routine podiatry care alone.

Objectives

1. Investigate the clinical effectiveness and cost-effectiveness of a multifaceted podiatry intervention for falls prevention in a UK and Ireland setting.
2. Assess the participants' and podiatrists' views and experiences of the intervention and trial processes.

Methods

Study design

The REFORM study was a pragmatic multicentred cohort RCT with an economic evaluation and embedded qualitative study. This design involved the recruitment of an observational cohort from which eligible, consenting participants were randomised into a RCT. The cohort RCT design offered several possible advantages over the traditional RCT. It was expected that trial recruitment rates would be enhanced, as some participants would be eligible immediately and others could become eligible if they reported a subsequent fall. Under this design, all participants were informed upon enrolment into the cohort that they may at some point be offered a package of podiatry care. This was offered to participants subsequently randomised to the intervention group; however, the usual-care group was not explicitly notified of their allocation to minimise attrition and reporting bias by reducing cases of 'resentful demoralisation'. We also expected that the inclusion of a 'run-in' period in which participants had to return at least one falls calendar before randomisation would reduce post-randomisation attrition rates.

Participant recruitment

Recruitment took place through 37 NHS podiatry clinics in primary or secondary care in nine NHS trusts across the UK and at a university school of podiatry in Ireland. Potential participants were identified via a search of electronic and/or paper medical records of registered patients and were posted a recruitment pack inviting them to take part in the REFORM study.

Exclusion criteria for the REFORM cohort

Participants who returned a background information form and valid consent form were screened for eligibility. Participants were ineligible for the REFORM cohort if they:

1. were < 65 years of age
2. reported having neuropathy, dementia or another neurological condition such as Parkinson's disease, Alzheimer's disease, multiple sclerosis, Lou Gehrig's disease/amyotrophic lateral sclerosis or Huntington's disease
3. were unable to walk household distances (10 metres) without the help of a walking aid such as a walking frame, a walker or a person to assist
4. had had a lower limb amputation
5. were unwilling to attend their podiatry clinic for a REFORM appointment.

Eligible participants were then sent a baseline questionnaire and pack of falls calendars to return each month to indicate if and when they fell.

Inclusion criteria for the REFORM cohort

All eligible consenting participants who completed a baseline questionnaire and at least one monthly falls calendar were included in the REFORM cohort.

While the cohort was being assembled, we invited a selection of participants eligible for the REFORM trial from pilot sites to take part in the internal pilot trial.

REFORM pilot trial objectives

1. Develop and pilot the multifaceted podiatry intervention.
2. Develop the podiatry training package.
3. Pilot the falls calendar and other participant data collection questionnaires.
4. Pilot, review and refine if necessary the recruitment methodology for the main trial.

Inclusion criteria for the REFORM trial

Participants in the cohort were eligible for inclusion in the REFORM trial if they:

1. had had a fall in the past 12 months, or a fall in the past 24 months requiring hospital attention, or reported worrying about falling at least some of the time in the 4 weeks prior to completing their baseline questionnaire
2. were community dwelling
3. were able to read and speak English.

If participants did not report a recent fall on their screening form but later reported a fall on the baseline questionnaire or monthly falls calendar, they became eligible to be randomised.

Sample size

Cohort

We aimed to recruit up to 2600 participants to the REFORM cohort.

Pilot trial

We considered a sample of 70 participants in the pilot trial (35 in each group) to be sufficient to test the objectives.

REFORM trial

The primary outcome measure for the trial was the incidence rate of falls reported by participants over the 12 months post randomisation; however, because of the inherent difficulties of estimating the parameters required to power a trial for a count outcome, the trial was instead powered for the binary outcome of whether

or not the participants experienced at least one fall, which was one of our key secondary outcomes. We retained rate of falls as the primary outcome, as we believed that the extra information contained in this outcome would result in the sample size being conservative for this outcome.

The REFORM trial was therefore designed to detect a 10 percentage point reduction in the percentage of people who fell over a 12-month period. We assumed that, among this high-risk group, 50% of participants in the usual-care group would experience a fall in 12 months. To detect a reduction to 40% in the intervention group, with 80% power, a two-sided 5% significance level and accounting for 10% loss to follow-up, we required 890 participants (445 participants in each group) to be recruited and randomised.

REFORM trial

Randomisation

Clinics informed the York Trials Unit (YTU) of when they had capacity to see trial participants and the number of participants who could be seen. The YTU then randomised a batch of participants in an allocation ratio driven by treatment slot availability. In most instances, participants were allocated 1 : 1 to the intervention or usual-care group; however, in some instances unequal randomisation was used if the clinic had capacity to see more or less than half the batch size.

Trial interventions

All participants continued to receive usual care from their podiatrist and general practitioner and also received a falls prevention advice leaflet.

Intervention group

The intervention group were offered a multifaceted podiatric intervention consisting of footwear advice, footwear provision if required, an orthotic device, foot- and ankle-strengthening exercises and a falls prevention leaflet.

Follow-up

All participants in the REFORM trial were followed up with questionnaires at 6 and 12 months post randomisation and were asked to return monthly falls calendars to indicate if and when they fell. The intervention participants were sent an exercise and orthosis compliance questionnaire at 3, 6 and 12 months.

Primary outcome

The primary end point for the trial was the incidence rate of falls per participant in the 12 months following randomisation as indicated on the monthly falls calendars. A fall was defined as ‘an unexpected event in which the participant comes to rest on the ground, floor or lower level’.

Secondary outcomes

Secondary outcomes included the proportion of fallers and those reporting multiple falls, time to first fall, fear of falling, Short Falls Efficacy Scale – International, Frenchay Activities Index, Geriatric Depression Scale (GDS), depression (as indicated by a score of ≥ 6 on the GDS), the two-item abbreviated version of the Connor–Davidson Resilience Scale (CD-RISC2), foot pain, fracture rate, health-related quality of life (HRQoL) and cost-effectiveness.

Other data collected

Details of the treatment received by intervention participants, and their adherence to the orthoses and exercises, were collected. Any adverse events reported to the YTU were recorded.

Statistical methods

Analyses were conducted using Stata® version 13 (StataCorp LP, College Station, TX, USA) on an available case, modified intention-to-treat (ITT) basis using a two-sided statistical significance level of 0.05. All regression models were adjusted for sex, age and history of falling, with centre as a random effect. The rate of falls was analysed using a mixed-effects negative binomial regression, which took account of the different observation periods for each individual. A complier average causal effect (CACE) analysis to assess the impact of compliance with the intervention on the treatment estimate was undertaken for the primary analysis. The proportion of fallers, and of multiple fallers, was analysed using mixed logistic regression.

Qualitative study

A qualitative study was undertaken via interviews to examine the views and experiences of the podiatrists who delivered the intervention and of the trial participants. Topic guides were developed based on the study's research questions and provided the framework for the interviews.

Sampling strategy and recruitment

The principal investigator (PI) and the podiatrists who delivered the intervention at each site were invited by e-mail to take part.

A purposive sample of 21 trial participants living in Yorkshire and Lincolnshire who indicated that they would be willing to participate in the qualitative interview was sent a patient information sheet and invitation letter in the post.

Interview design

The interviews lasted between 30 and 70 minutes, were semistructured and were conducted face to face, or over the telephone if preferred.

Analysis

Following transcription, the interviews were analysed thematically.

Economic analysis

The economic analysis was conducted on an ITT basis from the NHS and Personal Social Services perspective. Data on HRQoL, obtained from the EuroQoL-5 Dimensions (EQ-5D) instrument, were converted into quality-adjusted life-years (QALYs) for each participant using the area under the curve method. Costs were expressed in UK pounds sterling (£) at 2015 prices.

Differences in mean costs and QALYs at 12 months post randomisation, estimated by means of regression methods, were used to assess the cost-effectiveness of the intervention compared with usual care. Multiple imputation (MI) was used to impute missing cost and QALY data, and the base-case analysis was conducted on this imputed data set. Sensitivity analyses were conducted to test assumptions regarding the missing data mechanism, level of imputation on HRQoL, resource use and perspective of analysis. Cost-effectiveness acceptability curves (CEACs) were used to express the probability of whether or not the intervention is cost-effective at the willingness-to pay threshold used by the National Institute for Health and Care Excellence (NICE).

In addition, HRQoL was extrapolated to 5 years in order to explore how the differences in HRQoL evolve beyond the study follow-up. For this exploratory projection, we used a decision-modelling approach and assumed that the difference in HRQoL and costs observed at 1 year would remain unchanged.

Results

A total of 37,389 recruitment packs were mailed out between October 2012 and August 2014; 3458 (9.2%) were returned with valid screening and consent forms. Eligible participants were sent a baseline

questionnaire and a pack of falls calendars ($n = 2536$); 2301 participants returned a baseline questionnaire and a falls calendar and joined the epidemiological cohort. In total, 1010 participants were randomised to the trial: 493 to the intervention group and 517 to the usual-care group. The primary analysis comprised 991 participants [484/493 (98.2%) in the intervention group and 507/517 (98.1%) in the usual-care group]. There was a non-statistically significant reduction in the incidence rate of falls in the intervention group [adjusted incidence rate ratio (IRR) 0.88, 95% confidence interval (CI) 0.73 to 1.05; $p = 0.16$]. In the CACE analysis, the intervention was seen to have a marginally greater benefit than in the ITT analysis (IRR 0.86, 95% CI 0.69 to 1.06; $p = 0.16$). The proportion of participants experiencing a fall, or multiple falls, was lower in the intervention group [50% vs. 55%, adjusted odds ratio (OR) 0.78, 95% CI 0.60 to 1.00; $p = 0.05$; and 28% vs. 35%, adjusted OR 0.69, 95% CI 0.52 to 0.90; $p = 0.01$, respectively]. No statistically significant differences were observed in any of the other fall-related secondary outcomes. No serious, unexpected and related adverse events were reported.

The base-case economic analysis showed that, over 12 months, the cost of the intervention was, on average, £252.17 higher per participant (95% CI –£69.48 to £589.38) than the cost of usual care but that it was marginally more beneficial in terms of QALYs. The net monetary benefit associated with the intervention is positive, indicating that the resources to be displaced would be smaller than the benefit in QALYs gained if the intervention were implemented in the NHS. The CEAC showed that the intervention has a 65% probability of being cost-effective at the NICE threshold of £30,000 per QALY gained. These findings were robust to sensitivity analyses. When we investigated the likely differences in HRQoL up to 5 years post randomisation, the incremental cost per QALY for the base case ranged between £19,950 at 2 years and £21,406 at 5 years.

Qualitative interviews were conducted with 15 podiatrists and 21 intervention participants. Most podiatrists found the intervention acceptable and straightforward to deliver; however, some raised concerns regarding the implementation of the intervention into routine care. These concerns included the time to measure footwear and deliver the exercise component of the intervention. It was suggested that footwear advice and exercise instruction could be delivered in groups to avoid repetition. Footwear provision for falls prevention is not currently part of routine care; podiatrists felt that adherence to footwear advice/orthotic use would be much reduced given the lack of resources (financial and physical) available to many service users to provide appropriate footwear. Adherence to the three components of the intervention varied across trial participants. At 12-month follow-up, approximately one-quarter of the intervention group were not performing the exercises or wore the orthotic a little or none of the time. Adherence was affected by the comfort of the footwear/orthosis, whether or not the participants could incorporate the elements of the intervention alongside current morbidity problems and whether or not participants perceived there to be a benefit of carrying out the intervention components.

Conclusions

The multifaceted package of podiatry care was seen to be a safe, acceptable and potentially effective intervention in reducing the proportion of older adults who experience a fall over 12 months. Although the primary outcome (incidence rate of falls) did not reach statistical significance, the intervention appeared to be cost-effective in terms of QALYs gained, based on the HRQoL measure, the EQ-5D.

Trial registration

This trial is registered as ISRCTN68240461.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

Chapter 1 Introduction

Burden of falls and falling in the UK

Falls and fall-related fractures are a serious cause of morbidity and cost to individuals and society.[1] This burden is likely to increase owing to an ageing population. Falls are associated with a loss of independence and functional decline, and may result in the need for long-term care.[2] Each year, approximately 30% of people aged ≥ 65 years living in the community will have a fall, and among those aged ≥ 80 years this increases to 50%.[3,4] Older adults who fall once are two to three times more likely to fall again within 1 year. One-fifth of all falls require medical attention, with 5% of falls leading to a fracture.[5] The financial cost of injurious falls has been estimated at £2B per annum, a cost that is mainly attributed to resultant hip fractures.[6] The National Service Framework for Older People highlighted the importance of fall-related injuries and called for health improvement plans to reduce this burden.[7]

Risk factors for falling

It is well recognised that falls occur for a variety of reasons. They may result from interactions between environmental hazards, medical conditions and physiological risk factors.[3] Foot problems, which affect one in three community-dwelling people aged ≥ 65 years,[8] have been associated with reduced walking speed and difficulty in performing activities of daily living. Results from cohort studies have indicated that there is a relationship between foot and ankle problems and risk of falling.[9,10]

In addition to causing foot problems, inappropriate footwear may contribute to poor balance and an increased risk of falling.[11] Footwear characteristics that are considered detrimental to balance include higher heels, soft soles and inadequate slip resistance.[11,12] Prospective studies have shown that walking barefoot, wearing only stockings inside the home and wearing shoes with an increased heel height and smaller contact area all increase the risk of falling.[9,13,14]

Podiatry interventions to improve balance

Given the emerging evidence that foot problems and inappropriate footwear increase the risk of falling, it has been suggested that podiatry may have a role to play in falls prevention, with several guidelines recommending that older people have their feet and footwear examined by a podiatrist.[15,16] Previous studies have looked at treatments that may improve balance in older adults, such as lesion debridement,[17] foot orthoses,[18] foot and ankle exercises[19,20] and footwear advice. Lesion debridement can improve function during gait if pain is reduced, exercise programmes focus on internal strengthening and flexibility, and appropriate footwear fitted with orthotic devices can provide external support, improved kinaesthesia and improved function. Combining these therapies could, therefore, improve function and stability.

At the time of designing the current study there were two published Cochrane reviews on falls prevention. One related to falls in community-dwelling older people[21] and one focused on falls in hospitals and aged care facilities.[22] Neither identified any randomised controlled trials (RCTs) focusing on podiatry-related interventions. A subsequent update identified one Australian trial of a podiatry-based intervention for the prevention of falls.[23] In this study of 305 community-dwelling older people who had foot pain, participants allocated to receive a multifaceted podiatry intervention ($n = 153$) experienced 36% fewer falls than participants in the control group [incidence rate ratio (IRR) 0.64, 95% confidence interval (CI) 0.45 to 0.91; $p = 0.01$]. The intervention comprised foot and ankle exercises, foot orthoses, footwear advice, subsidy for

new footwear and a falls prevention booklet combined with routine podiatry care and was compared with those receiving only routine podiatry. This trial did not include an economic evaluation.

Aims and objectives of the podiatry intervention for podiatry patients at increased risk of falling

The REducing Falls with ORthoses and a Multifaceted podiatry intervention (REFORM) study was funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme in response to a call to evaluate the clinical effectiveness and cost-effectiveness of foot orthoses. Its aim was to establish the clinical effectiveness and cost-effectiveness of a package of podiatric care within a UK health-care setting.

The main objectives of the REFORM study were to:

1. investigate the clinical effectiveness of a multifaceted podiatry intervention for falls prevention
2. investigate the cost-effectiveness of a multifaceted podiatry intervention for falls prevention
3. assess the participants' and podiatrists' views and experiences of the intervention and trial processes.

Chapter 2 Methods

Trial design

The REFORM study was a pragmatic multicentred cohort RCT.[24] We chose this approach to test whether or not the cohort RCT design could address some of the issues that other trial designs encounter with regard to recruitment, attrition and participant preference. We expected that using this design would offer the following advantages. First, trial recruitment rates would be enhanced. Some participants would be immediately eligible for the study and could be randomised straight away and others who subsequently fell over time would become eligible and could also then be randomised. If a traditional trial design had been used, then these additional participants who were not immediately eligible would have been lost. In addition, as we were undertaking an internal pilot, this could be undertaken while recruitment proceeded for the main study. Second, we expected that this design would minimise the possibility of introducing attrition and reporting bias. As participants were receiving routine podiatry care outside the study, the only incentive to take part in the study, apart from altruistic reasons, was the possibility of receiving the intervention. Under this design, all participants were informed upon enrolment into the cohort that they may at some point be offered a package of podiatry care. This was offered to participants subsequently randomised into the intervention group of the RCT; however, the usual-care group were not explicitly notified of their group allocation as they would have been in the classic randomised design. We expected that this would reduce attrition caused by 'resentful demoralisation' and minimise the risk of participants in the usual-care group either knowingly or unknowingly biasing the trial by reporting the number of falls they had experienced less conscientiously than those allocated to the intervention group. Third, we also expected that that the inclusion of a 'run-in' period of falls data collection before randomisation would reduce post-randomisation attrition rates and, therefore, the risk of selection bias. Participants had to demonstrate engagement with the study by returning at least one falls calendar before they were randomised, which enriched the sample with those participants most likely to keep responding.

The cohort RCT design allowed us to test the feasibility of this design and determine whether or not it would enhance recruitment, minimise attrition and lower participant preference effects. It also enabled us to establish a cohort of older adults who could be followed up, thereby helping to inform the knowledge base around health and well-being in older adults. This approach also allowed the possibility for us to invite participants, who had agreed to be contacted again, to take part in future studies.

Participants in the REFORM trial were randomised to receive one of either:

1. a multifaceted intervention consisting of footwear advice (and footwear provision if required), an orthotic insole or review of an existing insole prescription, a programme of foot and ankle balance exercises and a falls prevention leaflet
2. a falls prevention leaflet and usual care from their podiatrist and general practitioner (GP).

Approvals obtained

The study protocol was approved by the East of England – Cambridge East Research Ethics Committee (REC) (multicentre REC) (and substantial amendments) on 9 November 2011 (REC reference number 11/EE/0379). Galway REC approved the study (and substantial amendments) on 26 April 2013 (REC reference number C.A 886). The University of York, Department of Health Sciences Research Governance Committee approved the study (and substantial amendments) on 2 August 2011. Research management and governance approval was obtained for each trust thereafter (see *Appendix 1*).

The trial was registered as ISRCTN68240461 on 1 July 2011.

Study sites

Recruitment of all participants into the study took place through 37 NHS podiatry clinics based in either primary or secondary care in nine NHS trusts across the UK, and at one international site in a university school of podiatry in Ireland. Each participating podiatry clinic was associated with the trust under which it operates, and each trust acted as a trial 'centre', except the Harrogate and District NHS Foundation Trust, which cares for the population of North Yorkshire. As this is a particularly large and diverse area, the clinics in this trust were split into four groups according to their geographical location: Scarborough, York, Harrogate and Skipton. These four groups were also considered as trial 'centres', resulting in a total of 13. The Ireland centre was set up to aid study recruitment. This site was chosen because some of the authors had previously collaborated with this site on another NIHR HTA-funded podiatry study in which recruitment had gone well. The NIHR HTA programme gave permission to include the site.

REFORM observational cohort

The REFORM study was initially designed to include people aged ≥ 70 years; however, following the pilot phase, the age limit was reduced to include adults aged ≥ 65 years (see *Chapter 3*) to facilitate recruitment and reflect the age range seen within the routine podiatry clinics. Participants were first recruited to the REFORM observational cohort. While this cohort was being assembled, we invited a selection of eligible participants from the pilot sites to take part in the internal REFORM pilot trial. After completion of the pilot phase, the remaining eligible participants were invited to take part in the REFORM trial. *Figure 1* reports how participants were recruited to the observational cohort and when they were randomised to the trial.

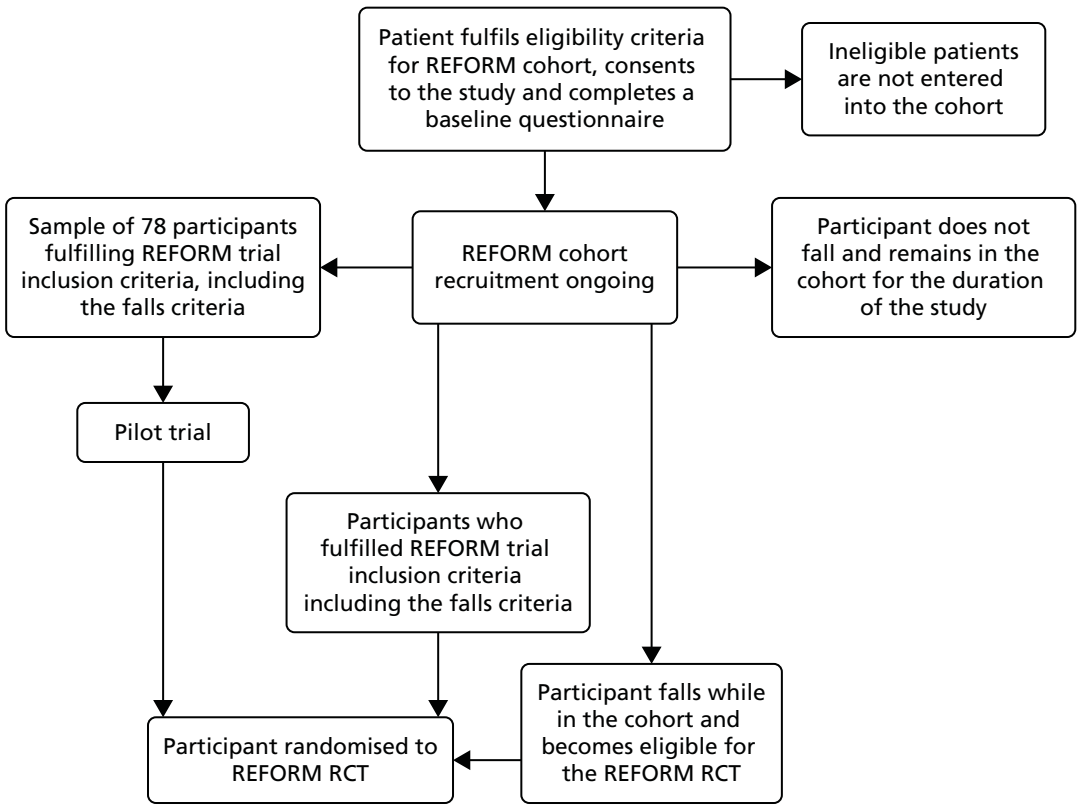

FIGURE 1 Recruitment of participants to the REFORM study.

Participant recruitment

Recruitment of all participants into the study took place through NHS podiatry clinics based in either primary or secondary care in the UK and at one international site in a university school of podiatry in Ireland. The reasoning for recruiting only from podiatry clinics and not from general practices was because of the requirement for all participants to be receiving routine podiatry care so that we could disentangle the effects of the novel intervention from those of routine podiatry care. Recruitment directly from general practices would most probably have identified many patients who were not receiving routine podiatry care. For these patients to have been entered into the REFORM study, they would have to have been receiving routine podiatry care. NHS podiatry service managers informed us that the burden of providing routine podiatry care for all trial participants as well as delivering the intervention would have made the study unfeasible.

Potential participants were identified by either the REFORM research podiatrist or a podiatrist within the clinic undertaking a search of either electronic or paper medical records of patients registered with the service. Two search criteria were used: (1) age $\geq$ 65 years and (2) having attended routine podiatry services within the past 6 months from the date of the search. People living in nursing homes were excluded, as participants had to be community dwelling to be eligible for the study. At the time of undertaking the search, it was not possible to easily identify those patients with neuropathy who would be ineligible for the study. Therefore, to minimise the risk of approaching these patients, those who had attended high-risk clinics, for example diabetes mellitus clinics, were excluded from the search. Potential participants were invited to participate in the REFORM study by their podiatry clinic via a postal recruitment pack. This pack comprised an invitation letter (see *Appendix 2*) electronically signed by the principal investigator (PI) at the site, a consent form (see *Appendix 3*), a participant information sheet (see *Appendix 4*), a background information form (see *Appendix 5*) and a prepaid return envelope addressed to the York Trials Unit (YTU). During the pilot phase of the study, a decline form (see *Appendix 6*) was also included so that data could be collected on people's reasons for declining to participate. No identifiable data were available to the study teams until a participant had returned their consent and background information forms.

To aid recruitment, the opportunistic screening of patients attending routine podiatry clinics was undertaken when clinics had capacity to do so. Potential participants were given the recruitment pack and verbal information about the study.

Potential participants who wished to take part in the REFORM study returned their completed consent and background information forms by post to the YTU. The research team assessed the forms for eligibility.

Consenting participants

Participation in the REFORM study was voluntary. Participants who wished to take part were given written information about the study and contact details for the research team should they have had any queries about the study. The participants were asked to complete a consent form to indicate that they wished to take part in the study. The qualitative researcher obtained consent for the qualitative study either face to face or, for interviews conducted over the telephone, by post.

At the consent stage, participants were informed about the opportunity to participate in other related studies. Participants were informed about the 'possibility' of being offered an additional podiatric intervention for the prevention of falls and were asked to tick a box if they were interested in taking part in such an intervention. If participants did not wish to be contacted about these studies, they were asked to indicate this by ticking a box on the consent form.

Baseline assessment

On receipt of written consent, researchers at the YTU assessed the participants' responses on the background information forms for eligibility. Participants assessed as being ineligible for the study were notified in writing and no further correspondence was sent. Participants who were deemed eligible were then sent a baseline questionnaire (see *Appendix 7*) and a pack of falls calendars (see *Appendix 8*).

Participant eligibility

Exclusion criteria for the REFORM cohort

Participants were ineligible for the REFORM cohort if they:

1. were > 65 years of age
2. reported having neuropathy, dementia or another neurological condition such as Parkinson's disease, Alzheimer's disease, multiple sclerosis, Lou Gehrig's disease/amyotrophic lateral sclerosis or Huntington's disease
3. were unable to walk household distances (10 metres) without the help of a walking aid, such as a walking frame, a walker or a person to assist
4. had had a lower limb amputation
5. were unwilling to attend their podiatry clinic for a REFORM appointment.

Inclusion criteria for the REFORM cohort

All eligible consenting participants who completed a baseline questionnaire and at least one monthly falls calendar were eligible for inclusion in the REFORM cohort.

Inclusion criteria for the REFORM trial

Participants in the cohort were eligible for inclusion in the REFORM trial if they:

1. had had a fall in the past 12 months, or a fall in the past 24 months requiring hospital attention, or reported worrying about falling at least some of the time in the 4 weeks prior to completing their baseline questionnaire
2. were community dwelling
3. were able to read and speak English.

If participants did not report a recent fall on their screening form but later reported a fall on the baseline questionnaire or monthly falls calendar, they became eligible to be randomised.

REFORM internal pilot

An internal pilot was conducted at the start of the study. The objectives of the pilot trial were to:

1. develop and pilot the multifaceted podiatry intervention
2. develop the podiatry training package
3. pilot the falls calendar and other participant data collection questionnaires
4. pilot, review and refine if necessary the recruitment methodology for the main trial.

In order to progress to the main REFORM trial, the study team were asked by the NIHR HTA monitoring team to fulfil the following progression criteria by the end of November 2013:

1. Recruit 580 participants to the REFORM cohort study.
2. Randomise 70 participants to the REFORM pilot trial.
3. Decide which orthotic insole would be used in the main trial.

Sample size

Pilot sample size

The pilot phase of the study ran from October 2012 until November 2013. No formal sample size calculation was conducted but we aimed to randomise at least 70 participants into the pilot trial (35 in each group), which we believed to be sufficient to test the objectives.

REFORM trial sample size

The primary outcome measure for the trial was the incidence rate of falls reported by the participants over the 12 months post randomisation. This was analysed using a mixed-effects negative binomial regression model. However, because of the inherent difficulties of estimating the parameters required to power a trial for a count outcome, such as the IRR to detect and the measure of overdispersion, the trial was instead powered for the binary outcome of whether or not the participants experienced at least one fall, which was one of our key secondary outcomes. We retained incidence rate of falls as the primary outcome as we believed the extra information contained in this outcome would result in the sample size being conservative for this outcome.

A previous falls prevention trial conducted by some of the authors in community-dwelling older adults with a history of recent falls found a 12% absolute reduction in the proportion of participants who fell among those allocated to receive an environmental falls prevention intervention delivered by qualified occupational therapists, relative to the control group.[25] The REFORM trial was powered at 80% using a two-sided 5% significance level to detect a more conservative absolute difference of 10 percentage points from 50% to 40% in the number of people experiencing at least one fall over the 12 months following randomisation. The total sample size required, allowing for a 10% loss to follow-up, was 890 participants (445 in each group).

Randomisation

Participants who fulfilled the eligibility criteria for the REFORM trial and who had provided written informed consent and indicated that they were interested in receiving the intervention were eligible for randomisation. Randomisation was carried out by the YTU secure remote computer randomisation service. Trial clinics informed the YTU when they had capacity to schedule baseline appointments for participants and how many participants they felt that they could manage to schedule appointments for at that time. A group of participants waiting to be randomised from the centre associated with that clinic were selected and randomised in a single block (mainly) 1 : 1 to either the intervention or usual-care groups; however, when clinics had the capacity to see more or less than half the group size, an appropriate alternative allocation ratio was used. Prediction of allocated group by clinician was not possible because of the dynamic nature of the randomisation and the use of a remote service; thus, allocation concealment was maintained. Once intervention participants had been randomised, they were sent a letter informing them of their group allocation and that the podiatry clinic would be in contact to arrange a trial appointment. Participants who were allocated to the usual-care group were not informed of their group allocation in order to minimise potential attrition and the possibility of resentful demoralisation.

Trial interventions

Intervention group

Participants in the intervention group were allocated to receive a multifaceted intervention comprising footwear advice (and footwear provision if required), an orthotic insole or review of an existing prescription, a programme of foot and ankle balance exercises and a falls prevention leaflet. The trial protocol recommended that participants be invited to attend two appointments: the first as soon as possible after randomisation and the second 2–4 weeks later. Further trial visits could be offered if required, in addition to routine podiatry care appointments in accordance with usual practice.

Footwear advice and provision

Participants were asked to bring their indoor and outdoor footwear to their REFORM appointment. The podiatrist assessed the following characteristics of the participant's footwear that have been identified in the literature as risk factors for falls in older people:[12] correct size, method of fastening, height and width of the heel, thickness of outsole, heel counter stiffness, longitudinal sole rigidity, sole flexion point and tread pattern. Footwear was assessed as inappropriate if it had any of the following characteristics: (1) heel height > 4.5 cm, (2) no adjustable fixation of the upper, (3) no heel counter or a heel counter that could be depressed to > 45°, (4) a fully worn/smooth/thin sole, (5) heel width narrower than the participant's heel width by ≥ 20% or (6) incorrect shoe size. Participants were counselled about any hazardous footwear features identified during the assessment and advised on safer footwear characteristics to select when purchasing footwear in the future.

If a participant's footwear was deemed inappropriate, and they did not own a suitable pair of shoes that they could be advised to wear instead, new footwear was provided where possible. The podiatrists ordered footwear directly from one of two companies participating in the Healthy Footwear Guide scheme:[26] DB shoes (DB Shoes Ltd, Rushden, UK) or Hotter company (Beaconsfield Footwear Limited, Skelmersdale, UK). Not all of the footwear manufactured by these companies fulfil the characteristics of a 'safe' shoe; therefore, participants chose footwear from a catalogue of preselected makes and models that the trial team had previously assessed as being suitable. In order to avoid incentivising participants to take part in the study, participants were told about footwear provision only if they were assessed as requiring new footwear.

Foot orthoses

Participants were considered for fitting with an X-Line standard orthotic insole (Healthystep, Mossley, UK). If required, the insole was modified with prefabricated self-adhesive additions to improve the participant's foot posture. For those participants already wearing an orthotic insole, the treating podiatrist made a clinical judgement on the suitability of replacing the insole with one used in the trial. If the participant's current insole was replaced, then any current prescription or modifications were repeated. If, however, the podiatrist deemed it to be detrimental to replace their current insole with that of the trial insole, then the participant continued to wear their own insole and this component of the intervention was considered to be addressed. In cases in which the treating podiatrist felt that the participant required more or a prescription that the trial insole could not provide, then a referral was made in line with routine practice.

Participants were advised to 'wear-in' the orthotic insole slowly. It was suggested that it should be worn for 1 hour on the first day and wear time increased by a few hours each day, and that the insole could be transferred from one pair of shoes to another.

Home-based foot and ankle exercise programme

When safe and appropriate, participants were prescribed a 30-minute home-based foot and ankle exercise programme to be undertaken three times a week, indefinitely. The aim of the exercises was to stretch and strengthen the muscles of the foot and ankle and improve balance. The exercises were based on the programme developed by Spink *et al.*,[23] which had been adapted for a UK and Irish setting during the pilot phase of the study. A summary of the individual exercises is listed in *Table 1*. The podiatrist assessed competence and safety at the baseline appointment through demonstration and participant repetition of the exercises. These were supplemented by an explanatory illustrated booklet and a digital versatile disc (DVD), which the participant took home along with the resistive bands and therapy ball that were required to undertake the exercises. At subsequent appointments the podiatrists reviewed the participant's exercise techniques and, when required, advised the participant to ensure that the exercises were being conducted safely and as intended.

Routine podiatry care

Participants continued to receive routine podiatry care as separate podiatry appointments in accordance with usual practice. The aim of these appointments was to reduce painful conditions such as corns and calluses that have been found to be associated with an increased risk of falls.

TABLE 1 Summary of the home-based foot and ankle exercises

Activity	Description	Dosage	Increments
Ankle range of motion/warm-up	Sitting, with the knee at 90°. Lift the foot to clear the ground and then rotate the foot slowly in a clockwise direction and then an anticlockwise direction	1 × 10 repetitions for each foot in each direction	None
Ankle inversion strength	Sitting upright, with the hip, knee and ankle at 90°. Invert foot against resistive exercise band. The band should be fixed at 90° to the foot from an additional chair/table leg	3 × 10 repetitions for each foot	Increase resistance strength of resistive exercise band
Ankle eversion strength	Sitting upright, with hip, knee and ankle at 90°. Evert foot against resistive exercise band. The band should be fixed at 90° to the foot from an additional chair/table leg	3 × 10 repetitions for each foot	Increase resistance strength of resistive exercise band
Ankle dorsiflexion strength	Sitting, with hip, knee and ankle at 90°. Dorsiflex both feet to end range of motion and hold. Keep pulling feet up towards the body during the hold	Hold feet in dorsiflexion for 3 × 10 seconds	Increase repetitions up to a maximum of 10
Intrinsic strengthening, toe plantarflexion strength and toe stretch	Sitting, with hip, knee and ankle at 90°. (1) Use the therapy ball under the toes to stretch the toes. The rest of the foot should be plantigrade. Then curl and point the toes up and over the ball. (2) Use the therapy ball under the toes to stretch the toes. The rest of the foot should be plantigrade. With the heel on/close to the floor, curl the toes over the ball and attempt to pick up the ball with the toes	3 × 10 repetitions for each exercise for both feet. Have a 30-second break between each repetition	Increase up to a maximum of 50 repetitions
Ankle plantarflexion strength	From standing position, rise up onto toes of both feet and then slowly lower back down. Just before the heels contact the floor, rise back up onto the toes	3 × 10 repetitions	Increase repetitions up to a maximum of 50
Calf stretch	Facing a wall and using hands on the wall for balance, step one foot in front of the other keeping feet hip width apart and hips, knees and feet facing the wall. Bend the knee closest to the wall and keep the back leg straight. Keep both heels in contact with the floor	Hold stretch for 3 × 20 seconds on each leg	Increase the stride length and forward lean to increase the stretch
Proprioception/ balance training	From a standing position and holding on to a work surface/chair/wall for support, stand on one leg. Repeat on the other side	Hold for 30 seconds, repeat for three repetitions	Increase slowly to hold for 1 minute per repetition. If competent, rise up on to toes on the one supporting leg: 3 × 10 repetitions

Podiatrist training to deliver the intervention

The podiatrists delivering the trial intervention attended a half-day face-to-face training session facilitated by the research podiatrist (author LG). The training included instructions on the delivery of the individual components of the intervention including footwear assessment and provision, prescribing and fitting trial insoles and prescribing foot and ankle exercises. Podiatrists were given the opportunity to practice delivering the intervention during role-play sessions. In addition, information about the day-to-day management of podiatry tasks, for example booking appointments or ordering footwear, adverse event reporting and completion of trial paperwork, was provided. When possible, the research podiatrist attended the first participant appointment delivered by each podiatrist to give advice on the delivery of the intervention when requested.

Falls prevention leaflet and trial newsletter

Participants were sent a falls prevention leaflet in the post along with their baseline questionnaire. Participants living in the UK received the Age UK *Staying Steady* leaflet[27] and those in Ireland received the Irish Osteoporosis Society *Fall Prevention* leaflet.[28]

A postal group-specific trial newsletter was sent to participants at 3 months post randomisation, as well as a generic trial newsletter at 12 months. The aim of the newsletters was to keep participants updated with the progress of the trial in an attempt to minimise attrition and improve response rates to postal questionnaires.[29] The 3-month newsletter to the intervention group also included information about how to undertake the foot and ankle exercises and wear the insoles and it aimed to aid compliance. It included anonymised quotations reporting the benefit some participants had experienced after following the package of care. The content of the newsletter was informed by issues raised by participants with the research team during the course of the trial.

Usual-care group

Participants in the control group continued to receive usual care from their podiatrist and GP, which may have included prescription of an orthosis and footwear advice. They also received the same falls prevention advice leaflet sent to the intervention participants and a group-specific trial newsletter at the same time points.

Participant follow-up

All participants in the REFORM trial were followed up with monthly falls calendars for 12 months post randomisation. If a participant did not return their falls calendar after 10 days, a member of the study team telephoned or wrote to them to collect the primary outcome data. The study team contacted participants who had reported a fall to collect further information relating to the nature, cause and location of the fall (see *Appendix 9*). Participants were also sent follow-up questionnaires at 6 (see *Appendix 10*) and 12 months (see *Appendix 11*) post randomisation. Follow-up questionnaires were posted to participants, along with a pre-addressed envelope, and reminder letters were sent after 2 and 4 weeks if unreturned. Participants also received an unconditional £5 in cash with their 12-month postal questionnaire in recognition of their participation in the study and to offset any incidental expenses that they may have incurred when completing postal questionnaires. Telephone follow-up by one of the study team's researchers was conducted 2 weeks after the second postal reminder for any participant who had not returned a questionnaire to complete the primary outcome data as a minimum. In addition, intervention participants were sent an exercise and orthosis compliance questionnaire at 3, 6 and 12 months (see *Appendix 12*). Any change in the participant's trial status during the course of the study was recorded by the study team (see *Appendix 13*). Data collection ceased in December 2015.

Trial completion and exit

Participants were deemed to have exited the trial when they:

1. had been in the trial for 12 months post randomisation
2. withdrew from the trial, that is, they wished to exit the trial with no further contact for follow-up or treatment
3. were lost to follow-up
4. died.

Withdrawals

Withdrawals could occur at any point during the study at the request of the participant. The reason for their withdrawal did not have to be declared; however, if a reason was provided, then it was recorded. Participants could inform the trial team of their decision to withdraw from the study by contacting them either by telephone or in writing. When possible, a researcher would clarify to what extent they wished to withdraw: from the intervention only or from all aspects of the study. Treating podiatrists could also withdraw participants from the intervention or from all aspects of the trial when they felt that this was appropriate. When withdrawal was from the intervention only, follow-up data continued to be collected. Data were retained for all participants, unless a participant specifically requested that their details be removed.

Patient and public involvement in research

The REFORM trial was informed by the involvement of older people with a history of falls throughout the research period. A patient reference group was established at the start of the study. The group comprised four older people who provided valuable insights into the relevance and readability of the study documentation and advice regarding recruitment methods. They provided input into the content and layout of the patient information sheet, the exercise booklet, newsletters and recruitment posters. They reviewed the exercise DVD and the package of care, and provided feedback on the selection of footwear offered to participants. The patient reference group contributed to this HTA report by reviewing the plain English summary and they will provide guidance about our dissemination strategies on how best to share the study findings with trial participants.

Clinical effectiveness

Primary outcome

The primary end point for the trial was the incidence rate of falls per participant in the 12 months following randomisation. A fall was defined as 'an unexpected event in which the participant comes to rest on the ground, floor, or lower level'.[30] Data were collected via participant self-reported monthly falls calendars. These took the form of A5 pieces of card with a calendar grid of individual months printed on one side along with a definition of a fall and a freepost address to the YTU on the other. Participants were asked to record the day of the month on which they fell or to record that they did not fall that month and return the calendar to the YTU. Participants who did not return their monthly falls calendar were either telephoned or written to by the YTU to obtain the missing data. Participants were also given a freephone number to report any falls as soon as possible after they occurred, and these were recorded by research staff on a falls telephone data collection sheet (see *Appendix 9*). The information collected included the date and location of fall, the reason for the fall, any injuries sustained (e.g. a superficial wound or a broken bone), hospital admissions, the footwear worn at the time of the fall and if the participant was wearing an insole or using a walking aid.

Secondary outcomes

All secondary outcomes were self-reported by the participant and collected by questionnaires at 6 and 12 months post randomisation or by monthly falls calendars. Secondary outcomes include:

1. proportion of fallers (at least one fall and multiple falls)
2. time to first fall from date of randomisation
3. incidence rate of falls in 12 months post randomisation as recorded on the 6- and 12-month participant questionnaires
4. fear of falling as measured by the question 'During the past 4 weeks have you worried about having a fall?' at 6 and 12 months
5. fear of falling as measured by the Short Falls Efficacy Scale – International (FES-I) at 6 and 12 months[31]
6. activities of daily living as measured by the Frenchay Activities Index (FAI) at 6 and 12 months[32]
7. depression as measured by the short form Geriatric Depression Scale (GDS) at 6 and 12 months[33]
8. proportion of participants with depression (score of ≥ 6 on GDS) at 12 months
9. adaptability and resilience as measured by the 2-item abbreviated version of the Connor-Davidson Resilience Scale (CD-RISC2) at 6 months[34]
10. level of pain in the feet as measured on a visual analogue scale from 0 (no pain) to 10 (worst possible pain) at 12 months
11. fracture rate (single and multiple)
12. health-related quality of life (HRQoL) as measured by the EuroQoL-5 Dimensions-3 Levels (EQ-5D-3L)[35]
13. health service utilisation.

Scoring of instruments

Fear of falling

Fear of falling was measured by the question 'During the past 4 weeks have you worried about having a fall?' at screening and baseline and at 6 and 12 months. Response categories were all of the time, most of the time, a good bit of the time, some of the time, a little of the time and none of the time. These were scored from 1 to 6 and were treated as continuous data for analysis.

Short Falls Efficacy Scale – International

The Short FES-I asked participants at baseline and at 6 and 12 months to indicate how concerned they were about falling when performing seven different activities: not at all concerned, somewhat concerned, fairly concerned or very concerned. These were scored from 1 to 4, and a total score for the Short FES-I was obtained by summing the seven item scores. When a participant selected two or more responses to an item, this was treated as missing data. If data were missing on two or more items then the questionnaire was considered invalid. If data were missing on no more than one of the seven items then the total score was calculated for the six completed items, divided by six and multiplied by seven. The new total score was then rounded up to the nearest whole number.[31] A final total score of 7 or 8 indicates no/low concern, 9–13 indicates moderate concern and 14–28 indicates a high degree of concern about falling.

Frenchay Activities Index

This 15-item instrument was administered at baseline and at 6 and 12 months and assessed a broad range of activities of daily living. The frequency with which each item or activity was undertaken over the previous 3 or 6 months (depending on the nature of the activity) was assigned a score of 1–4, where a score of 1 is indicative of the lowest level of activity (e.g. never performed). The scale provides a summed total score from 15 to 60. When a participant selected two or more responses to an item, this was treated as missing data. Only when there were no missing item responses was a total score computed for an individual for this instrument.

Geriatric Depression Scale

The GDS is a 15-item scale used as a screening tool for geriatric depression and was administered at baseline and at 6 and 12 months. Each item requires a 'yes' or 'no' response. A score of 1 is assigned when the item response indicates a negative state of mind, for example responding 'no' to 'Are you basically satisfied with your life?'. A total score out of 15 can be calculated. When a participant selected both 'yes' and 'no', the worst-case scenario was assumed and a score of 1 was assigned to the item. More than five missing item responses invalidated the scale; otherwise, a total score when there were missing data was calculated by summing the item scores, dividing by the total number of completed items and multiplying by 15. The new total score was then rounded up to the nearest whole number to give the score for an individual (https://web.stanford.edu/~yesavage/GDS.html). A score of 0–5 is considered normal, whereas a score of > 5 suggests depression. Any participant reporting a score of ≥ 10 on the GDS,[33,36] that is, more severe depression, was referred to their GP.

The two-item abbreviated version of the Connor-Davidson Resilience Scale

The CD-RISC2 is a two-item abbreviated version of the full 25-item Connor-Davidson Resilience Scale. It is based on items 1 ('I am able to adapt to change') and 8 ('I tend to bounce back after illness or hardship') of the original instrument. Each item is scored from 0 ('not true at all') to 4 ('true nearly all the time'), so the CD-RISC2 can be scored from 0 to 8. Higher scores reflect greater 'bounce-back' and adaptability. This instrument was administered at baseline and at 6 months.

Other data collected

Non-consenting participants

Participants who did not wish to take part in the study were not required to return any forms to the YTU; however, some chose to complete the screening form, thus providing us with some demographic information. In addition, all participants in the pilot phase of the study were sent an invitation pack that included a decline form, so that if they were willing they could provide a reason for declining. This provided us with sufficient information to document the reasons why participants did not wish to take part in the study, and allowed us to compare participants who declined with those who participated. The recruitment pack in the main study did not contain a decline form.

Intervention: details and adherence

Treatment details were recorded by the podiatrist, including the number of podiatry visits, an eligibility checklist with details on relevant health conditions and test results, characteristics of current indoor and outdoor shoes, details relating to shoes ordered, details on the type and prescription of any current insole use, the type of insole issued/retained with any modifications made, details of the size of any therapy ball and the strength of any resistive band prescribed and any amendments or advice given on the intervention owing to safety reasons.

Information on adherence to the exercise, footwear advice and orthotic insole components of the intervention was collected from participant self-reported questionnaires at 3, 6 and 12 months from participants in the intervention group only. Participants were asked if, during the past month, they had worn their insole all of the time, most of the time, some of the time, a little of the time or none of the time. Participants were also asked, for the past month, typically how many times a week they had done the exercises: not at all, once, twice, three times or more than three times. In addition, all participants were asked on the 12-month follow-up questionnaire if they had been given footwear advice by the trial podiatrist and whether or not they had followed the advice given.

Adverse events

Details of any adverse events reported to the YTU directly by the participant, a member of their family or by a member of the research team at the recruiting site were recorded. Details of the event were recorded

on a REFORM Adverse Event Form (see *Appendix 14*). Any serious adverse events (SAEs) judged to have been related and unexpected were required to be reported to the REC under the current terms of the standard operating procedures for RECs.

In this study, a SAE was defined as any untoward occurrence that:

1. resulted in death
2. was life-threatening
3. required hospitalisation or prolongation of existing hospitalisation
4. resulted in persistent or significant disability or incapacity
5. consisted of a congenital anomaly or birth defect
6. was otherwise considered medically significant by the investigator.

Expected events included aches and pains in the lower limb, new callus/corn formation, blisters or ulcers and skin irritation/injury including pressure sores and soft tissue injury.

The occurrence of adverse events during the trial was monitored by an independent Data Monitoring Ethics Committee and the Trial Steering Committee (TSC). The Data Monitoring and Ethics Committee/TSC would have immediately seen all SAEs that were thought to be related to treatment.

Clinical effectiveness analysis

All analyses were conducted on a modified intention-to-treat (ITT) basis using available cases, using a two-sided statistical significance level of 0.05 unless otherwise stated. The analyses were conducted using Stata® version 13 (StataCorp LP, College Station, TX, USA).

Data collected at screening and on the baseline questionnaire are summarised for (1) consenting individuals and those who assented to provide screening data but not to enter the trial, (2) the cohort and (3) trial participants as randomised and as analysed in the primary outcome model by treatment group. Comparisons between groups were made using chi-squared tests for categorical data, independent *t*-tests for continuous variables and negative binomial regression for count data.

Primary analysis

The primary analysis model controlled, as fixed effects, for sex (coded 0 = female, 1 = male), age at randomisation in years (integer) and history of falling. All participants had to have fallen at least once in the previous 12 months, have had a fall in the last 24 months requiring hospitalisation or have a fear of falling in order to be eligible for randomisation. Participants were classified into two groups for the history of falling covariate: (1) one or no falls in the 12 months prior to completion of the background information sheet; or (2) two or more falls reported in the 12 months prior to completion of the background information sheet. These were coded as 0 and 1, respectively.

As there was evidence of overdispersion in the data, Poisson regression was not considered to be appropriate, and so the incidence rate of falls was analysed using a mixed-effects negative binomial regression model. Participants recruited from the same centre, and therefore residing in a particular geographical area, are more likely to be similar to one another than to participants from other centres. This can result in a correlation between participant outcomes within centres. Failure to account for this clustering of outcomes in the analysis can lead to an increase in the type 1 error rate. Therefore, to account for the potential correlation of participant outcomes from participants in the same centre, we included trial centre ($n = 13$) as a random effect in the model. The model also took account of the different observation periods for each individual by including a variable for the number of months for which the participant returned a monthly falls calendar (using the *exposure* option within the Stata command).

The model equation is:

$$E(y_{ij}) = t_{ij}\exp[\beta_0 + \beta_1(\text{Sex} = \text{Male}) + \beta_2(\text{History of falling} = \text{Yes}) + \beta_3(\text{age at ramdomisation}) + \beta_4(\text{Allocation} = \text{Intervention})], \quad (1)$$

where

- $E(y_{ij})$ is the expected number of falls for participant i in centre j in time t_{ij}
- t_{ij} is the length of exposure (follow-up) for participant i in centre j
- β is a vector of fixed-effect regression coefficients and
- $\exp(\beta)$ is a vector of the IRRs.

Coefficients are presented as IRRs with 95% CIs and *p*-values.

Sensitivity analyses

A sensitivity analysis of the primary outcome was conducted, adjusting for any pre-randomisation variables found to be imbalanced by chance between the randomised groups.

Non-compliance

A complier average causal effect (CACE) analysis to assess the impact of compliance on the treatment estimate was undertaken for the primary analysis. CACE analysis allows an unbiased treatment estimate of, in this case, the podiatry intervention in the presence of non-compliance. It is less prone to biased estimates than the more commonly used approaches of per protocol or 'on treatment' analysis, as it preserves the original randomisation and uses the randomisation status as an instrumental variable to account for the non-compliance. The CACE analysis employed a two-stage regression process: first, compliance with the intervention was predicted using a linear mixed model adjusted for randomised group, sex, age and history of falling, with centre as a random effect; and, second, the primary analysis model was repeated but the variable for group allocation was replaced with the variable for compliance and the predicted residuals from the first regression was added as a covariate.

Compliance was based on whether or not the participant was seen in clinic for a trial appointment; therefore, all participants in the usual-care group and those in the intervention group who did not attend an appointment were assigned a compliance value of 0 and those in the intervention group who attended an appointment were assigned a value of 1. As this was a multifaceted intervention, it did not make sense to try and measure the extent to which participants used the orthotic insole, performed their prescribed exercises or wore their provided footwear. This would have been measured with too much error.

Excluding fear of falling participants

Over the course of the trial, it was observed that having a fear of falling was a strong predictor of having a fall in the near future. A protocol amendment was submitted to, and approved by, the REC to include 'fear of falling' as an inclusion criterion. Therefore, a small number of participants in the cohort were randomised into the trial who reported a fear of falling on their baseline form but who had not reported a previous fall. On advice from the TSC and the HTA programme, the trial over-recruited to make up for the number of participants recruited using the fear of falling criterion. A sensitivity analysis was conducted excluding these 'fear of falling' participants from the primary analysis to determine their effect on the estimates.

Missing data

We compared data collected prior to randomisation for participants who are included in the primary analysis to ensure that any attrition had not produced imbalance in the groups in important covariates. To account for any possible selection bias, univariate logistic regressions were run to predict missing outcome data. As the number of participants who did not return any falls calendars after randomisation was low, missing outcome data were based on returning fewer than 6 months' worth of data post randomisation. All variables found to be predictive of missingness were then included in a single stepwise logistic regression

model, which used a *p*-value of 0.1 to refine the covariates. The primary analysis was then repeated including as covariates the variables found to be significantly predictive of non-response to determine if this affected the parameter estimates.

Podiatrist effects

In 6 of the 13 sites, only one podiatrist delivered the intervention; therefore, podiatrist effects are to some extent captured by centre effects that are being accounted for in the primary analysis. However, in other sites, more than one podiatrist delivered the intervention to the participants. We therefore have potential clustering by podiatrist in the intervention group that is not completely captured by centre. The success of the intervention may depend on the skill/experience of the podiatrist and their relationship with the participant. To account for this variation between podiatrists, a sensitivity analysis was conducted in which every participant, whether allocated to the intervention or usual-care group, was associated with a podiatrist. For intervention participants, this podiatrist was the podiatrist who delivered their intervention appointments. For usual care participants or intervention participants who did not attend an appointment, we assigned them a counterfactual podiatrist, that is, one that they could have seen had they received the intervention. All participants at sites with only one trial podiatrist were assigned this podiatrist.
In sites with more than one trial podiatrist, the participants were randomly assigned one of the podiatrists who saw participants who were randomised in the same month as them, in the proportion that they saw intervention participants. Each podiatrist then had their own cluster of usual care and intervention participants. The primary analysis was then repeated with podiatrist, rather than centre, as a random effect.

Secondary analyses

The incidence rate of falls over the 12 months following randomisation (as reported for the previous 6 months on the 6- and 12-month participant questionnaires) was analysed in the same way as the primary outcome.

The proportion of fallers versus non-fallers, and of multiple fallers versus single or non-fallers, in each group was compared using a mixed logistic regression model adjusting for sex, age and history of falling, with centre included as a random effect.[37]

The time from randomisation to first fall in days was derived. Participants who did not have a fall were censored at their date of death or, if alive, their withdrawal from the trial, the date of the last available assessment or 365 days after randomisation, whichever was latest. Kaplan–Meier survival curves were produced for each group. The time to first fall was analysed by a Cox proportional hazard regression with shared centre frailty effects adjusting for sex, age and history of falling.[38]

Fear of falling in the past 4 weeks, and the total scores for the Short Falls Efficacy Scale – International, GDS and FAI were compared between the two groups using a covariance pattern mixed model incorporating all post-randomisation time points (6 and 12 months) adjusting for baseline score, sex, age, history of falling, treatment group, time and a treatment group-by-time interaction term, with centre as a random effect. Such an approach models the correlation of observations within participants over time. Different covariance structures for the repeated measurements, which are available as part of Stata version 13 (unstructured, exchangeable, independent and banded), were explored and the most appropriate pattern used for the final model based on the Akaike's information criterion (smaller values are preferred).[39] Participants were included in the model if they had full data for the baseline covariates and outcome data for at least one post-randomisation time point (6 or 12 months). An estimate of the difference between treatment groups in the outcome was extracted for each time point with a 95% CI and *p*-value.

The assumptions of the covariance pattern mixed model were checked visually. The normality of the standardised residuals was assessed via a histogram and Q–Q plot, and the homoscedasticity of the errors was checked by plotting the residuals against the fitted values.

The CD-RISC2 score at 6 months was compared between the two groups using a linear mixed model adjusting for baseline CD-RISC2 score, sex, age and history of falling, with centre as a random effect.

Participants with a score of ≥ 6 on the GDS were categorised as having depression; the proportion of people with depression in each group was compared at 12 months using a mixed logistic regression model adjusting for sex, age and history of falling, with centre as a random effect.

The proportion of participants obtaining at least one fracture over the 12-month follow-up period was compared using a mixed logistic regression adjusting for sex, age and history of falling, with centre as a random effect.

At 12 months, participants were asked to indicate their level of pain or discomfort in their feet on a visual analogue scale from 0 (no pain) to 10 (worst possible pain). This was analysed using a linear mixed model adjusting for sex, age and history of falling, with centre as a random effect in an ITT analysis, and also in a CACE analysis. We based compliance on whether or not the participant was seen in clinic for a trial appointment. The CACE analysis employed a two-stage regression process: first, compliance with the intervention was predicted using a linear mixed model adjusting for randomised group allocation, sex, age and history of falling, with centre as a random effect; and second, foot pain score was predicted using a linear mixed model adjusting for compliance, sex, age, history of falling and the predicted residuals from the first regression, with centre as a random effect.

Economic analysis

The economic analysis was conducted on an ITT basis from the NHS and Personal Social Services perspective. Data on HRQoL, obtained from the EuroQoL-5 Dimensions (EQ-5D) instrument collected from self-reported questionnaires, were converted into quality-adjusted life-years (QALYs) for each participant using the area under the curve method. Costs were expressed in UK pounds sterling (£) at 2015 prices.

Differences in mean costs and QALYs at 12 months post randomisation, estimated by means of regression methods, were used to assess the cost-effectiveness of the intervention compared with usual care. Multiple imputation (MI) was used to impute missing cost and QALY data, and the base-case analysis was conducted on this imputed data set. Sensitivity analyses were conducted to test assumptions regarding the missing data mechanism, level of imputation on HRQoL, resource use and perspective of analysis. Cost-effectiveness acceptability curves (CEACs) were used to express the probability of whether or not the intervention is cost-effective at the willingness-to-pay (WTP) threshold used by the National Institute for Health and Care Excellence (NICE).

In addition, HRQoL was extrapolated to 5 years in order to explore how the differences in HRQoL evolve beyond the study follow-up. For this exploratory projection, we used a decision-modelling approach and assumed that the difference in HRQoL and costs observed at 1 year would remain unchanged.

Qualitative study

A qualitative study was undertaken to explore the views, experiences and acceptability of the REFORM package of care from the perspective of both service users and service providers. In particular, this qualitative study considered the barriers to and facilitators of delivering and receiving the intervention, in the context of podiatry care. An in-depth appreciation of these issues is useful for the future successful implementation of complex podiatry interventions in this population group.

Design

A semistructured interview study was used to gather in-depth information on the trial participants' experiences of receiving the podiatry intervention, alongside the podiatrists' experiences of delivering the intervention. The interviews were conducted either face to face or over the telephone with participants and podiatrists in the trial (at the end of the intervention period).

Sampling

A purposive sampling strategy was used to achieve a hetergeneous sample of trial participants from the intervention group to ensure maximum variation[40] according to age, sex and history of falls. Previous studies have indicated that a sample of approximately 20–30 trial participants is sufficient to address the aforementioned aims from the point of view of the service users.

As podiatrists delivering the intervention were based in a wide variety of clinics, it was expected that their views and experiences may differ. For example, some podiatrists worked in biomechanics and others worked in routine podiatry clinics. All 28 podiatrists who delivered the REFORM intervention were invited for interviews through the PI at each site.

Recruitment and consent

All REFORM trial participants living in the Yorkshire or Lincolnshire areas who expressed an interest in undertaking other associated REFORM research studies on the consent form and who had received the intervention were eligible for participation in the qualitative study. Following sampling, study participants were approached by letter, which contained an information sheet (see *Appendix 15*) and two consent forms (see *Appendix 16*). The letter also informed trial participants that a qualitative researcher (authors AC and SC) would contact them via telephone to find out if they would be willing to take part and, if so, to arrange a time for the interview to take place. In accordance with ethics guidelines, informed consent was gained by the researcher before the commencement of the interview. The aim of the interview was explained to the participant, and this was followed by an opportunity for them to ask questions about the study. The anonymity and confidentiality of participants' personal information were assured by the researcher.

Podiatrists were also invited to take part in the qualitative interviews. The PI at each site was sent an e-mail asking if he or she and the podiatrists who delivered the intervention would like to be interviewed. The PI was asked to forward the e-mail on to podiatrists at their site who delivered the intervention. Podiatrists were asked to contact the research team directly if they wished to take part. The recruitment e-mail included an invitation, information sheet (see *Appendix 17*) and consent form (see *Appendix 18*). This was followed up by a telephone call or an e-mail. Prior to the interviews, podiatrists were assured anonymity and confidentiality and were given the opportunity to ask questions. For podiatrists interviewed face to face, a similar process to that used to obtain consent for trial participants was used. For interviews conducted over the telephone, verbal consent was obtained prior to the start of the interview and a copy of the consent form was sent to the qualitative researcher either in the post or via e-mail.

Data collection

The semistructured interviews with trial participants were carried out in participants' homes or at the University of York between November 2013 and March 2016 and on average lasted 40 minutes using a topic guide (see *Appendix 19*). All interviews were audio-recorded, transcribed and anonymised before data analysis.

The semistructured interviews with podiatrists were carried out between July 2015 and January 2016 in a private room on premises where the podiatrist was based or over the telephone. The interviews lasted between 30 and 70 minutes and were conducted using a topic guide (see *Appendix 20*).

The topic guides provided a framework for the semistructured interviews and ensured that all podiatrists and trial participants were asked the same questions, allowing comparisons to be made during the analysis. However, the wording of questions was not fixed to allow interviews to flow and to allow for probing when more detail was required.

Data analysis

An initial thematic analysis was carried out using the stages as outlined by Braun and Clarke:[41] (1) familiarisation, (2) generating initial codes, (3) searching for themes, (4) reviewing themes, (5) defining and naming themes and (6) data reporting. An initial coding framework was developed based on a priori themes relating to issues included in the topic guide while allowing for emergent themes. Descriptive coding was conducted, following familiarisation with the data, by the main qualitative researcher on the project (author SC), informed by regular discussion with the qualitative team (authors JA and AC). Subsequently, initial codes were refined in order to address the aims of the qualitative study outlined above, following the analysis of the main trial. A constant comparison method[42] was used to check and compare across the data set and to establish appropriate analytical categories. This also ensured that any additional codes were added to reflect as many of the nuances or outlier views in the data as possible, taking into consideration the participants' wider contexts. Anonymised participant identifiers are used for the reporting of results.

To promote quality, the following strategies were used: description of the participants to provide context (credibility and transferability), transparency of the research process (transferability), evidence of consistency using multiple examples from data (dependability) and engagement of the wider research team with interim findings (confirmability). In addition, a reflexive approach was taken to data analysis. The main interviewers (authors SC and AC) were academic research fellows with no podiatry training. SC was the main REFORM trial co-ordinator and AC had no prior knowledge or experience of podiatry interventions, orthotic insoles or RCTs. The other member of the qualitative team (author JA) had an academic research background and also did not have previous knowledge or experience of podiatry care. This placed the qualitative research team in a very neutral position relating to any prior expectations relating to the study intervention.

Chapter 3 Protocol changes

Clarification to trial documentation and collection of data

Following review of the trial documentation in March 2012, we decided to simplify the participant self-report question regarding neuropathy status. Participants were asked to report if they had any numbness or tingling in their feet or lower limbs as opposed to being asked if they had neuropathy. This was because it was felt that participants may not have known that they had neuropathy but would be able to report if they had numbness or tingling in their lower limbs. Baseline data regarding referrals to a falls service were also collected.

Following completion of the pilot study, it was felt that sufficient data had been collected about the reasons why potential participants did not wish to take part in the study. To reduce the postage costs for the study and on advice of the patient representative, who expressed concerns about this additional data collection, it was agreed that data on reasons for declining participation in the study would not be collected in the main study.

To minimise participant burden and to improve data collection, it was agreed that qualitative data from participants could be collected over the telephone and that information regarding exercise and orthosis compliance would be collected via postal questionnaire at 3, 6 and 12 months post randomisation rather than by the completion of an exercise diary.

Amendments were made to the participant information sheet and consent form in August 2012 to clarify that not all participants would be offered an additional podiatry visit.

Recruitment

The original protocol stated that we planned to recruit 1700 participants to the REFORM cohort, of whom we would randomise 890 to the REFORM trial over a 24-month period from three NHS trusts (Harrogate, Sheffield and Leeds). However, the study commencement was delayed by approximately 5 months because of contractual issues and delays in obtaining service support costs for the study and research and development approval. As the trial progressed, recruitment fell below the expected level because, in the main, a lower than expected uptake rate to the study by participants and a lower than expected number of eligible participants expressing an interest in taking part. Approval was obtained from the funder to extend the study by 10 months to a total of 52 months (December 2011 to March 2016). This permitted the recruitment of seven additional sites. The details of the recruiting sites and date on which research governance approval was received can be found in *Appendix 1*.

With the number of eligible participants lower than expected, the number of participants in the REFORM cohort had to be increased from 1700. It was decided to aim to recruit 2600 participants into the cohort. To assist with recruitment, approval was obtained to implement the opportunistic screening of participants by podiatrists in clinics, falls practitioners, physiotherapists and the research podiatrist.

Inclusion criteria

The following changes were made to the eligibility criteria during the study.

1. Responses on the 'decline forms' received from participants who did not wish to take part in the study during the pilot phase indicated that participants declined because they assumed that they would not be eligible as they considered themselves either too old or too ill. The participant information sheet was modified to try and address this concern stating that, in effect, no one was 'too old' to take part and having a chronic illness did not necessarily exclude people from participation. In addition, the TSC reviewed the age limit and agreed to a change from $\geq$ 70 years to $\geq$ 65 years, as it was felt that younger participants may also potentially benefit from the intervention. It was hoped that this change would increase the size of the eligible population and improve recruitment. An amendment to reduce the age limit of participants in the study was approved by the multicentre REC in February 2013.
2. Responses from the screening forms sent out during the pilot phase indicated that participants were being excluded as they were already wearing an insole. In order to aid recruitment the TSC agreed that as the trial was evaluating a multifaceted intervention and not insoles on their own, from February 2013 patients could be included if they were currently wearing a full or three-quarter length insole for the purpose of altering or modifying foot function. For participants allocated to the intervention group who were already wearing an orthotic insole, the treating podiatrist made a clinical judgement on the suitability of replacing the insole with one used in the trial. Usual care participants continued to wear their insole but may have had a new insole prescribed by their podiatrist as part of their routine care.
3. To minimise post-randomisation attrition rates, participants had to demonstrate their commitment to the study by returning three falls calendars before they could be randomised. This was thought to cause considerable delay in participants being randomised at new sites. Therefore, to aid recruitment, in April 2013 the need to return a minimum of three falls calendars was reduced to a minimum of one.
4. We undertook an analysis of the predictors of falling in those participants who had been recruited to the study but were in the 3-month 'run-in' phase, so were yet to be randomised. As expected, those who reported having had a previous fall were at a higher risk of falling during the run-in period than those who had not [odds ratio (OR) 2.4]. We also observed that those who reported having a fear of falling on their baseline questionnaire were at an elevated risk (OR 2.1). In a previous trial of fracture prevention, a similar relationship was found: fear of falling is a risk factor nearly as strong as a history of falls.[43] Following advice from our TSC and the funders, it was agreed that from June 2014 an additional inclusion criterion (i.e. fear of falling) could be used at clinics that had the capacity to see participants but did not currently have any participants eligible under the current criteria. We felt that this would improve the generalisability of the study and aid recruitment.

To enhance participant safety, it was agreed that, from February 2015, participants should be excluded from the study if they:

1. Had a lower limb amputation.
2. Were unable to walk household distances without the help of a walking aid such as a walking frame, a walker or a person to assist. Participants who used one walking stick, however, were still eligible for the study.

Orthoses

In the original protocol, we intended to use the same orthotic insole (Formthotics™, Foot Science International, Sockburn, New Zealand) used by one of the authors (HBM) in an Australian study,[23] as it was found to be acceptable to participants and had been associated with a reduction in falls. However, during the setup of the pilot phase of the study, podiatrists at the recruiting sites reported difficulties using Formthotics, particularly in relation to fitting and modifying. Feedback from a group of podiatrists at recruiting sites indicated that they frequently used an alternative range of orthotic insoles called the

'X-Line range', as they were reportedly easier to fit in participant's current shoes and easily modifiable. In addition to basic functional foot support and control, cushioning properties were also identified as desirable. Therefore, during the pilot phase of the study, 31 participants were given both a Formthotics and an X-Line insole to take home and wear; they were then questioned about their insole preference. As the majority of participants (84%, 26/31) preferred the X-Line range, it was decided to use it in the main trial instead of the Formthotics insole.

Exercises

The exercises developed by one of the authors (HBM) for his Australian trial were reviewed and adapted to take on board lessons learned from the study and to make them more suitable for a UK population. Owing to cost and safety reasons the use of the Archxerciser™ device (Elgin Archxerciser Foot Exercisers, Elgin Division, IL, USA) and marbles were replaced with a therapy ball, which simplified the toe exercises using one device, reflecting current UK practice. Standing calf stretch exercises were adapted for an older UK population by providing an option to use a firm belt/band to stretch while in a sitting position. A further proprioception/balance training exercise was also added.

Additional criteria to expected adverse events

Following discussion with the Trial Management Group it was decided to include some additional expected adverse events relating to wearing an orthotic insole or undertaking foot- and ankle-strengthening exercises to the protocol. These included aches and pains in the lower limb for longer than 48 hours, new callus/corn formation, blisters or ulcers, skin irritation/injury including pressure sores and soft tissue injury.

Provision of footwear

In the original protocol participants were to be provided with a voucher allowing them to purchase their new footwear from participating designated shoe shops. However, this system became unworkable as the number of sites increased and sites became more geographically dispersed. Participants therefore chose their footwear from a catalogue of footwear reviewed and compiled by the research team for suitability. These were then ordered directly from the company by the podiatrist. Footwear that did not fit the participant could be returned to the supplier and exchanged for a different size.

Chapter 4 Clinical effectiveness results

Participant flow

Participants were enrolled into the REFORM study from nine NHS trusts based in either primary or secondary care in the UK (Harrogate and District NHS Foundation Trust; Sheffield Teaching Hospitals NHS Foundation Trust; Leeds Community Healthcare NHS Trust; Solent NHS Trust; Kent Community Health NHS Foundation Trust; Humber NHS Foundation Trust; Northern Lincolnshire and Goole NHS Foundation Trust; South Tyneside NHS Foundation Trust; and North Tees and Hartlepool Hospitals NHS Foundation Trust) and one international site in a university school of podiatry in Galway, Ireland. Harrogate and District NHS Foundation Trust was split into four geographical locations, which were considered to serve distinct populations (Scarborough, York, Harrogate and Skipton), thus forming 13 trial centres. A total of 42 podiatry clinics consented to screen their practice lists and identify participants who met the initial inclusion criteria: those aged $\geq$ 65 years who were registered with the service and had attended routine podiatry services within the past 6 months. Patients who had attended high-risk clinics (e.g. a diabetes clinic) or who lived in a nursing home were excluded from the invitation mail-out. In addition, sites were requested to screen out, when possible, patients in the following groups: patients with a life expectancy of < 6 months, patients known to have dementia, a neurodegenerative disorder, neuropathy or a lower limb amputation, and patients who were chair or bed bound.

A total of 37,389 recruitment packs were mailed out to potential participants between October 2012 and August 2014: 4428 background information forms (screening forms) were returned to the YTU, of which 3458 (78.1%) were also sent back with a valid consent form. Consenting participants were screened for eligibility to the cohort and potentially eligible participants were sent a baseline questionnaire and a pack of falls calendars ($n = 2536$). Of the 2389 participants who returned a baseline questionnaire, 88 did not ever return a falls calendar; the remaining 2301 participants joined the epidemiological cohort. Within the cohort, 990 participants were immediately eligible to be randomised, as they reported that they had had at least one fall in the previous 12 months, or one fall in the previous 24 months requiring hospitalisation; 750 of these went on to be randomised into the main trial (participants could be randomised only as and when there was capacity at the clinic to schedule them a baseline appointment). A further 234 participants were randomised after a subsequent fall, and 26 participants were randomised when the eligibility criteria were widened to include participants who had not had a fall but reported a fear of falling. A median of 47 participants were recruited from each centre (range 20–323).

Patents were mostly randomised 1 : 1, although at some sites the ratio was fixed depending on the number of participants the clinic had capacity to see and the number of participants available to be randomised. Of the 1010 participants randomised, 493 were allocated to the intervention group and 517 to the usual-care group. The randomised number of 1010 participants exceeded that of the planned sample size of 890 participants. The flow of participants is illustrated in a Consolidated Standards of Reporting Trials (CONSORT) diagram in *Figure 2*.

Pilot trial

During the pilot phase of the study, the following quantitative progression criteria were imposed to permit continuation to the main trial: (1) recruit 580 participants to the REFORM cohort study and (2) randomise 70 participants to the REFORM pilot trial. By the end of November 2013, 972 participants had been recruited to the REFORM cohort, and 78 had been randomised (39 participants per group) from York and Scarborough podiatry clinics.

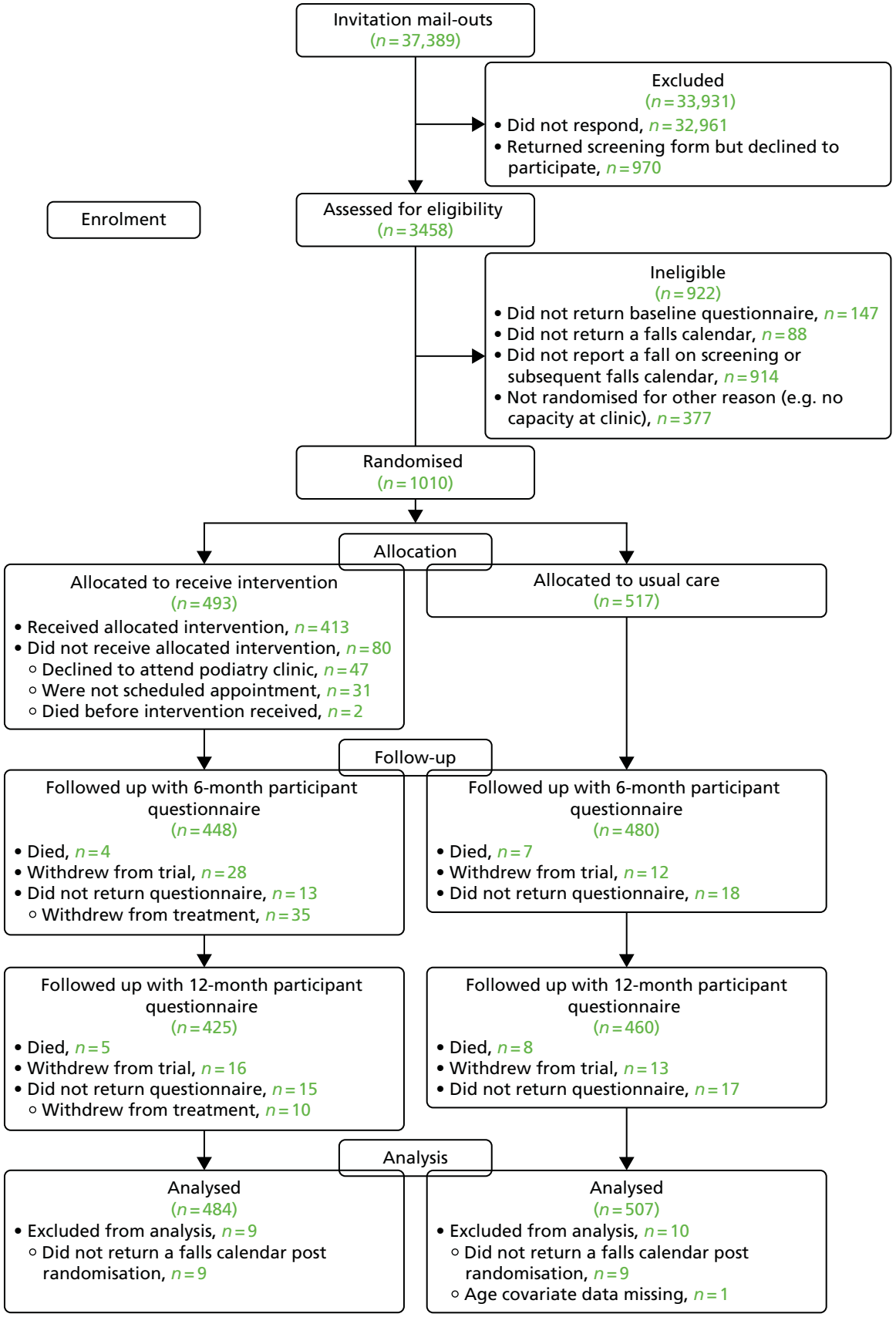

FIGURE 2 Consolidated Standards of Reporting Trials (CONSORT) flow diagram of participants in the REFORM study. Reproduced from Cockayne *et al.*[44] This is an open access article distributed under the terms of the Creative Commons Attribution Licence (CC BY 4.0), which permits unrestricted use, distribution and reproduction in any medium, provided the original author and source are credited (https://creativecommons.org/licenses/by/4.0/).

Reasons for non-participation

In total, 567 potential participants provided a reason on a decline form for their decision not to participate in the study (*Table 2*). The most commonly cited reason was not having an interest in the study ($n = 330$, 58.2%). Many of the 'other' reasons stated by participants could potentially fall into one of the other three broad categories and included the participant feeling too old/unwell to take part, having too many other commitments (e.g. being a carer to a partner) or feeling they would be unsuitable for the study as they do not fall. Collection of this form ceased after the pilot phase of the study.

Trial completion and trial exit

Participants were able to withdraw from the study at any point. They were offered the options of withdrawing from the intervention only or from all aspects of the study. Data were retained for all participants who withdrew, as no participant specifically requested that their details be removed. Of the 493 (9.1%) participants in the intervention group, 45 (9.1%) formally withdrew from treatment, 38 (7.7%) withdrew fully from the trial, 17 (3.5%) were withdrawn by the podiatrist, and there were 9 (1.8%) reported deaths (including one participant who died shortly before they were randomised but whose death was only reported later). These withdrawals were not necessarily mutually exclusive: six participants who withdrew from treatment later went on to fully withdraw from the trial and one of the participants who died had previously withdrawn from treatment. In the usual-care group, 28 out of 517 (5.4%) participants withdrew from the trial and 15 out of 517 (2.9%) participants died (mutually exclusive participants). When reasons for withdrawal were provided, these were grouped into common categories, which are listed in *Table 3*.

Timing of follow-up and response

The median time between completion of the screening form and baseline questionnaire for participants in the entire cohort was 38 days. Owing to the study design, there was often a delay between completion of the baseline questionnaire and randomisation (median 152 days, range 2–584 days). The timing of the 6- and 12-month participant questionnaires was based on the date of randomisation. Time between randomisation and completion of the 6- and 12-month participant questionnaires and the time between when the questionnaires were sent and returned is presented by randomised group in *Table 4*.

Questionnaire return rates by randomised group

The return rates for participant questionnaires administered at 6 and 12 months post randomisation and exercise and orthosis diaries administered to intervention participants only at 3, 6 and 12 months are presented in *Table 5*. The 'expected' columns take into account participants who withdrew or died before the questionnaire was due to be completed. Response rates were consistently high in this trial; overall, 885 participants (87.6% of randomised participants) returned the 12-month participant questionnaire.

TABLE 2 Reasons for non-participation from the decline form (pilot phase only)

Reason for non-participation[a]	Frequency (%)
I am not interested in taking part in this study	330 (58.2)
I feel too unwell to take part in this study	167 (29.5)
I do not have time to take part in this study	137 (24.2)
Other reason	107 (18.9)

a Participants could select more than one reason.

TABLE 3 Details of full withdrawal from the trial by participant, full withdrawal by podiatrist (intervention group only) and withdrawal from treatment (intervention group only)

Participation in the trial	Treatment group, *n* (%)		
	Intervention (*N* = 493)	Usual care (*N* = 517)	Total (*N* = 1010), *n* (%)
Full participation	438 (88.8)	489 (94.6)	927 (91.8)
Withdrew from trial	38 (7.7)	28 (5.4)	66 (6.5)
Ill health	15 (3.0)	11 (2.1)	26 (2.6)
Relative is ill	3 (0.6)	0 (0.0)	3 (0.3)
Too busy	1 (0.2)	2 (0.4)	3 (0.3)
Feels cannot contribute/study is not relevant to them	2 (0.4)	3 (0.6)	5 (0.5)
Other	4 (0.8)	0 (0.0)	4 (0.4)
No reason given	13 (2.6)	12 (2.3)	25 (2.5)
Podiatrist withdrew participant from trial	17 (3.5)	–	–
Neuropathy in feet or poor mobility	9 (1.8)	–	–
Ill health	3 (0.6)	–	–
No reason given	5 (1.0)	–	–
Withdrawal from treatment	45 (9.1)	–	–
Ill health/mobility issues	12 (2.4)	–	–
Problem with intervention[a]	7 (1.4)	–	–
Declined to attend baseline appointment	5 (1.0)	–	–
Does not attend routine podiatry care	3 (0.6)	–	–
Too busy	3 (0.6)	–	–
Moved out of area	2 (0.4)	–	–
Clinic too far away	2 (0.4)	–	–
No reason given	11 (2.2)	–	–

a Prefers other exercises; shoes gave participant cellulitis; participant received insole and footwear from another podiatrist; caused increased pain (*n* = 2); shoes too large and hurt feet; and participant not suitable for exercise.

TABLE 4 Timing of follow-up and time to response to participant questionnaires by randomised group

Time in days between time points	Treatment group					
	Intervention (*N* = 493)		Usual care (*N* = 517)		Total (*N* = 1010)	
	Mean (SD)	Median (minimum, maximum)	Mean (SD)	Median (minimum, maximum)	Mean (SD)	Median (minimum, maximum)
Completion of baseline questionnaire and randomisation	175.0 (133.3)	149 (2, 544)	183.1 (135.5)	161 (5, 584)	179.1 (134.4)	152 (2, 584)
Randomisation and completion of 6-month participant questionnaire	198.0 (13.8)	194 (180, 294)	196.5 (14.3)	193 (174, 279)	197.2 (14.0)	193 (174, 294)
Sent and returned dates for 6-month participant questionnaire	16.4 (13.0)	13 (5, 111)	14.9 (14.4)	12 (4, 126)	15.6 (13.7)	12 (4, 126)
Randomisation and completion of 12-month participant questionnaire	376.9 (13.0)	373 (359, 467)	375.9 (13.0)	372 (337, 465)	376.4 (13.0)	373 (337, 467)
Sent and returned dates for 12-month participant questionnaire	13.6 (10.0)	11 (4, 101)	12.1 (10.0)	10 (1, 147)	12.8 (10.0)	11 (1, 147)

SD, standard deviation.

TABLE 5 Questionnaire return rates for randomised participants by treatment group

	Treatment group, *n* (%)					
	Intervention (*N* = 493)[a]		Usual care (*N* = 517)[a]		Total (*N* = 1010), *n* (%)[a]	
Questionnaire	Expected	Received	Expected	Received	Expected	Received
Questionnaire						
6 months	461 (93.5)	448 (97.2)	498 (96.3)	480 (96.4)	959 (95.0)	928 (96.8)
12 months	440 (89.2)	425 (96.6)	477 (92.3)	460 (96.4)	917 (91.8)	885 (96.5)
Intervention diary						
3 months	476 (96.6)	457 (96.0)	–	–	–	–
6 months	461 (93.5)	427 (92.6)	–	–	–	–
12 months	440 (89.2)	408 (92.7)	–	–	–	–

a Percentages given out of number randomised for expected column and number expected for received column.

The intervention: package of podiatry care

Of the 493 participants allocated to receive the podiatry intervention, 412 (83.6%) attended at least one podiatry appointment and one further participant had a telephone baseline appointment, as the podiatrist was ill on both occasions on which appointments were booked. The trial protocol stated that participants were to be invited to attend two podiatry visits, one as soon as possible after randomisation and another 2–4 weeks later. Further appointments could be offered if required in addition to the participant's routine podiatry care. In total, 38 participants attended only one appointment and 375 had more than one contact with the podiatrist (occasionally follow-up appointments were conducted over the telephone rather than in person). Participants received a median of two podiatry appointments each (range 1–7 appointments). The first appointment occurred a median of 22 days after randomisation (range 3–275 days) and the second appointment occurred a median of 20 days after the first (range 6–184 days, with one outlier at 343 days for one participant who failed to attend several follow-up appointments booked for them because of conflicting hospital appointments).

The reasons why the remaining 80 participants did not receive the intervention are detailed in *Table 6*. The intervention was delivered by 28 podiatrists across the 13 centres. Podiatrists saw a median of 10 participants each (range 2–83 participants).

TABLE 6 Compliance with the intervention

Intervention received, or reason participant did not receive intervention	Intervention (*N* = 493), *n* (%)
Attended at least one podiatry appointment	413 (83.8)
Was offered but declined baseline appointment[a]	47 (9.5)
Was not made an appointment[b]	31 (5.3)
Died shortly before or after randomisation	2 (0.4)

a Declined appointment when contacted (e.g. did not want to take part, too busy, unknown reason), *n* = 18; declined appointment because of ill health, *n* = 7; cancelled or did not attend scheduled appointment, *n* = 22.
b No capacity to be seen, *n* = 9; participant not receiving routine podiatry care, *n* = 8; podiatrist felt participant not suitable for intervention because of ill health, *n* = 5; participant moved out of area, *n* = 2; unknown reason, *n* = 7.

Package of podiatry care

A baseline appointment form completed by the treating podiatrist was received for 380 participants. From this, we can summarise details of the intervention delivered, when this was provided. Twenty of 351 participants (5.7%) were reported as currently wearing custom-made shoes. Of the 364 participants who had their usual outdoor footwear assessed by the podiatrist at this visit, 249 (68.4%) were deemed to be wearing appropriate footwear; therefore, 115 (31.6%) exhibited a feature that made the shoes a risk for falling. The most common reason was inappropriate fixation/fastening ($n = 81$, 70.4%), followed by an inappropriate heel counter ($n = 57$, 49.5%), incorrect size ($n = 43$, 37.4%), unsuitable sole ($n = 42$, 36.5%), inappropriate heel width ($n = 17$, 14.8%) and excessive heel height ($n = 15$, 13.0%). New footwear was provided to 260 (52.7% of 493, 63.0% of 413) intervention participants throughout the course of the trial.

At the baseline appointment, 115 out of 363 (31.7%) participants were currently wearing an insole. The type of current insole being used was not recorded for six participants, and two participants reported wearing two different types of insole in different shoes or for different occasions. The most common type of insole being used was a simple flat-bed insole ($n = 37$, 32.2%), followed by a contoured prefabricated insole with simple modification ($n = 25$, 21.7%), a bespoke total contact insole ($n = 23$, 20.0%), a simple contoured prefabricated insole ($n = 21$, 18.2%) and a contoured prefabricated insole with complex modifications ($n = 5$, 4.4%).

An orthotic insole was fitted for 241 of the 413 (58.4%) participants who received the intervention (X-Line blue, $n = 209$; X-Line red, $n = 23$; Formthotics, $n = 9$). A therapy ball and theraband were prescribed for 355 (93.4%) and 358 (94.2%) participants, respectively, of the 380 for whom we have this information.

Screening and baseline characteristics

Data collected on the screening form are summarised for consenting participants and those who declined to participate but completed a screening form in *Tables 7–9*. Consenting participants appear to be more

TABLE 7 Demographic information for individuals who returned a screening form stratified by whether or not they consented to take part in the study ($N = 4428$)

Characteristic	Consent ($N = 3458$)	Did not consent ($N = 970$)	Total ($N = 4428$)
Age (years)*			
Mean (SD)	76.7 (7.1)	78.8 (7.5)	77.1 (7.2)
Median (minimum, maximum)	77 (64, 99)	79 (64, 99)	77 (64, 99)
Sex, *n* (%)*			
Male	1621 (47.1)	381 (40.5)	2002 (45.7)
Female	1819 (52.9)	559 (59.5)	2378 (54.3)
Ethnic group, *n* (%)			
White	3386 (98.8)	905 (97.6)	4291 (98.5)
Asian or Asian British	18 (0.5)	11 (1.2)	29 (0.7)
Black or Black British	19 (0.6)	8 (0.9)	27 (0.6)
Other	6 (0.2)	3 (0.3)	9 (0.2)
Willing to attend local podiatry clinic if required, *n* (%)*	1800 (52.1)	298 (30.7)	2098 (47.4)

*$p < 0.05$.
SD, standard deviation.

TABLE 8 Clinical information for individuals who returned a screening form stratified by whether or not they consented to take part in the study ($N = 4428$)

Characteristic	Consent ($N = 3458$), *n* (%)	Did not consent ($N = 970$), *n* (%)	Total ($N = 4428$), *n* (%)
Able to walk for 10 metres unaided*	2987 (86.4)	711 (73.3)	3698 (83.5)
Had lower limb surgery in the previous 3 months	109 (3.2)	23 (2.4)	132 (3.0)
Lower limb surgery planned in the next 6 months*	94 (2.7)	13 (1.3)	107 (2.4)
Has had any toe or lower limb amputations	98 (2.8)	18 (1.9)	116 (2.6)
Requires modifications to shoes*	556 (16.1)	122 (12.6)	678 (15.3)
Currently wearing an insole or orthosis*	1156 (33.4)	201 (20.7)	1357 (30.7)
Comorbidities[a]			
ALS/Lou Gehrig's disease	21 (0.6)	5 (0.5)	26 (0.6)
Alzheimer's disease*	38 (1.1)	27 (2.8)	65 (1.5)
Arthritis*	1945 (56.3)	472 (48.7)	2417 (54.6)
Dementia*	52 (1.5)	43 (4.4)	95 (2.2)
Depression*	345 (10.0)	76 (7.8)	421 (9.5)
Diabetes	1339 (38.7)	374 (38.6)	1713 (38.7)
Dizziness/vertigo*	642 (18.6)	152 (15.7)	794 (17.9)
Huntington's disease	22 (0.6)	7 (0.7)	29 (0.7)
Ménière's disease/conditions affecting balance	142 (4.1)	29 (3.0)	171 (3.9)
Multiple sclerosis	25 (0.7)	9 (0.9)	34 (0.8)
Numbness or tingling in feet or lower limbs*	1067 (30.9)	222 (22.9)	1289 (29.1)
Osteoporosis	466 (13.5)	122 (12.6)	588 (13.3)
Parkinson's disease	61 (1.8)	15 (1.6)	76 (1.7)

*$p < 0.05$.
ALS, amyotrophic lateral sclerosis.
a Participant could select more than one option.

physically able than those who chose not to participate (e.g. tended to be slightly younger, more likely to be willing to attend their local podiatry clinic if required and more likely to be able to walk 10 metres unaided); however, they also appeared to be at a higher risk of falling (e.g. more likely to require a modification to shoes or wear an insole, to have had a previous fall or have concern about falling).

Characteristics for all participants in the cohort (eligible, consenting participants who returned a baseline questionnaire and at least one falls calendar, $n = 2301$) at screening and baseline are presented in *Tables 10–12*. The average age of participants in the cohort was 76 years (range 64–99 years), and 44.3% were male ($n = 1015$). One-third of participants reported experiencing at least one fall in the 12 months prior to completing the screening questionnaire ($n = 784$, 34.1%). The median number of falls reported in this time was two; however, participants reported up to 60 falls in this time.

TABLE 9 Data collected on falls, fear of falling and injuries for individuals who returned a screening form stratified by whether or not they consented to take part in the study ($N = 4428$)

Characteristic	Consent ($N = 3458$)	Did not consent ($N = 970$)	Total ($N = 4428$)
Experienced at least one fall in previous 12 months, *n* (%)*	1342 (38.8)	283 (29.2)	1625 (36.7)
If yes, number of falls,* median (minimum, maximum)	2 (1, 90)	2 (1, 24)	2 (1, 90)
Experienced at least one fall in previous 24 months, *n* (%)*	1581 (45.7)	323 (33.3)	1904 (43.0)
If yes, did any require hospitalisation?, *n* (%)*	518/1581 (32.8)	137/323 (42.4)	655/1904 (34.4)
Worried about falling during previous 4 weeks, *n* (%)*			
All of the time	199 (5.8)	48 (5.3)	247 (5.7)
Most of the time	193 (5.6)	51 (5.6)	244 (5.6)
A good bit of the time	242 (7.1)	35 (3.9)	277 (6.4)
Some of the time	619 (18.0)	144 (15.9)	763 (17.6)
A little of the time	894 (26.0)	162 (17.9)	1056 (24.3)
None of the time	1288 (37.5)	465 (51.4)	1753 (40.4)
Broken a bone in the previous 12 months, *n* (%)[a]	146 (4.2)	44 (4.5)	190 (4.3)

*$p < 0.05$.
a Participants reported one broken bone (consent, $n = 128$; did not consent, $n = 37$), two broken bones (consent, $n = 16$; did not consent, $n = 7$) or three broken bones (consent, $n = 2$; did not consent, $n = 0$).

TABLE 10 Demographic and clinical information for participants in the cohort ($N = 2301$)

Characteristic	Cohort ($N = 2301$)
Age (years)	
Mean (SD)	76.7 (7.0)
Median (minimum, maximum)	77 (64,[a] 99)
Sex, *n* (%)	
Male	1015 (44.3)
Female	1279 (55.8)
BMI (kg/m^2)	
Mean (SD)	27.6 (5.2)
Median (IQR)	27.0 (24.0–30.5)
Ethnic group, *n* (%)	
White	2267 (99.1)
Asian or Asian British	8 (0.4)
Other	9 (0.4)
Missing	4 (0.2)

TABLE 10 Demographic and clinical information for participants in the cohort ($N = 2301$) (*continued*)

Characteristic	Cohort ($N = 2301$)
Living arrangements, *n* (%)[b]	
Lives alone	925 (40.2)
Lives with a partner or spouse	1257 (54.6)
Lives with a friend or relative	97 (4.2)
Lives in sheltered accommodation	69 (3.0)
Education continued after minimum school leaving age, *n* (%)	1227 (53.3)
Has degree or equivalent professional qualification, *n* (%)	758 (32.9)
Comorbidities, *n* (%)[b]	
ALS/Lou Gehrig's disease	4 (0.2)
Alzheimer's disease	6 (0.3)
Arthritis	1234 (53.6)
Dementia	4 (0.2)
Depression	185 (8.0)
Diabetes	834 (36.3)
Dizziness/vertigo	368 (16.0)
Huntington's disease	5 (0.2)
Ménière's disease/conditions affecting balance	67 (2.9)
Multiple sclerosis	4 (0.2)
Numbness or tingling in feet or lower limbs	373 (16.2)
Osteoporosis	289 (12.6)
Parkinson's disease	5 (0.2)
Taking more than four medications prescribed by a doctor, *n* (%)	1347 (58.5)
Able to walk for 10 metres unaided, *n* (%)[a]	2144 (93.2)
Had lower limb surgery in the previous 3 months, *n* (%)	56 (2.4)
Lower limb surgery planned in the next 6 months, *n* (%)[a]	35 (1.5)
Has had any toe or lower limb amputations, *n* (%)	8 (0.4)
Requires modifications to shoes, *n* (%)	301 (13.1)
Currently wearing an insole or orthosis, *n* (%)	739 (32.1)

ALS, amyotrophic lateral sclerosis; BMI, body mass index; IQR, interquartile range; SD, standard deviation.
a A small ($n = 7$) number of participants were aged 64 years when they returned their baseline questionnaire. As they were all less than 6 months from turning 65 years old, the decision was made to retain these participants in the cohort but randomise them only when they had turned 65 years.
b The participant could select more than one option.

TABLE 11 Data collected at screening on falls, fear of falling and injuries for participants in the cohort ($N = 2301$)

Characteristic	Cohort ($N = 2301$)
Experienced at least one fall in previous 12 months, *n* (%)	784 (34.1)
If yes, number of falls, median (minimum, maximum)	2 (1, 60)
Experienced at least one fall in previous 24 months, *n* (%)	955 (42.0)
If yes, did any require hospitalisation?, *n* (%)	292/955 (30.6)
Worried about falling during previous 4 weeks, *n* (%)	
All of the time	72 (3.1)
Most of the time	90 (3.9)
A good bit of the time	125 (5.5)
Some of the time	379 (16.5)
A little of the time	651 (28.4)
None of the time	976 (42.6)
Broken a bone in the previous 12 months, *n* (%)[a]	87 (3.8)

a Participants reported one broken bone ($n = 76$), two broken bones ($n = 10$) or three broken bones ($n = 1$).

TABLE 12 Data collected at baseline on falls and fear of falling for participants in the cohort ($N = 2301$)

Characteristic	Cohort ($N = 2301$)
Experienced at least one fall in previous 6 months, *n* (%)	647 (28.1)
If yes, number of falls, median (minimum, maximum)	1 (1, 30)
Worried about falling during previous 4 weeks, *n* (%)	
All of the time	72 (3.2)
Most of the time	98 (4.3)
A good bit of the time	130 (5.7)
Some of the time	396 (17.4)
A little of the time	732 (32.1)
None of the time	851 (37.3)
Referred to a falls clinic/service, *n* (%)	103 (4.5)

Data collected at screening and baseline are presented for all 1010 randomised participants (intervention, $n = 493$; usual care, $n = 517$) in *Tables 13–16*. The average age of the trial participants was 77 years (range 65–99 years) and 39.6% were male ($n = 400$). The proportion of participants currently wearing an orthotic insole was slightly higher in the intervention group than in the usual-care group (38.7% vs. 31.5%), as was the proportion who reported at least one fall in the 6 months prior to baseline (51.5% vs. 47.6%); otherwise, the randomised groups appear comparable.

TABLE 13 Demographic information for randomised participants by randomised group ($N = 1010$)

Characteristic	Treatment group		Total ($N = 1010$)
	Intervention ($N = 493$)	Usual care ($N = 517$)	
Age (years)			
Mean (SD)	78.1 (7.2)	77.7 (7.0)	77.9 (7.1)
Median (minimum, maximum)	78 (65, 96)	78 (65, 99)	78 (65, 99)
Sex, *n* (%)			
Male	190 (38.5)	210 (40.6)	400 (39.6)
Female	303 (61.5)	307 (59.4)	610 (60.4)
BMI (kg/m^2)			
Mean (SD)	27.6 (5.3)	27.7 (5.4)	27.6 (5.4)
Median (IQR)	26.9 (23.9–30.6)	27.1 (24.1–30.6)	27.0 (24.0–30.6)
Ethnic group, *n* (%)			
White	492 (99.8)	510 (98.7)	1002 (99.2)
Asian or Asian British	0 (0.0)	2 (0.4)	2 (0.2)
Other	0 (0.0)	2 (0.4)	2 (0.2)
Missing	1 (0.2)	3 (0.6)	4 (0.4)
Living arrangements, *n* (%)[a]			
Lives alone	236 (47.9)	220 (42.6)	456 (45.2)
Lives with a partner or spouse	230 (46.7)	266 (51.5)	496 (49.1)
Lives with a friend or relative	22 (4.5)	27 (5.2)	49 (4.9)
Lives in sheltered accommodation	19 (3.9)	14 (2.7)	33 (3.3)
Education continued after minimum school leaving age, *n* (%)	269 (54.6)	296 (57.3)	565 (55.9)
Has degree or equivalent professional qualification, *n* (%)	170 (34.5)	194 (37.5)	364 (36.0)

BMI, body mass index; IQR, interquartile range; SD, standard deviation.
a Participant could select more than one option.

TABLE 14 Clinical information for randomised participants by randomised group ($N = 1010$)

Characteristic	Treatment group, *n* (%)		Total ($N = 1010$), *n* (%)
	Intervention ($N = 493$)	Usual care ($N = 517$)	
Comorbidities[a]			
Arthritis	292 (59.2)	300 (58.0)	592 (58.6)
Depression	49 (9.9)	48 (9.3)	97 (9.6)
Diabetes	158 (32.1)	175 (33.9)	333 (33.0)
Dizziness/vertigo	107 (21.7)	95 (18.4)	202 (20.0)
Ménière's disease/conditions affecting balance	21 (4.3)	15 (2.9)	36 (3.6)
Numbness or tingling in feet or lower limbs	76 (15.4)	85 (16.4)	161 (15.9)
Osteoporosis	86 (17.4)	65 (12.6)	151 (15.0)
Taking more than four medications prescribed by a doctor	313 (63.5)	304 (58.8)	617 (61.1)
Requires modifications to shoes	67 (13.6)	69 (13.4)	136 (13.5)
Currently wearing an insole or orthosis	191 (38.7)	163 (31.5)	354 (35.1)

a Participant could select more than one option. One participant (in the usual-care group) with dementia was randomised even though this was an exclusion criteria.

TABLE 15 Data collected at screening on falls, fear of falling and injuries for randomised participants by randomised group (*N* = 1010)

Characteristic	Treatment group		
	Intervention (*N* = 493)	Usual care (*N* = 517)	Total (*N* = 1010)
Experienced at least one fall in previous 12 months, *n* (%)	325 (65.9)	332 (64.2)	657 (65.0)
If yes, number of falls, median (minimum, maximum)	2 (1, 25)	2 (1, 20)	2 (1, 25)
Experienced at least one fall in previous 24 months, *n* (%)	329 (66.7)	330 (63.8)	659 (65.2)
If yes, did any require hospitalisation?, *n* (%)	113/329 (34.4)	99/330 (30.0)	212/659 (32.2)
Worried about falling during previous 4 weeks, *n* (%)			
All of the time	23 (4.7)	22 (4.3)	45 (4.5)
Most of the time	30 (6.1)	25 (4.9)	55 (5.5)
A good bit of the time	42 (8.5)	43 (8.4)	85 (8.4)
Some of the time	100 (20.3)	129 (25.1)	229 (22.7)
A little of the time	168 (34.1)	154 (29.9)	322 (31.9)
None of the time	130 (26.4)	142 (27.6)	272 (27.0)
Broken a bone in the previous 12 months, *n* (%)	38 (7.7)	27 (5.2)	65 (6.4)
Bones broken, *n* (%)[a]			
Crown or facial bone	1 (2.6)	0 (0.0)	1 (1.5)
Breast or collar bone	1 (2.6)	0 (0.0)	1 (1.5)
Rib	4 (10.5)	2 (7.4)	1 (1.5)
Back or spine	1 (2.6)	2 (7.4)	3 (4.6)
Shoulder	5 (13.2)	2 (7.4)	7 (10.8)
Arm	3 (7.9)	3 (11.1)	6 (9.2)
Wrist	8 (21.1)	6 (22.2)	14 (21.5)
Hand or finger	1 (2.6)	4 (14.8)	5 (7.7)
Hip or pelvis	2 (5.3)	2 (7.4)	4 (6.2)
Leg	4 (10.5)	4 (14.8)	8 (12.3)
Ankle	3 (7.9)	2 (7.4)	5 (7.7)
Foot or toe	11 (29.0)	3 (11.1)	14 (21.5)

a Percentage of participants reporting at least one broken bone in previous 12 months; participants reported one broken bone (intervention, *n* = 33; usual care, *n* = 24), two broken bones (intervention, *n* = 4; usual care, *n* = 3) or three broken bones (intervention, *n* = 1; usual care, *n* = 0).

Primary outcome

Raw data

In total, 992 (98.2%) trial participants returned at least one falls calendar following randomisation [intervention, *n* = 484, 98.2%; usual care, *n* = 508, 98.3%], with 762 (75.5%) returning a complete 12 months' worth of calendars post randomisation (intervention, *n* = 360, 73.0%; usual care, *n* = 402, 77.8%). In total, 1423 falls were reported: 661 in the intervention group (median 1 fall, range 0–23 falls) over a median of 365 days (range 6–365 days), and 762 in the usual-care group (median 1 fall, range 0–28 falls) over a median of 365 days (range 27–365 days) (*Figures 3* and *4*).

TABLE 16 Data collected at baseline on falls and fear of falling for randomised participants by randomised group ($N = 1010$)

Characteristic	Treatment group		
	Intervention ($N = 493$)	Usual care ($N = 517$)	Total ($N = 1010$)
Experienced at least one fall in previous 6 months, *n* (%)	254 (51.5)	246 (47.6)	500 (49.5)
If yes, number of falls, median (minimum, maximum)	1 (1, 20)	1 (1, 8)	1 (1, 20)
Worried about falling during previous 4 weeks, *n* (%)			
All of the time	24 (4.9)	18 (3.5)	42 (4.2)
Most of the time	40 (8.2)	27 (5.3)	67 (6.7)
A good bit of the time	47 (9.6)	42 (8.2)	89 (8.9)
Some of the time	109 (22.2)	138 (27.0)	247 (24.6)
A little of the time	165 (33.6)	178 (34.8)	343 (34.2)
None of the time	106 (21.6)	109 (21.3)	215 (21.4)
Referred to a falls clinic/service, *n* (%)	32 (6.5)	35 (6.8)	67 (6.6)

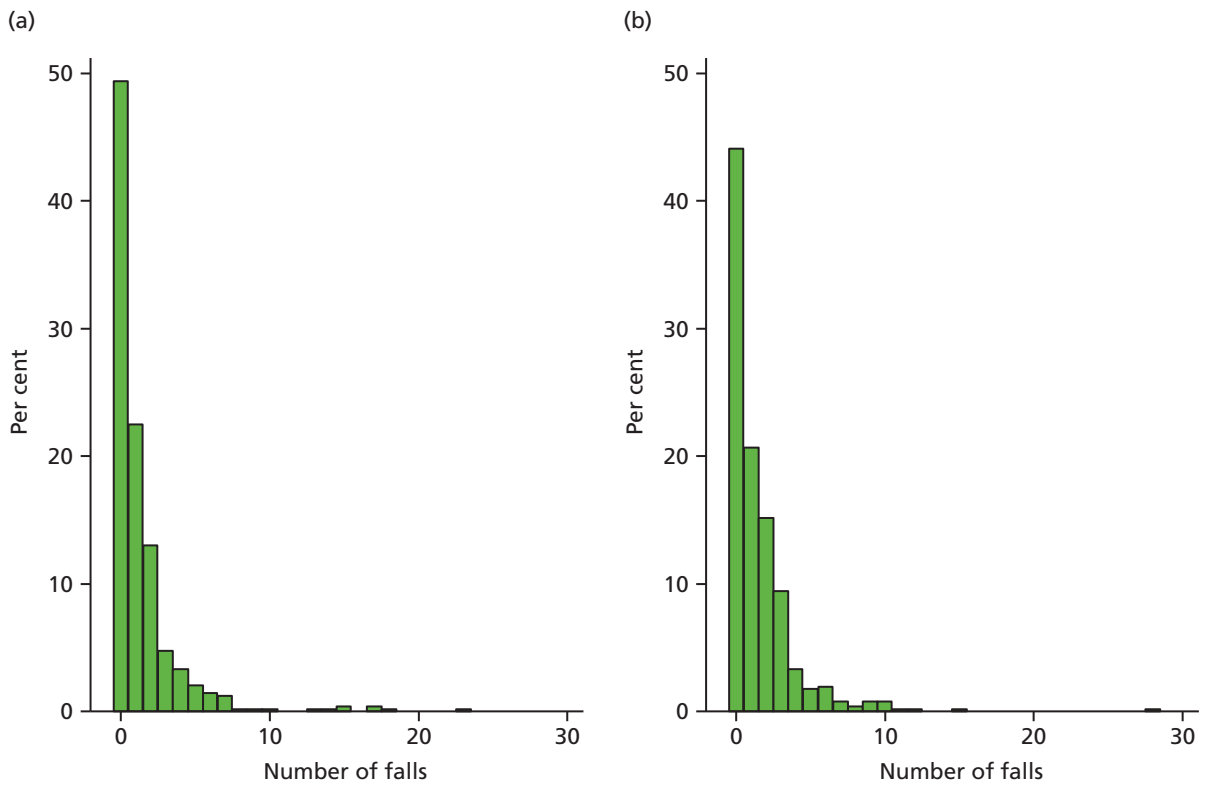

FIGURE 3 Histogram displaying the distribution of the number of falls by treatment group. (a) Intervention; and (b) usual care.

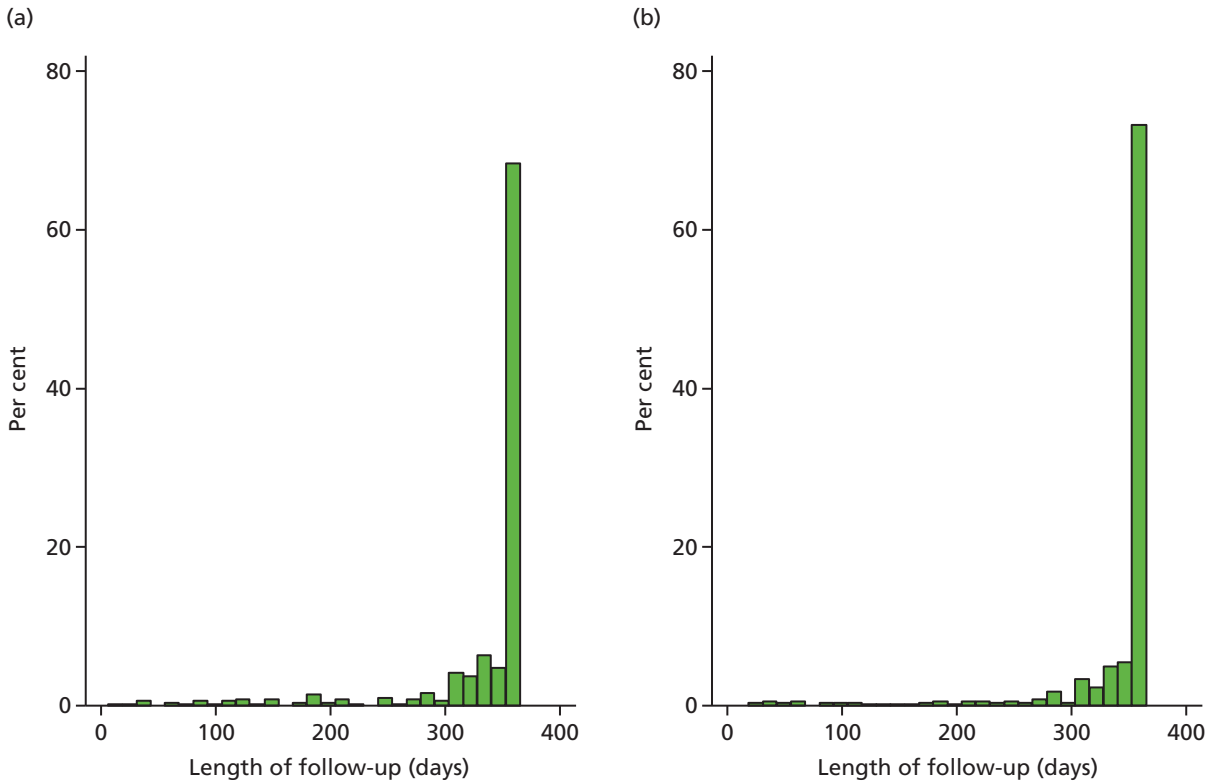

FIGURE 4 Histogram displaying the distribution of the length of follow-up for falls data by treatment group. (a) Intervention; and (b) usual care.

Information, such as the cause and location, was available for 1172 (82.7%) falls (intervention, $n = 549$, 83.3%; usual care, $n = 623$, 82.1%; *Table 17*). Over one-third of the falls were reportedly caused by a trip ($n = 457$, 39%), and an injury was sustained in over half of the falls ($n = 655$, 55.9%). These injuries include 31 broken bones (from 17 falls in the intervention group and 14 in usual care). The most common bones broken in a fall were the hip or bones in the hand ($n = 5$ each).

Covariates

The primary analysis model controlled for sex, age at randomisation and history of falling. The age of one participant in the usual-care group was not available so the primary model was based on 991 participants (484 in the intervention group and 507 in the usual-care group).

Screening and baseline data for participants analysed in the primary model

Data collected on the screening form and baseline questionnaire are presented by randomised group for the 991 participants included in the primary analysis ('as analysed' population; *Tables 18–21*). The composition of the analysis groups is virtually identical to that at randomisation, indicating that the loss of the 19 participants from the primary analysis has not introduced any selection bias.

Number of falls by centre

A summary of the number of falls for participants contributing to the primary analysis is presented by centre in *Table 22*, in order of largest to smallest contributing centre.

Primary analysis

The adjusted negative binomial model indicated a non-statistically significant reduction in the fall rate in the intervention group relative to usual care (IRR 0.88, 95% CI 0.73 to 1.05; $p = 0.16$). History of falling was seen to be a significant predictor in the model (IRR 2.10, 95% CI 1.74 to 2.54; $p < 0.001$; *Table 23*).

TABLE 17 Details relating to the cause and location of the falls reported

Information about fall	Treatment group, *n* (%)		
	Intervention (*N* = 549)	Usual care (*N* = 623)	Total (*N* = 1172), *n* (%)
Cause of/reason for fall			
Trip	205 (37.3)	252 (40.5)	457 (39.0)
Slip	55 (10.0)	76 (12.2)	131 (11.2)
Turning	51 (9.3)	42 (6.7)	93 (7.9)
Legs gave way	50 (9.1)	67 (10.8)	117 (10.0)
Dizzy	23 (4.2)	34 (5.5)	57 (4.9)
Lost balance	60 (10.9)	48 (7.7)	108 (9.2)
Unknown/cannot remember	48 (8.7)	42 (6.7)	90 (7.7)
Other	70 (12.8)	77 (12.4)	147 (12.5)
Location of fall			
Inside own home	221 (40.3)	263 (42.2)	484 (41.3)
Inside, but not in own home	40 (7.3)	54 (8.7)	94 (8.0)
Outside	259 (47.2)	280 (44.9)	539 (46.0)
Missing	29 (5.3)	26 (4.2)	55 (4.7)
If fall was inside, was it . . ?			
On one level	169 (64.5)	195 (61.5)	364 (62.9)
Accessing shower/bath	6 (2.3)	23 (7.3)	29 (5.0)
Getting out of bed	17 (6.5)	23 (7.3)	40 (6.9)
Getting out of a chair	22 (8.4)	19 (6.0)	41 (7.1)
Walking up or down stairs	42 (16.0)	52 (16.4)	94 (16.2)
Accessing the toilet	6 (2.3)	5 (1.6)	11 (1.9)
If fall was outside, was it. . ?			
Car park/driveway	16 (6.2)	13 (4.6)	29 (5.4)
Crossing a street	4 (1.5)	8 (2.9)	12 (2.2)
Garden/grassed area	73 (28.2)	76 (27.1)	149 (27.6)
Getting in or out of a vehicle	5 (1.9)	5 (1.8)	10 (1.9)
On a bus or train	3 (1.2)	1 (0.4)	4 (0.7)
On a footpath	77 (29.7)	86 (30.7)	163 (30.2)
On a kerb	13 (5.0)	13 (4.6)	26 (4.8)
On a step/escalator	18 (7.0)	29 (10.4)	47 (8.7)
On one level	8 (3.1)	11 (3.9)	19 (3.5)
Other	27 (10.4)	21 (7.5)	48 (8.9)
Missing	15 (5.8)	17 (6.1)	32 (5.9)
Footwear worn			
Barefoot	45 (8.2)	66 (10.6)	111 (9.5)
Slippers	126 (23.0)	121 (19.4)	247 (21.1)
Shoes/boots	292 (53.2)	332 (53.3)	624 (53.4)

continued

TABLE 17 Details relating to the cause and location of the falls reported (*continued*)

Information about fall	Treatment group, *n* (%)		
	Intervention (*N* = 549)	Usual care (*N* = 623)	Total (*N* = 1172), *n* (%)
Wellington boots	11 (2.0)	4 (0.6)	15 (1.3)
Flip-flops/sandals	22 (4.0)	36 (5.8)	58 (5.0)
Cannot remember	24 (4.4)	34 (5.5)	58 (5.0)
Missing	29 (5.3)	30 (4.8)	59 (5.0)
Using a walking aid			
Yes	83 (15.1)	91 (14.6)	174 (14.9)
No	414 (75.4)	483 (77.5)	897 (76.5)
Missing	52 (9.5)	49 (7.9)	101 (8.6)
Wearing an insole or orthosis			
Yes	200 (36.4)	135 (21.7)	335 (28.6)
No	289 (52.6)	410 (65.8)	699 (59.6)
Missing	60 (10.9)	78 (12.5)	138 (11.8)
Injuries suffered			
None	195 (35.5)	259 (41.6)	454 (38.7)
Superficial	305 (55.6)	319 (51.2)	624 (53.2)
Broken bone	17 (3.1)	14 (2.3)	31 (2.7)
Missing	32 (5.8)	31 (5.0)	63 (5.4)
Bones broken			
Crown or facial bone	1 (5.9)	0 (0.0)	1 (3.2)
Breast or collar bone	0 (0.0)	0 (0.0)	0 (0.0)
Rib	2 (11.8)	1 (7.1)	3 (9.7)
Back or spine	1 (5.9)	0 (0.0)	1 (3.2)
Shoulder	2 (11.8)	0 (0.0)	2 (6.5)
Arm	0 (0.0)	1 (7.1)	1 (3.2)
Wrist	1 (5.9)	14 (14.3)	3 (9.7)
Hand or finger	2 (11.8)	3 (21.4)	5 (16.1)
Hip or pelvis	3 (17.7)	14 (14.3)	5 (16.1)
Leg	1 (5.9)	1 (7.1)	2 (6.5)
Ankle	1 (5.9)	0 (0.0)	1 (3.2)
Foot or toe	2 (11.8)	14 (14.3)	4 (12.9)
Other/unknown	1 (5.9)	14 (14.3)	3 (9.7)
Overnight stay in hospital required			
Yes	15 (2.7)	16 (2.6)	31 (2.7)
No	473 (86.2)	527 (84.6)	1000 (85.3)
Missing	61 (11.1)	80 (12.8)	141 (12.0)
If yes, how many nights?			
Median (minimum, maximum)	7 (1, 21)	5 (1, 21)	6 (1, 21)

TABLE 18 Demographic information for 'as analysed' participants by randomised group ($N = 991$)

Characteristic	Treatment group		Total ($N = 991$)
	Intervention ($N = 484$)	Usual care ($N = 507$)	
Age (years)			
Mean (SD)	78.1 (7.2)	77.6 (7.0)	77.8 (7.1)
Median (minimum, maximum)	78 (65, 96)	78 (65, 99)	78 (65, 99)
Sex, *n* (%)			
Male	189 (39.1)	207 (40.8)	396 (40.0)
Female	295 (61.0)	300 (59.2)	595 (60.0)
BMI (kg/m^2)			
Mean (SD)	27.6 (5.3)	27.7 (5.4)	27.6 (5.4)
Median (IQR)	27.0 (23.9–30.6)	27.1 (24.1–30.6)	27.1 (24.0–30.6)
Ethnic group, *n* (%)			
White	483 (99.8)	500 (98.6)	983 (99.2)
Asian or Asian British	0 (0.0)	2 (0.4)	2 (0.2)
Other	0 (0.0)	2 (0.4)	2 (0.2)
Missing	1 (0.2)	3 (0.6)	4 (0.4)
Living arrangements, *n* (%)[a]			
Lives alone	230 (47.5)	214 (42.2)	444 (44.8)
Lives with a partner or spouse	227 (46.9)	262 (51.7)	489 (49.3)
Lives with a friend or relative	22 (4.6)	27 (5.3)	49 (4.9)
Lives in sheltered accommodation	18 (3.7)	14 (2.8)	32 (3.2)
Education continued after minimum school leaving age, *n* (%)	263 (54.3)	289 (57.0)	552 (55.7)
Has degree or equivalent professional qualification, *n* (%)	167 (34.5)	191 (37.7)	358 (36.1)

BMI, body mass index; IQR, interquartile range; SD, standard deviation.
a Participant could select more than one option.

TABLE 19 Clinical information for 'as analysed' participants by randomised group ($N = 991$)

Characteristic	Treatment group, *n* (%)		Total ($N = 991$), *n* (%)
	Intervention ($N = 484$)	Usual care ($N = 507$)	
Comorbidities[a]			
Arthritis	286 (59.1)	290 (57.2)	576 (58.1)
Depression	46 (9.5)	48 (9.5)	94 (9.5)
Diabetes	155 (32.0)	168 (33.1)	323 (32.6)
Dizziness/vertigo	102 (21.1)	91 (18.0)	193 (19.5)
Ménière's disease/conditions affecting balance	20 (4.1)	15 (3.0)	35 (3.5)
Numbness or tingling in feet or lower limbs	76 (15.7)	83 (16.4)	159 (16.0)
Osteoporosis	83 (17.2)	65 (12.8)	148 (14.9)
Taking more than four medications prescribed by a doctor	305 (63.0)	297 (58.6)	602 (60.8)
Requires modifications to shoes	67 (13.8)	68 (13.4)	135 (13.6)
Currently wearing an insole or orthosis	189 (39.1)	161 (31.8)	350 (35.3)

a Participant could select more than one option.

TABLE 20 Data collected at screening on falls, fear of falling and injuries for 'as analysed' participants by randomised group ($N = 991$)

Characteristic	Treatment group		
	Intervention ($N = 484$)	Usual care ($N = 507$)	Total ($N = 991$)
Experienced at least one fall in previous 12 months, *n* (%)	319 (65.9)	323 (63.7)	642 (64.8)
If yes, number of falls, median (minimum, maximum)	2 (1, 25)	1 (1, 20)	2 (1, 25)
Experienced at least one fall in previous 24 months, *n* (%)	323 (66.7)	321 (63.3)	644 (65.0)
If yes, did any require hospitalisation?, *n* (%)	110/323 (34.1)	96/321 (29.9)	206/644 (32.0)
Worried about falling during previous 4 weeks, *n* (%)			
All of the time	22 (4.6)	21 (4.2)	43 (4.4)
Most of the time	27 (5.6)	24 (4.8)	51 (5.2)
A good bit of the time	42 (8.7)	41 (8.1)	83 (8.4)
Some of the time	100 (20.7)	128 (25.4)	228 (23.1)
A little of the time	163 (33.7)	151 (29.9)	314 (31.8)
None of the time	130 (26.9)	140 (27.7)	270 (27.3)
Broken a bone in the previous 12 months, *n* (%)[a]	36 (7.4)	27 (5.3)	63 (6.4)

a Percentage of participants reporting at least one broken bone in previous 12 months; participants reported one broken bone (intervention, $n = 31$; usual care, $n = 24$), two broken bones (intervention, $n = 4$; usual care, $n = 3$) or three broken bones (intervention, $n = 1$; usual care, $n = 0$).

TABLE 21 Data collected at baseline on falls and fear of falling for 'as analysed' participants by randomised group ($N = 991$)

Characteristic	Treatment group		
	Intervention ($N = 484$)	Usual care ($N = 507$)	Total ($N = 991$)
Experienced at least one fall in previous 6 months, *n* (%)	248 (51.2)	246 (47.6)	500 (49.5)
If yes, number of falls, median (minimum, maximum)	1 (1, 20)	1 (1, 8)	1 (1, 20)
Worried about falling during previous 4 weeks, *n* (%)			
All of the time	22 (4.6)	18 (3.6)	40 (4.1)
Most of the time	40 (8.3)	26 (5.2)	66 (6.7)
A good bit of the time	44 (9.1)	40 (8.0)	84 (8.5)
Some of the time	106 (22.0)	137 (27.3)	243 (24.7)
A little of the time	165 (34.2)	173 (34.5)	338 (34.4)
None of the time	105 (21.8)	108 (21.5)	213 (21.7)
Referred to a falls clinic/service, *n* (%)	30 (6.2)	35 (6.9)	65 (6.6)

TABLE 22 Summary of the number of falls by centre

Centre	Number of participants contributing to primary analysis	Number of falls	
		Mean (SD)	Median (minimum, maximum)
1	320	1.4 (2.2)	1 (0, 15)
2	131	1.6 (3.0)	1 (0, 23)
3	102	1.3 (2.0)	1 (0, 10)
4	91	1.5 (2.4)	0.5 (0, 10)
5	63	0.8 (1.4)	0 (0, 6)
6	56	1.9 (3.2)	1 (0, 18)
7	46	1.5 (2.3)	1 (0, 13)
8	41	1.6 (2.7)	1 (0, 15)
9	38	1.6 (2.9)	1 (0, 17)
10	31	2.2 (5.1)	1 (0, 28)
11	27	1.1 (1.3)	1 (0, 5)
12	26	1.2 (1.6)	0.5 (0, 6)
13	19	1.1 (1.7)	0 (0, 6)

SD, standard deviation.

TABLE 23 Model parameters from the primary analysis for incidence rate of falls

Variable	IRR (standard error)	95% CI (*p*-value)
Allocation (0, usual care; 1, intervention)	0.88 (0.08)	0.73 to 1.05 ($p = 0.16$)
Sex (0, female; 1, male)	1.10 (0.10)	0.91 to 1.32 ($p = 0.33$)
Age at randomisation (years)	1.01 (0.01)	0.99 to 1.02 ($p = 0.31$)
History of falling (0, fewer than two falls in 12 months before screening; 1, more than two falls)	2.10 (0.20)	1.74 to 2.54 ($p < 0.001$)
Constant	0.002 (0.001)	< 0.001 to 0.005 ($p < 0.001$)

Little difference in the estimate of the treatment effect was observed when centre was included as a fixed, as opposed to a random, effect in the primary analysis model in a sensitivity analysis (IRR 0.88, 95% CI 0.73 to 1.07; $p = 0.20$).

Sensitivity analyses

Non-compliance

When non-compliance with the intervention was accounted for using an instrumental variable CACE analysis approach, the intervention was seen to have a marginally greater benefit than in the ITT analysis but the conclusions were otherwise consistent (IRR 0.86, 95% CI 0.69 to 1.06; $p = 0.16$).

Podiatrist effects

A single podiatrist appeared to deliver the intervention to all participants in 6 of the 13 centres. In the other seven centres, two, three, four (two centres each) or six (one centre) podiatrists held intervention appointments. Counterfactual podiatrists were assigned to the 80 participants in the intervention group who did not receive the intervention and the 517 usual care participants. Repeating the primary analysis with podiatrist as a random effect in the place of centre had a negligible effect on the treatment estimate (IRR 0.88, 95% CI 0.73 to 1.05; $p = 0.16$).

Baseline imbalance by chance

A sensitivity analysis of the primary outcome was planned, which adjusted the model for any pre-randomisation variables found to be imbalanced by chance between the randomised groups, namely proportion of participants wearing an insole, number of falls in 6 months prior to completion of baseline questionnaire and total FAI score. However, owing to concerns that this model could be overparameterised by including two variables relating to past falls history (a dichotomous variable indicating two or more falls in the 12 months prior to screening and a continuous variable of the number of falls recalled in the 6 months before baseline), the number of falls variable was not included.

The resultant model was based on 912 participants (intervention, $n = 448$, 90.9%; usual care, $n = 464$, 89.7%). Of those included in the primary model, 77 did not have a valid baseline FAI score and three did not provide a response to whether or not they were wearing an orthotic insole at screening; 79 participants were missing at least one of these additional covariates.

When these variables were added to the primary model, the predicted IRR was 0.88 (95% CI 0.72 to 1.06; $p = 0.18$), which is virtually unchanged from the primary model.

Fear of falling participants

Excluding the 26 fear of falling participants from the primary model had a negligible effect on the treatment estimate (IRR 0.88, 95% CI 0.73 to 1.05; $p = 0.16$).

Missing data

Not living with a partner or spouse, not having a degree or equivalent professional qualification, reporting dizziness or vertigo at screening and number of falls in the 6 months prior to completion of the baseline questionnaire were observed to predict returning less than 6 months' worth of falls calendar data post randomisation. When these variables were included in the primary analysis model (excluding the number of falls variable for the same reasons as cited above), the parameter estimate for the treatment effect was IRR 0.86 (95% CI 0.72 to 1.04; $p = 0.11$). This model was based on 976 participants (intervention, $n = 477$, 96.8%; usual care, $n = 499$, 96.5%).

Post hoc analysis

Prior to the analysis of this study, a trial of structured physical activity for the prevention of serious fall injuries in adults aged 70–89 years [Lifestyle Interventions and Independence for Elders (LIFE) study] was published.[45] In subgroup analyses the authors observed that the hazard ratio for time to first serious fall injury did not differ significantly according to sex (interaction $p = 0.14$); however, a clinically meaningful qualitative difference was observed with a hazard ratio of 0.62 (95% CI 0.34 to 1.12) in men and of 1.05 (95% CI 0.72 to 1.52) in women. In an analysis that was not prespecified, we repeated the primary analysis in the subgroups of males and females and found similar treatment effects in each (men: IRR 0.87, 95% CI 0.64 to 1.17; women: 0.86, 95% CI 0.68 to 1.09). When an interaction between sex and treatment allocation was included in the primary model, the interaction was not observed to be statistically significant ($p = 0.93$).

Secondary analyses

Number of falls as reported for the previous 6 months on the 6- and 12-month participant questionnaires

This outcome was computed for 450 (91.3%) participants in the intervention group and 484 (93.6%) in the usual-care group. In the intervention group, 423 (85.8%) participants responded to this question at both 6 and 12 months and 27 (5.5%) responded at either 6 or 12 months only; the average number of falls reported in this group was 1.5 (median 1 fall, range 0–20 falls). In the usual-care group, 457 (88.4%) participants responded to this question at both 6 and 12 months and 27 (5.2%) responded at either 6 or 12 months only; the average number of falls reported in this group was 1.7 (median 1 fall, range 0–29 falls). The adjusted IRR obtained from the negative regression model was 0.87 (95% CI 0.72 to 1.06; $p = 0.17$).

Proportion of fallers and multiple fallers

In total, 245 out of 493 (49.7%) intervention participants and 284 out of 517 (54.9%) usual care participants reported at least one fall on their monthly falls calendars (adjusted OR 0.78, 95% CI 0.60 to 1.00; $p = 0.05$). An OR of 0.6 (lower confidence limit) approximately relates to a decrease in the percentage of fallers from 55% in the usual-care group to 42% in the intervention group, which exceeds the 10 percentage point difference for which the trial was powered.

To calculate the percentage of the intervention group, let us say that the 2 × 2 table for falls by allocation is as given in *Table 24*.

In this case, we know that $a + b = 493$, $c = 284$, $d = 233$, $c + d = 517$ and $N = 1010$. The calculation for the OR is:

$$\text{OR} = (a/b)/(c/d). \quad (2)$$

We want to know the values of a and b if c and d are as observed in the trial and the OR is 0.6. Rearranging (2), we get:

$$(a/b) = 0.6(284/233) = 0.73. \quad (3)$$

We know that $a + b = 493$, so if we rearrange and solve these equations, we conclude that $a = 208$ and $b = 285$. Therefore, if there were 208 fallers, this would equate to a percentage of $208/493 \times 100 = 42\%$.

The analysis of fallers assumes that the 18 participants who did not return any falls calendars following randomisation into the trial did not fall. To test the sensitivity of the results to this assumption we repeated the logistic regression (1) dropping these participants and (2) assuming, conversely, that they *did* fall at least once. Estimates were robust: adjusted OR 0.77 (95% CI 0.59 to 0.99; $p = 0.04$); and OR 0.77 (95% CI 0.60 to 0.99; $p = 0.05$), respectively. In addition, if participants did not report a fall, it is implicitly assumed that these participants did not fall in the months for which they did not return a falls calendar. To test this, we assumed that a random 50% of the 185 participants [99/493 (20.1%) participants in the intervention group and 86/517 (16.6%) participants in the usual-care group] who did not report a fall and did not complete a falls calendar for all 12 months post randomisation fell at least once in a month for which data were missing. This increased the effect (adjusted OR 0.72, 95% CI 0.55 to 0.93; $p = 0.01$).

TABLE 24 Falls by allocation

Treatment group	Fall	No fall	Total
Intervention	a	b	$a + b$
Usual care	c	d	$c + d$
Total	$a + c$	$b + d$	N

The proportion of participants who reported two or more falls on their falls calendars following randomisation was also lower in the intervention group than in the usual-care group [27.6% ($n = 136/493$) vs. 34.6% ($n = 179/517$); adjusted OR 0.69, 95% CI 0.52 to 0.90; $p = 0.01$].

Time to first fall

The median time to the first fall and its associated 95% CIs were estimated at 314 days (95% CI 267 days, upper limit not calculable) in the intervention group and 257 days in the usual-care group (95% CI 209 to 319 days). Kaplan–Meier survival curves are presented for each group in *Figure 5*. The adjusted hazard ratio from the Cox proportional hazards model for the treatment effect was 0.88 (95% CI 0.74 to 1.04; $p = 0.13$), indicating that the hazard or chance of falling at any particular time is lower in the intervention group than in the usual-care group, but this ratio is not statistically significant. Log-log plots of the categorical covariates indicated slight violation of the proportional hazard assumption for sex and allocation (and indeed we observe that the survival curves cross one another on the Kaplan–Meier curve but this occurs relatively early on); however, the Grambsch and Therneau test did not provide evidence that the assumptions did not hold.

Participant-reported outcome measures

No statistically significant differences between the two groups were observed at 6 or 12 months in the fear of falling question, the Short FES-I, the FAI or the GDS (*Tables 25–28*). For the Short FES-I and the GDS, the residuals from the model showed slight violation from normality, so the models were repeated using a log-transformed outcome, but this did not change the conclusions. The results presented in the main body of the table are for the untransformed analysis, with the results from the transformed analysis included in the footer. The Short FES-I total score was categorised and is presented in *Table 29*. At 12 months, a similar proportion of participants in each group reported no, or low, concern about falling (intervention, 21.2%; usual care, 22.2%), but, of those who were concerned, the proportion reporting high concern about falling was slightly higher in the intervention group (32.2% vs. 30.0%). No difference in CD-RISC2 score at 6 months was observed between the groups (adjusted means: intervention 6.4, usual care 6.3; adjusted mean difference: 0.10, 95% CI –0.08 to 0.28; $p = 0.26$). Higher scores reflect greater resilience and adaptability.

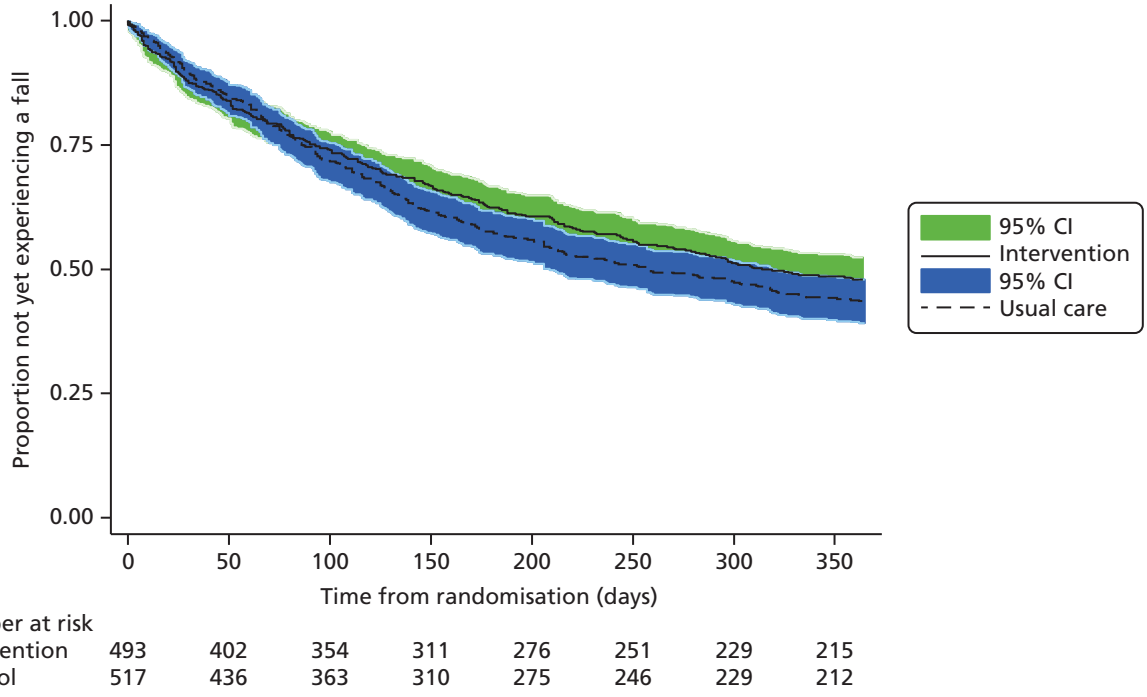

FIGURE 5 Kaplan–Meier curves by randomised group for time to first fall. Reproduced from Cockayne *et al.*[44] This is an open access article distributed under the terms of the Creative Commons Attribution Licence (CC BY 4.0), which permits unrestricted use, distribution and reproduction in any medium, provided the original author and source are credited (https://creativecommons.org/licenses/by/4.0/).

TABLE 25 Unadjusted and adjusted results for fear of falling outcome by randomised group

	Unadjusted									Adjusted[a]				
	Treatment group									Treatment group				
	Intervention ($N = 493$)			Usual care ($N = 517$)			Total ($N = 1010$)			Intervention		Usual care		
Time point	*n*	Mean (SD)	Median (minimum, maximum)	*n*	Mean (SD)	Median (minimum, maximum)	*n*	Mean (SD)	Median (minimum, maximum)	Mean (SE)	95% CI	Mean (SE)	95% CI	Mean difference (95% CI); *p*-value
Baseline	491	4.4 (1.4)	5 (1, 6)	512	4.5 (1.3)	5 (1, 6)	1003	4.4 (1.3)	5 (1, 6)	–	–	–	–	–
Month 6	424	4.4 (1.4)	5 (1, 6)	461	4.4 (1.3)	5 (1, 6)	885	4.4 (1.3)	5 (1, 6)	4.4 (0.06)	4.3 to 4.5	4.4 (0.05)	4.3 to 4.5	0.08 (–0.05 to 0.21); $p = 0.24$
Month 12	417	4.4 (1.4)	5 (1, 6)	453	4.3 (1.3)	4 (1, 6)	870	4.3 (1.4)	5 (1, 6)	4.4 (0.06)	4.3 to 4.5	4.3 (0.06)	4.2 to 4.4	0.13 (–0.01 to 0.27); $p = 0.07$

SD, standard deviation; SE, standard error.

a Adjusted for baseline fear of falling response, sex, age at randomisation, history of falling and centre (random effect); an unstructured covariance pattern was used in the final model.

Note

Higher score indicates less concern about falling.

TABLE 26 Unadjusted and adjusted results for Short FES-I score by randomised group

	Unadjusted									Adjusted[a]				
	Treatment group									Treatment group				
	Intervention ($N = 493$)			Usual care ($N = 517$)			Total ($N = 1010$)			Intervention		Usual care		
Time point	*n*	Mean (SD)	Median (minimum, maximum)	*n*	Mean (SD)	Median (minimum, maximum)	*n*	Mean (SD)	Median (minimum, maximum)	Mean (SE)	95% CI	Mean (SE)	95% CI	Mean difference (95% CI); *p*-value
Baseline	481	12.4 (4.6)	11 (7, 28)	504	12.2 (4.2)	11 (7, 27)	985	12.3 (4.4)	11 (7, 28)	–	–	–	–	–
Month 6	425	12.4 (4.9)	11 (7, 28)	451	12.2 (4.3)	11 (7, 28)	876	12.3 (4.6)	11 (7, 28)	12.4 (0.16)	12.1 to 12.7	12.2 (0.15)	11.9 to 12.5	0.13 (–0.30 to 0.56); $p = 0.56$
Month 12	410	12.7 (4.9)	11 (7, 28)	447	12.2 (4.4)	11 (7, 28)	857	12.4 (4.7)	11 (7, 28)	12.6 (0.16)	12.3 to 12.9	12.3 (0.16)	12.0 to 12.6	0.30 (–0.14 to 0.73); $p = 0.19$

SD, standard deviation; SE, standard error.

a Adjusted for baseline Short FES-I score, sex, age at randomisation, history of falling and centre (random effect); unstructured covariance pattern used in the final model. Adjusted mean difference with log-transformed response variable (month 6: –0.001, 95% CI –0.03 to 0.03; $p = 0.94$; month 12: 0.01, 95% CI –0.02 to 0.05; $p = 0.42$).

Note

A score of 7 or 8 indicates no/low concern, 9–13 indicates moderate concern and 14–28 indicates high concern about falling.

TABLE 27 Unadjusted and adjusted results for FAI score by randomised group

	Unadjusted									Adjusted[a]				
	Treatment group									Treatment group				
	Intervention ($N = 493$)			Usual care ($N = 517$)			Total ($N = 1010$)			Intervention		Usual care		
Time point	*n*	Mean (SD)	Median (minimum, maximum)	*n*	Mean (SD)	Median (minimum, maximum)	*n*	Mean (SD)	Median (minimum, maximum)	Mean (SE)	95% CI	Mean (SE)	95% CI	Mean difference (95% CI); *p*-value
Baseline	456	45.5 (7.9)	47 (20, 60)	473	46.8 (7.0)	48 (19, 60)	929	46.2 (7.5)	48 (19, 60)	–	–	–	–	–
Month 6	365	45.2 (8.3)	47 (18, 59)	405	45.9 (7.9)	48 (16, 59)	770	45.5 (8.1)	47 (16, 59)	45.7 (0.26)	45.2 to 46.2	45.9 (0.25)	45.4 to 46.4	–0.22 (–0.84 to 0.41); $p = 0.50$
Month 12	372	45.3 (8.0)	46 (18, 59)	388	45.8 (8.0)	48 (15, 60)	760	45.6 (8.0)	47 (15, 60)	45.4 (0.27)	44.9 to 46.0	45.4 (0.26)	44.9 to 45.9	0.01 (–0.65 to 0.67); $p = 0.98$

SD, standard deviation; SE, standard error.

a Adjusted for baseline FAI score, sex, age at randomisation, history of falling and centre (random effect); unstructured covariance pattern used in the final model.

Note

Higher score indicates greater activity.

TABLE 28 Unadjusted and adjusted results for GDS score by randomised group

	Unadjusted									Adjusted[a]				
	Treatment group									Treatment group				
	Intervention ($N = 493$)			Usual care ($N = 517$)			Total ($N = 1010$)			Intervention		Usual care		
Time point	*n*	Mean (SD)	Median (minimum, maximum)	*n*	Mean (SD)	Median (minimum, maximum)	*n*	Mean (SD)	Median (minimum, maximum)	Mean (SE)	95% CI	Mean (SE)	95% CI	Mean difference (95% CI); *p*-value
Baseline	484	3.8 (3.1)	3 (0, 14)	510	3.6 (3.0)	3 (0, 15)	994	3.7 (3.0)	3 (0, 15)	–	–	–	–	–
Month 6	439	3.8 (3.2)	3 (0, 15)	467	3.6 (3.0)	3 (0, 14)	906	3.7 (3.1)	3 (0, 15)	3.7 (0.10)	3.5 to 3.9	3.7 (0.09)	3.5 to 3.9	0.05 (–0.21 to 0.32); $p = 0.70$
Month 12	418	3.7 (3.3)	3 (0, 14)	450	3.4 (3.0)	3 (0, 15)	868	3.5 (3.2)	3 (0, 15)	3.7 (0.11)	3.5 to 3.9	3.5 (0.10)	3.3 to 3.7	0.22 (–0.07 to 0.51); $p = 0.13$

SD, standard deviation; SE, standard error.

a Adjusted for baseline GDS score, sex, age at randomisation, history of falling and centre (random effect); unstructured covariance pattern used in the final model. Adjusted mean difference with log-transformed response variable (month 6: –0.01, 95% CI –0.08 to 0.06; $p = 0.82$; month 12: 0.04, 95% CI –0.04 to 0.12; $p = 0.38$).

Note

A score of 0–5 is considered normal, 5–9 indicates depression and 10–15 indicates severe depression.

TABLE 29 Categorised Short FES-I data by randomised group

	Treatment group											
	Intervention ($N = 493$)				Usual care ($N = 517$)				Total ($N = 1010$)			
		Level of concern				Level of concern				Level of concern		
Time point	*n*	None/low	Moderate	High	*n*	None/low	Moderate	High	*n*	None/low	Moderate	High
Baseline	481	75 (15.6)	260 (54.1)	146 (30.4)	504	73 (14.5)	293 (58.1)	138 (27.4)	985	148 (15.0)	553 (56.1)	284 (28.8)
Month 6	425	90 (21.2)	201 (47.3)	134 (31.5)	451	89 (19.7)	226 (50.1)	136 (30.2)	876	179 (20.4)	427 (48.7)	270 (30.8)
Month 12	410	87 (21.2)	183 (44.6)	140 (34.2)	447	99 (22.2)	214 (47.9)	134 (30.0)	857	186 (21.7)	397 (46.3)	274 (32.0)

Proportion of participants with depression

The proportion of participants who were depressed was higher in the intervention group than in the usual-care group (as measured by a score of ≥ 6 on the GDS) at all three assessment time points (12 months: 23.2% vs. 19.1%; *Table 30*). The adjusted OR at 12 months was 1.26 but this effect was not statistically significant (95% CI 0.91 to 1.75; $p = 0.16$).

Proportion of participants obtaining a fracture or multiple fractures

Over the 12-month follow-up, 31 participants (intervention, $n = 17$; usual care, $n = 14$) reported breaking or fracturing a bone as a result of a fall (adjusted OR 1.21, 95% CI 0.59 to 2.49; $p = 0.60$). Two participants, both in the intervention group, reported fractures from two distinct events. The types of fractures reported are presented in *Table 31*.

TABLE 30 Summary of depression indicator by time point and randomised group

	Treatment group		
GDS score of ≥ 6	Intervention ($N = 493$)	Usual care ($N = 517$)	Total ($N = 1010$)
Baseline			
n	484	510	994
Depressed, *n* (%)	120 (24.8)	104 (20.4)	224 (22.5)
Not depressed, *n* (%)	364 (75.2)	406 (79.6)	770 (77.5)
Month 6			
n	439	467	906
Depressed, *n* (%)	113 (25.7)	101 (21.6)	214 (23.6)
Not depressed, *n* (%)	326 (74.3)	366 (78.4)	692 (76.4)
Month 12			
n	418	450	868
Depressed, *n* (%)	97 (23.2)	86 (19.1)	183 (21.1)
Not depressed, *n* (%)	321 (76.8)	364 (80.9)	685 (78.9)

TABLE 31 Types of fractures reported as a result of a fall by randomised group

	Treatment group, *n* (%)		
Type of fracture	Intervention ($N = 19$)	Usual care ($N = 14$)	Total ($N = 33$), *n* (%)
Hip	5 (26.3)	2 (14.3)	7 (21.2)
Hand/finger	2 (10.5)	3 (21.4)	5 (15.2)
Toe/foot	2 (10.5)	2 (14.3)	4 (12.1)
Wrist	2 (10.5)	2 (14.3)	4 (12.1)
Leg	2 (10.5)	1 (7.1)	3 (9.1)
Rib	1 (5.3)	1 (7.1)	2 (6.1)
Shoulder	2 (10.5)	0 (0.0)	2 (6.1)
Ankle	1 (5.3)	0 (0.0)	1 (3.0)
Arm	0 (0.0)	1 (7.1)	1 (3.0)
Spine/back	1 (5.3)	0 (0.0)	1 (3.0)
Unknown	1 (5.3)	2 (14.3)	3 (9.1)

Foot pain

Participants in the intervention group reported greater foot pain at 12 months (adjusted mean 3.1 vs. 2.6; adjusted mean difference 0.43, 95% CI 0.06 to 0.80; $p = 0.02$). When non-compliance with the intervention was accounted for through CACE analysis, the predicted mean pain score among compliers in the intervention group was 3.1, and among the counterfactual group of compliers in the usual-care group was 2.6 (adjusted mean difference 0.50, 95% CI 0.08 to 0.92; $p = 0.02$).

Adverse events

Serious adverse events

A total of 95 SAEs were reported in the period between randomisation and 1 month following the trial end (12 months after randomisation), by 49 (9.9%) participants in the intervention group and 37 (7.2%) participants in the usual-care group (*Table 32*). The majority of participants (90.7%) reported only one event. During the reporting period, there were 23 reported deaths (eight in the intervention group and 15 in usual care); all deaths were considered expected. For seven deaths, the relationship to research procedures could not be assessed owing to a lack of information, but, for those that could, none was deemed to be related. Nearly two-thirds of all SAEs were hospitalisations ($n = 62$, 65.3%). The two events considered to be life- or limb-threatening were in the intervention group, and one of these was related to the intervention. Details of the SAEs deemed to be at least possibly related to the research are presented in *Table 33*. None of these events was attributable to the exercise programme but tended to relate to the trial shoes or orthosis.

TABLE 32 Serious adverse events by randomised group

	Treatment group		
SAEs	Intervention ($N = 493$)	Usual care ($N = 517$)	Total ($N = 1010$)
Total number of SAEs	53	42	95
Number of participants with one or more SAEs	49	37	86
Number of events per participant, *n* (%)			
1	45 (91.8)	33 (89.2)	78 (90.7)
2	4 (8.2)	3 (8.1)	7 (8.1)
3	0 (0.0)	1 (2.7)	1 (1.2)
Event details, *n* (%)			
Death	8 (15.1)	15 (35.7)	23 (24.2)
Hospital required/prolonged	36 (67.9)	26 (61.9)	62 (65.3)
Life-/limb-threatening	2 (3.8)	0 (0.0)	2 (2.1)
Disability	0 (0.0)	0 (0.0)	0 (0.0)
Other	7 (13.2)	1 (2.4)	8 (8.4)
Intensity, *n* (%)			
Mild	0 (0.0)	0 (0.0)	0 (0.0)
Moderate	5 (9.4)	2 (4.8)	7 (7.4)
Severe	47 (88.7)	40 (95.2)	87 (91.6)
Missing[a]	1 (1.9)	0 (0.0)	1 (1.1)

TABLE 32 Serious adverse events by randomised group (*continued*)

SAEs	Treatment group		Total (*N* = 1010)
	Intervention (*N* = 493)	Usual care (*N* = 517)	
Outcome, *n* (%)			
Recovered fully	22 (41.5)	12 (28.6)	34 (35.8)
Recovered partially	6 (11.3)	2 (4.8)	8 (8.4)
Ongoing	16 (30.2)	13 (31.0)	29 (30.5)
Died	8 (15.1)	15 (35.7)	23 (24.2)
Missing	1 (1.9)	0 (0.0)	1 (1.1)
Relationship to any of the research procedures, *n* (%)			
Unrelated	35 (66.0)	31 (73.8)	66 (69.5)
Unlikely	8 (15.1)	6 (14.3)	14 (14.7)
Possibly	3 (5.7)	0 (0.0)	3 (3.2)
Probably	0 (0.0)	0 (0.0)	0 (0.0)
Definitely	2 (3.8)	0 (0.0)	2 (2.1)
Not able to assess	4 (7.6)	5 (11.9)	9 (9.5)
Missing	1 (1.9)	0 (0.0)	1 (1.1)
Expectedness, *n* (%)			
Expected	48 (90.6)	37 (88.1)	85 (89.5)
Unexpected	4 (7.6)	5 (11.9)	9 (9.5)
Missing	1 (1.9)	0 (0.0)	1 (1.1)

a Event with missing outcome, relationship and expectedness was initially reported on participant's 12-month questionnaire and followed up by a member of the research team. Participant reported breaking their leg and developing tendinopathy following a fall 8 months earlier. Event was not reported at the time and limited information was available when this event was followed up.

TABLE 33 Details of the SAEs deemed to be at least possibly related to the research (all in intervention group)

Event type	Description	Intensity	Outcome	Relationship	Expectedness
Hospitalisation	Participant tripped while wearing trial shoes, fell and was hospitalised (found to have elevated blood pressure and low blood glucose)	Severe	Recovered partially	Possible related	Yes
Hospitalisation	Participant fell and fractured wrist and skull; they were not wearing trial shoes	Severe	Recovered partially	Possible related	Yes
Hospitalisation	Participant fell while wearing trial shoes with insoles. Laces were correctly fastened. Injured elbow and shoulder, and was hospitalised	Severe	Ongoing	Possible related	Yes
Hospitalisation	Participant fell while wearing trial shoes and broke hip	Severe	Recovered partially	Definitely	Yes
Life-/limb-threatening	Participant's shoes with an insole caused pressure ulceration at the toes and subsequent cellulitis, which required antibiotics	Severe	Recovered fully	Definitely	Yes

Non-serious adverse events

Non-SAEs that occurred within the reporting period and were deemed to be at least possibly related to any of the research procedures are summarised in *Table 34*. These were all in the intervention group. Participant self-reported occurrences of pain or cramp possibly resulting from the exercises were forwarded to the treating podiatrist for review. If these events lasted for > 48 hours, then an adverse event was recorded. Pain and cramp lasting for < 48 hours was considered an expected occurrence within this population and for this component of the intervention, and so was not recorded.

TABLE 34 Non-SAEs that occurred within the reporting period and were deemed to be at least possibly related to any of the research procedures

Non-SAEs	Intervention (*N* = 493)
Total number of non-SAEs	58
Number of participants with one or more non-SAEs	49
Number of events per participant, *n* (%)	
1	42 (85.7)
2	5 (10.2)
3	2 (4.1)
Event details, *n* (%)	
Aches/pains in lower limbs lasting for ≥ 48 hours	26 (44.8)
Injury attributable to exercise equipment	1 (1.7)
Soft tissue injury	5 (8.6)
Skin irritation/injury (e.g. pressure sore, callus/corn)	9 (15.5)
Other	22 (37.9)
Intensity, *n* (%)	
Mild	36 (62.1)
Moderate	22 (37.9)
Severe	0 (0.0)
Outcome, *n* (%)	
Recovered fully	28 (48.3)
Recovered partially	15 (25.9)
Ongoing	15 (25.9)
Relationship to any of the research procedures, *n* (%)	
Possibly	11 (19.0)
Probably	29 (50.0)
Definitely	18 (31.0)
Expectedness, *n* (%)	
Expected	46 (79.3)
Unexpected	12 (20.7)

Chapter 5 Economic evaluation

Introduction

As stated in earlier chapters, the aim of the REFORM trial is to provide rigorous trial evidence for the role of a complex podiatry care intervention that combines foot and ankle exercise with footwear advice and orthotic inserts for falls prevention within a UK setting.

Economic evaluation supports decision-making in prioritising the allocation of limited health-care resources.[46] Economic evaluation alongside clinical trials, as in the REFORM trial, can therefore be a valuable tool to help decide what interventions should be implemented, based not only on clinical effectiveness but also on cost-effectiveness. Moreover, RCTs are often the best means for providing unbiased estimates of both health effects and costs.[47]

This chapter reports on the economic evaluation that was conducted alongside the REFORM trial. The aim of this economic analysis is to help decision-making in determining whether or not the multifaceted intervention represents a cost-effective alternative within the UK NHS for falls prevention compared with usual care provided by the podiatrist or GP and a falls prevention leaflet.

Methods

Overview

Individual participant data collected in the REFORM trial were used to perform a within-trial economic analysis that comprised (1) a cost–utility analysis, in terms of the cost per QALY, and (2) a cost-effectiveness analysis (CEA), in terms of the cost per fall averted (i.e. using the primary effectiveness outcome of the trial). Costs are presented in UK pounds sterling (£) at 2015 prices, and the analysis has been undertaken in Stata version 13.1. The NICE guidelines were applied to all methods used for this economic analysis.[48]

Base-case analysis

The base-case analysis was conducted on an ITT basis using multiple imputed data and from the perspective of the UK NHS and Personal Social Services, which included resource use related to falls only. The ITT aspect compares participants in the two groups (intervention vs. usual care) on the basis of their initial random allocation, irrespective of protocol deviations or withdrawal. A secondary analysis was undertaken from the societal perspective. Costs and outcome data are compared for the two groups over 12 months and, hence, discounting was not required.

Owing to the impact of missing data for the within-trial CEA, our economic analysis plan indicated that the base-case analysis would be conducted as an imputed analysis by means of MI at the utility level. This has been recommended as the appropriate method to reflect the uncertainty in the results of the economic evaluation attributable to missing data.[49]

Sensitivity analysis

Additional sensitivity analyses were conducted to explore the extent to which the results change with different assumptions. Sensitivity analyses were conducted in order to test (1) complete case as an alternative method to MI for handling missing data, (2) the impact of imputing HRQoL at aggregated level (e.g. QALY level), (3) the impact of including both fall- and non-fall-related visits and hospitalisations in the calculation of total costs and (4) the societal perspective (e.g. cost of the shoes as a personal expense for the patient). Finally, we used a probabilistic sensitivity analysis to explore the uncertainty associated with the mean difference in costs and health outcomes using both the imputed and the complete data sets.

Economic data collection

Data for outcomes and resource use for the economic analysis were collected prospectively. Health service usage was measured using participant-reported questionnaires at baseline and at 6 and 12 months during the 12 months' follow-up.

Health-related quality of life

Health-related quality of life is expressed in terms of utilities, which were assessed at baseline and at 6 months and 12 months using the EQ-5D-3L.[50] The EQ-5D is a standardised and validated generic instrument for the measurement of HRQoL that allows the translation of patient utilities into QALYs, which is the primary outcome for the base-case analysis.

The QALY is a measure of health that simultaneously incorporates changes in both morbidity (related to quality of life) and mortality (related to the quantity of years lived). As well as being one of the most widely used generic health status measures, the EQ-5D is the instrument recommended by the NICE appraisal guidance.[48] The EQ-5D considers health (functioning) in terms of five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has three possible levels: no problems, moderate problems and severe problems. This five-domain and three-level system generates 245 mutually exclusive health states, including unconscious and dead. To estimate HRQoL weights (known as utilities) and to reflect the preferences of the UK population, each of these health states has been validated in a large UK population sample[30] using the time trade-off method, ranging from 1 for perfect health (thus, the maximum value possible) to –0.594 for severe problems; 0 corresponds to death. Utility values were generated by valuing health status (using a social tariff) as measured using the EQ-5D system. Mean utility values were reported for each trial group, and differences in utilities between the two treatment groups were estimated using ordinary least squares (OLS) regression.

The EQ-5D has been recommended by The Prevention of Falls Network Europe Consensus as the measure of HRQoL to be used in fall prevention trials.[32] The rationale behind this is that the EQ-5D is simple and responsive to changes in health and, more importantly, it has been used widely in older populations.[51] Similarly, the EQ-5D has been used before in a UK setting to assess HRQoL and costs implications of falls in elderly people.[1] We converted the utilities derived from the EQ-5D into QALYs for each participant using the area under the curve method, following the trapezium rule, which assumes linear interpolation between follow-up points.[52] Despite the randomisation process, which should ensure that, on average, baseline variables are balanced between the groups of the trial, in practice (regardless of sample size) it is not unusual to find imbalance in mean baseline utility. As baseline utility is likely to be correlated with participants' QALY gains over time, there are robust reasons to control for baseline utility when estimating QALYs;[53] therefore, incremental mean QALYs between treatment groups were estimated with and without adjustment for baseline utility, using regression methods according to ITT allocation. In addition, incremental mean QALYs were adjusted for the same set of covariates as in the primary clinical effectiveness analysis model: age at randomisation, sex and history of falling. Centre was treated as a fixed effect in all models.

Health benefits in terms of falls

The primary outcome of the trial was the incidence rate of falls per participant during the 12 months following randomisation. The primary clinical effectiveness analysis used a mixed negative binomial regression model to analyse the number of falls per person per year controlling, as fixed effects, for sex, age at randomisation and history of falling, with centre as a random effect.

In order to interpret the cost-effectiveness results, the health outcome was reported as 'falls averted'. The number of falls averted was estimated as the difference in mean reduction in the fall rate between the two groups in the trial estimated as per the adjusted negative binomial model used for the primary clinical effectiveness analysis.

Health-care resource use

Health-care resource use data were collected via participant-reported questionnaires. Participants were asked to complete information on their number of visits to primary care facilities (e.g. contacts with a GP and general practice nurse), use of community care (e.g. contacts with occupational therapist) and their number of hospital visits [inpatient, day case, outpatient, and accident and emergency (A&E) department] at baseline and at 6 and 12 months. Patients were also asked about the number of times they made an emergency service call or the used the Patient Transportation Service. All resource use (except inpatient hospital stay) was split into 'fall-related' and 'non-fall-related'. The base-case analysis was based on fall-related resource use, except for inpatient hospital stay, given the format of the questionnaire. A sensitivity analysis explored the impact of including both fall- and non-fall-related resource use in the analysis.

Participants were asked to record the total number of times they stayed in hospital as an inpatient as well as the number of nights for each visit and the reason for attendance. The number of inpatient visits did not differentiate fall- from non-fall-related incidents and, hence, the base-case analysis included all inpatient stays reported by participants during the trial. Following a reported fall, participants were contacted to obtain information about the nature, location and cause of the fall. They were asked whether or not they sustained any injuries from the fall and, if so, whether or not they required an overnight stay in hospital. Only 28 participants (intervention, $n = 14$; usual care, $n = 14$) reported that they had to spend a night in hospital as a result of their fall. We assumed that missing answers (boxes left blank) to the second question (i.e. number of nights in hospital) when participants reported no hospital stay indicated no use of services and, thus, no overnight stays. There were participants with missing responses to number of nights but who reported the reason for their stay; for these cases the length of stay (nights in hospital) was assumed to be one night. Similarly, there were participants who reported not being in hospital but who gave information on the reason for their attendance; it was assumed that these participants stayed in hospital for one night. Finally, there were participants who reported that they stayed overnight in hospital but left blank the remaining information regarding number of occasions, number of nights and reason for stay. As a conservative assumption, we assumed that these participants stayed in hospital for one night on one occasion.

The number of visits made by the participant to their podiatry clinic in the previous 12 months was collected on the 12-month participant questionnaire. This information was available for participants in both treatment groups. In the case of participants in the intervention group, the number of visits made to the podiatry clinic as part of the intervention was collected via a trial-specific podiatrist database. Therefore, for participants in the intervention group, the number of podiatry appointments self-reported at 12 months was assumed to consist of trial appointments and unrelated routine care appointments. We knew the number of appointments received as part of the intervention and, therefore, assumed that all other reported visits were unrelated; hence, these were not included as part of the cost of the intervention.

We also asked about the use of Meals on Wheels and paid care; however, few participants reported using either Meals on Wheels (96.14% did not use this service) or paid-for help (92.87% did not pay for care). Therefore, it was decided not to incorporate these into the societal perspective analysis. Resource use was valued in monetary terms and unit costs were reported in UK pounds sterling (£) for the financial year 2014/15. The cost for each participant in the REFORM trial was calculated by multiplying health-care resource use by associated unit costs. *Table 35* details the unit costs for the estimation of costs related to patient care that were used in the analysis.

Costing the intervention

The cost of the podiatry intervention was assessed based on the data collected as part of a baseline appointment questionnaire and the podiatrist database, which included information directly related to the podiatrist assessments and the intervention package received by the participant (e.g. orthosis prescription, exercise programme and exercise equipment).

TABLE 35 Unit costs (and sources) of health-care services used to estimate total cost for each individual participant: primary and community care, secondary care and podiatry care

Resource use	Unit cost (£)	Source
Cost component: primary care		
Visit to GP	44.00	*Unit Costs of Health and Social Care 2015*[54]
Visit to general practice nurse	25.00	*Unit Costs of Health and Social Care 2015*[54]
Occupational therapist	44.00	*Unit Costs of Health and Social Care 2015*[54]
Cost component: secondary care		
Hospital stay	3106.00	[a]*NHS Reference Costs 2014–15*[55]
Excess hospital stay	303.00	[b]*NHS Reference Costs 2014–15*[55]
Outpatient visit	114.50	[c]*NHS Reference Costs 2014–15*[55]
Day case	720.00	[d]*NHS Reference Costs 2014–15*[55]
A&E	140.60	[e]*NHS Reference Costs 2014–15*[55]
Emergency service call	154.00	[f]*Unit Costs of Health and Social Care 2015*[54]
Patient transportation service	99.00	*Unit Costs of Health and Social Care 2015*[54]
Cost component: podiatrist		
Podiatrist first visit (assessment)	46.00	[g]*NHS Reference Costs 2014–15*[55]
Podiatrist second visit	44.00	[g]*NHS Reference Costs 2014–15*[55]
Podiatrist follow-up visit	39.00	[g]*NHS Reference Costs 2014–15*[55]

a Averaged (elective and non-elective), weighted by activity levels across all NHS trusts and NHS foundation trusts.
b Excess bed-day averaged (elective and non-elective) per activity across all NHS trusts and NHS foundation trusts.
c Averaged total outpatient attendances, weighted by activity levels across all trusts and specialties.
d Day cases averaged per activity across all trusts and specialties.
e A&E averaged per activity across all NHS trusts and NHS foundation trusts.
f Ambulance services weighted average of attendances by activity level ('see and treat and refer'; 'see and treat and convey').
g The podiatrist visits for the intervention group were classified as first assessment visit (podiatrist Tier 3, management of at-risk complex foot); second visit (podiatrist specialist care 1) and the rest as follow-up visits (general podiatry). For the usual-care group, podiatrist visits were costed as follow-up (podiatrist specialist care 2).

Unit costs, together with their sources, for the podiatry intervention are provided in *Table 36*. Aside from manufacturer prices, the unit costs used in the analysis were obtained from published national sources: *Unit Costs of Health and Social Care* (Personal Social Services Research Unit)[54] and *NHS Reference Costs*.[55]

The base-case analysis includes only costs falling within the NHS and, hence, the cost of the shoe was not included in the primary analysis. This issue was discussed at length within the trial team and with the trial podiatrists; all were in strong agreement that, if the intervention were implemented, the NHS would not cover the cost of the shoes. We therefore considered the price of the shoes as a personal expense for the patient (e.g. as part of the societal perspective). A secondary analysis from the societal perspective that included the cost for the shoe was conducted.

We calculated the cost for each participant in the trial by multiplying their use of health-care resources by the associated unit costs. The total costs for the base-case analysis included only fall-related resource use (except for inpatient stay, which included both fall- and non-fall-related resource use). The total cost comprises five main components: (1) podiatrist visits, (2) hospital visits (inpatient, outpatient and day cases), (3) visits to primary and community health-care professionals (GP, practice nurse and occupational therapist), (4) patient transportation and (5) the cost of the podiatrist intervention. Other scenarios were

TABLE 36 Unit costs and sources of the multifaceted podiatry intervention

Resource use	Unit cost (£)	Source
Cost component: podiatry intervention		
Shoes provided, per pair	64.00	Manufacturer price 2015
Therapy ball (large)	0.95	Manufacturer price 2013[a]
Therapy ball (small)	0.90	Manufacturer price 2013[a]
Resistive exercise band (band 1)	1.11	Manufacturer price 2013[a]
Resistive exercise band (band 2)	1.21	Manufacturer price 2013[a]
Resistive exercise band (band 3)	1.28	Manufacturer price 2013[a]
Resistive exercise band (band 4)	1.45	Manufacturer price 2013[a]
Resistive exercise band (band 5)	1.72	Manufacturer price 2013[a]
Resistive exercise band (band 6)	1.50	Manufacturer price 2013[a]
Resistive exercise band (band 7)	1.74	Manufacturer price 2013[a]
Resistive exercise band (band 8)	1.89	Manufacturer price 2013[a]
Resistive exercise band (band 9)	1.97	Manufacturer price 2013[a]
Resistive exercise band (band 10)	2.09	Manufacturer price 2013[a]
X-Line Extra insoles	5.95	Manufacturer price 2015
X-Line Pressure Perfect insoles	4.75	Manufacturer price 2015
Formthotics Dual insoles	14.99	Manufacturer price 2015
DVD and booklet	3.82	Manufacturer price 2013[a]
Podiatrist first visit (assessment)	46.00	*NHS Reference Costs 2014–15*[55]
Podiatrist second visit	44.00	*NHS Reference Costs 2014–15*[55]
Podiatrist follow-up visit	39.00	*NHS Reference Costs 2014–15*[55]

a Price inflated to 2014/15 prices using Personal Social Services Research Unit 2015[54] (Hospital and Community Service Index).

tested as part of the sensitivity analysis, in which we explored the impact of incorporating both types of resource use (fall- and non-fall-related) into the analysis.

Multiple imputation

Missing data occur frequently in RCTs, irrespective of how well designed the data collection is. This is a major concern for within-trial CEA, as costs and QALYs, the main outcomes in CEAs, are cumulative measures collected over the trial follow-up. Therefore, missing data at one follow-up time point (e.g. one dimension response missing to the EQ-5D at one time point) result in missing aggregate data (e.g. total QALYs over the trial) for that participant. This problem is common in economic evaluations, as the analysis has to draw on all aspects of the study, including resource use and health outcomes. Non-response to questionnaires and returned but incomplete questionnaires reduce, often considerably, the number of data on resource use that are available for analysis. The problem is amplified when there are frequent assessments, as in the REFORM trial.

Complete-case assessment and available case analysis are proposed as useful preliminary estimations for economic evaluation but should not constitute the base case for within-trial economic evaluation.[56]
An alternative method to address missing data in CEAs alongside clinical trials is MI,[57] which has been recommended as the appropriate method to reflect the uncertainty in the results of the economic evaluation attributable to missing data.[49] As already stated, our economic analysis plan indicated that the

base case would be conducted as an imputed analysis using MI with chained equations. Given the extent of missing data in the REFORM trial, this initial decision is justified; therefore, the base-case analysis was conducted on the imputed data set. A descriptive analysis of missing data was conducted in order to help inform the base-case assumption regarding the missing data mechanism. We described the number of missing data by treatment group at each follow-up point. We also examined the missing data pattern to find out whether or not participants with missing data were lost to follow-up throughout the duration of the trial.

Multiple imputation comprises three steps. First, the imputed data set is created through the use of regression models to predict plausible values for the missing observations from the observed values. The process includes all the variables that might be associated with the missingness mechanism (here, sex, age, history of falls, centre, baseline costs, primary care and hospital costs) and QALY utilities (at baseline and at 6 and 12 months). Costs and utilities were imputed simultaneously rather than separately in the model. Therefore, the covariates registered in the model were used for both costs and utilities, when a regression model was fitted for each variable with missing values, with the previous variables as covariates. Based on the resulting model, a new regression model is then estimated and used to impute the missing values for each variable. A random component is included to reflect the uncertainty around the predictions. Thus, MI reflects the uncertainty in the prediction of missing values while preserving the distribution and correlations in the data.[58] These values are then used to fill in the gaps in the data set. This process is repeated *m* times, creating *m* imputed data sets. It is suggested that, if missing values account for 20% of the total number of data, three imputations are sufficient.[59] Given the extent of missing data in REFORM, five imputations were performed. In the second stage, each data set is analysed independently using complete-case methods. Finally, the estimates obtained from each imputed data set are combined to generate mean estimates of costs and QALYs, variances and CIs using Rubin's rules.[60]

The correct specification of the regression model is vital to ensure that the distribution of imputed values does not differ from the observed values and, thus, that unbiased estimates are obtained. The specification of the regression models depends on the type and distribution of the variable to be imputed. Costs and QALYs are both continuous and non-normally distributed. Two alternative methods are proposed to deal with this difficulty when using MI with chained equations: (1) data transformation and (2) predictive mean matching.[61] Predictive mean matching was used for the imputation of REFORM data. This method ensures that observed data were used to estimate a predictive model (using the specified covariates) but, instead of replacing missing values with the model predicted values, the nearest observed value is used to fill the missing one. This guarantees that the imputed values are sampled from values in the original data set, and, therefore, that no imputed values will lie outside the bounds of the original data distribution. In addition to the description of the missing data mechanism, we used graphical plots to visualise whether or not the distribution of imputed data resembles the distribution of original data.

The main assumption that drives the MI mechanism is that the data are missing at random (MAR). Additional sensitivity analyses were conducted to test the robustness of the results to deviations from this assumption. In that sense we explored (1) the use of the complete data set [e.g. assume that the data are missing completely at random (MCAR)] and (2) imputation at various levels of aggregation (e.g. at utility level rather than QALY level).

Incremental analysis

Total health-care expenditure must be covered from a limited budget and, therefore, the most informative estimate for CEA is based on the difference of arithmetic mean effect from both budgetary and social perspectives.[62] Therefore, the focus of this economic evaluation was to estimate the mean costs and mean health outcomes. The cost-effectiveness of the podiatry intervention was evaluated by comparing the mean costs and outcomes (QALYs and falls) incurred in the intervention group with the mean costs and outcomes (QALYs and falls) in the usual-care group at 12 months' follow-up, using conventional decision rules and estimating incremental cost-effectiveness ratios (ICERs) when appropriate.

As expected, costs in the REFORM trial were right-skewed, and we found that some participants had costs that far exceeded the mean value. In order to deal with skewness and heteroscedasticity, non-parametric bootstrap procedures[62–64] are usually implemented as the primary statistical test for making inferences about arithmetic means for moderately sized samples of skewed cost data (such as the REFORM sample). Bootstrap methods assume that the empirical distribution of the data is an adequate representation of the true distribution of the data; the analysis is based on repeatedly sampling (with replacement) from the observed data. For the REFORM analysis we repeatedly randomly drew a sample of 1000 for each of the imputed five data sets. Each bootstrap repetition is the equivalent of a repetition of the trial. To obtain reliable results in practice it has been recommended to use at least 1000 resamples to estimate a bootstrap CI.[63] For the REFORM analysis we used 5000 resamples (bias corrected and accelerated). The mean difference in costs and QALYs for the base-case analysis was estimated using seemingly unrelated regression (SUR) equations for data on costs and QALYs. The SUR model used the same set of covariates as the mixed-effect regression model used for the clinical effectiveness analysis (sex, age at randomisation, fall history) as well as total number of falls and baseline utility. Incremental costs were also adjusted for baseline costs. SUR is used to address the correlation of standard errors between costs and QALYs.[65] This brings efficiency gains over unrelated OLS regression for three reasons: (1) it allows for explicit modelling of both costs and effects while allowing the inclusion of a set of different covariates in the two equations; (2) it exploits the existence of correlation between costs and effects; and (3) SUR does not require a new regression for every value of the cost-effectiveness threshold.[66] Again, the same set of covariates as used in the clinical effectiveness analysis was used. The baseline EQ-5D utility was also included in the utility regression to adjust for possible baseline imbalance and to reduce the standard errors of post-test EQ-5D. Incremental costs were also adjusted for baseline costs.

The ICER was estimated as the difference in mean total costs divided by the difference in mean total QALYs from baseline to 12 months. The ICER is estimated to inform decision-makers about the optimal use of NHS resources. According to standard cost-effectiveness decision rules, four different eventualities are plausible when comparing incremental costs and QALYs. If the new intervention provides better outcomes (positive incremental QALYs) at lower costs (negative incremental costs) it is considered a dominant intervention and, hence, cost-effective. If the new intervention achieves poorer outcomes (negative incremental QALYs) at higher costs (positive incremental costs) it is considered a dominated option and, hence, not cost-effective. Thus, the ICER is considered only if either intervention does not dominate, that is, both incremental costs and incremental QALYs are positive (or negative). In these last two situations, to determine whether or not the incremental health gain is worth the incremental cost, the ICER needs to be compared against a threshold value. For positive incremental costs and QALYs (the most frequent situation in HTA), an intervention will be considered cost-effective only if the ICER is lower than the threshold. According to NICE, the WTP threshold for an additional QALY ranges from £20,000 to £30,000.[48] This threshold has been used by NICE for more than a decade; however, it has recently been suggested that the threshold should be decreased to £13,000 per QALY gained.[67] According to the current established decision rules, if the result of this cost–utility analysis, namely the estimated cost per QALY, is below the £30,000 threshold, the podiatry intervention would be considered cost-effective in terms of QALYs gained.

The ICER can be rearranged in terms of net benefit, which is a more intuitive way of expressing whether or not the health benefits of the podiatry intervention are worth the additional costs.[68] The net benefit can be estimated on the cost scale as the incremental health gain, expressed in terms of money, minus the incremental cost of the intervention. The health benefits are translated into monetary value using the cost-effectiveness threshold, that is, incremental QALYs are multiplied by the WTP threshold. Therefore, the net monetary benefit (NMB) provides an estimation of the gain (or loss) in resources of investing in a particular intervention when those resources might be used elsewhere.[69] Current NICE guidance recommends presenting the NMB using values of £20,000 and £30,000 per QALY for the WTP threshold. The podiatry intervention would be considered cost-effective only if the NMB were positive.

Analysis of uncertainty

Uncertainty in economic evaluation is related to the expected values of model inputs but not to patient variability. The uncertainty around the cost-effectiveness estimates was explored by means of sensitivity analyses in order to test the robustness of the results under different scenarios. These scenarios captured variability in the estimates of costs and outcomes, which resulted from either different methods (e.g. imputation methods), from the costs included in the analysis or from the perspective for the analysis.

The extent of missing data in the REFORM trial justified the use of the imputed data set as the base-case analysis. Nevertheless, a complete-case analysis was explored as part of a sensitivity analysis. Similarly, we also conducted sensitivity analyses to test different levels of aggregation when imputing costs and QALYs.

The base case was based on the imputed data set and included only fall-related visits and hospitalisations. One-way sensitivity analyses were conducted to test the impact of including all visits and hospitalisations regardless of them having being classified as fall- or non-fall-related.

Finally, we used probabilistic sensitivity analysis to investigate the uncertainty associated with the mean difference in costs and QALYs between the two treatment groups using both the imputed and the complete-case data sets. Non-parametric bootstrapping was used to plot the joint distribution of costs and effects (QALYs) on the cost-effectiveness plane and to derive the CEAC to express the (Bayesian) probability that the podiatry intervention is cost-effective as a function of the WTP threshold.[70]

Exploration of the need for a long-term model

An exploratory model was developed to explore how the differences in HRQoL observed during the trial (e.g. at 1 year) evolve beyond the study (up to 5 years). For this exploratory projection, we used a decision-modelling approach and assumed that the difference in HRQoL and costs observed at 1 year would remain unchanged.

Validation of results

In order to validate the results of the analysis, two statistical codes (written in Stata) were independently developed and their results compared. The codes were developed by one analyst and checked independently by another. The distributions of the observed and imputed values were compared graphically.

Results

Patient population and missing data mechanism

Twenty-four participants died during the trial: 9 out of 493 (1.8%) in the intervention group and 15 out of 517 (2.9%) in the usual-care group. When there were missing data before these participants' deaths, the imputation process was applied in the same way as for the rest of the patients in the trial. The questionnaires that should have been received at any other assessment after their deaths were considered as part of the complete-case analysis with zero resource use and zero utilities. The complete-case analysis comprised those participants for whom data were available for the whole trial duration for utilities and all cost categories.

The proportion of participants with complete data decreased with the duration of follow-up but remained similar in both groups (*Table 37*): from 72.0% (baseline) to 54.4% (12 months) for the intervention group and from 71.8% (baseline) to 61.3% (12 months) for the usual-care group. In the usual-care group, more individuals are observed at 12 months than at 6 months; therefore, the missing data follow not a monotonic pattern but an intermittent one (i.e. there are participants with missing 6-month data but complete data at 12 months). A complete-case assessment would be, as a minimum, inefficient because it would discard observed data from individuals with some missing outcomes.

Table 38 presents the ORs from a logistic regression of indicators of missing QALY data on treatment group allocation and the covariates used for the main statistical model. Lower EQ-5D at baseline is

TABLE 37 Number and proportion of participants with complete-case data by treatment group

Time point	Intervention ($N = 493$), *n* (%)	Usual care ($N = 517$), *n* (%)
Baseline	355 (72.0)	371 (71.8)
6 months	285 (57.8)	305 (59.0)
12 months	268 (54.4)	317 (61.3)
Total trial duration	129 (26.2)	157 (30.4)

TABLE 38 Logistic regression to predict missing QALYs on baseline variables

Missing data on QALYs	OR (95% CI)
Treatment group	1.13 (0.82 to 1.55)
Sex	1.27 (0.92 to 1.77)
Age	1.04[a] (1.02 to 1.06)
History of fall	1.26 (0.89 to 1.77)
EQ-5D at baseline	0.68 (0.35 to 1.32)

a Statistically significant at 5% level.

associated with missing QALY data but is not statistically significant at the 5% level. This suggests that the data are unlikely to be MCAR. It was found that older and frailer (lower utility) participants with a history of falling were more likely to have missing QALY data. This information would support the MAR assumption (e.g. MI assumed missing data mechanism).

Multiple imputation and likelihood-based methods can handle non-monotonic missing data under the MAR assumption while incorporating the uncertainty around the unobserved data and maintaining the correlation structure.[56] Therefore, the base case for the REFORM analysis uses MI. A complete-case analysis, which is not valid under MAR, is presented only for comparison.

The MI model was validated by comparing the distributions of the observed and the imputed data (*Figures 6* and *7*). The distributions of imputed data are similar to the distribution of the observed data. The MI data sets were analysed with the same SUR model used for the complete-case analysis.

Health-related quality of life

The complete-case analysis for utilities consisted of the participants who returned all questionnaires and completed the EQ-5D questions. The EQ-5D is classified as complete only if its five dimensions contain a response. *Table 39* shows the number of questionnaires returned (including those with missing dimensions) and the number of completed EQ-5D questions for each time point. The number of questionnaires returned decreases with time.

Table 40 describes the number and proportion of participants in the REFORM trial reporting each of the levels on each EQ-5D dimension.

At baseline, participants reported problems in mobility and pain more than in the other dimensions. These domains are worse for the participants in the intervention group: mobility (56.9% usual care vs. 59.7% intervention) and pain (56.6% usual care vs. 78.4% intervention). As expected, the intervention improved mobility as data showed an 11% reduction in the number of participants reporting problems from baseline to 12 months in the intervention group (compared with 1% change in the usual-care group).

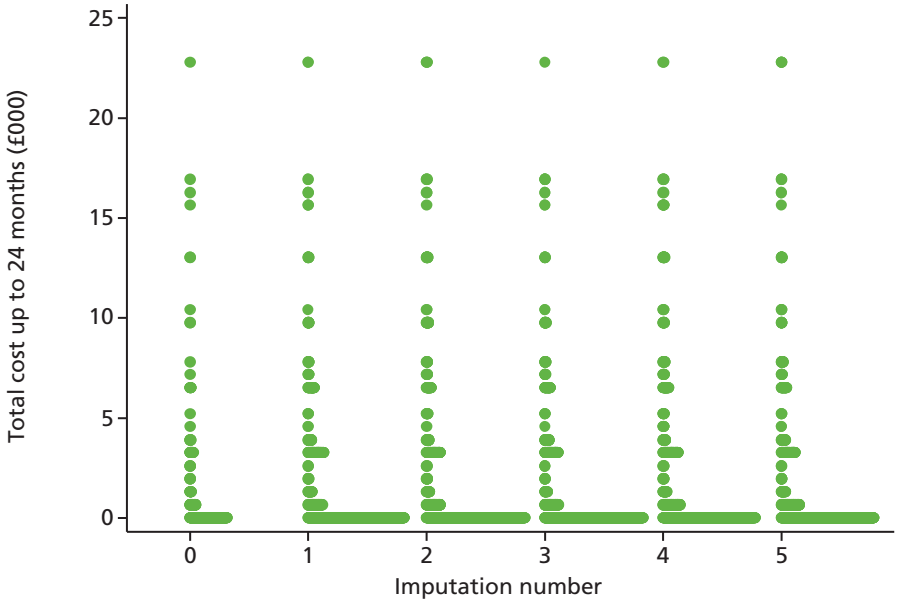

FIGURE 6 Comparison of the distribution of imputed values (imputations 1–5) with the observed data (imputation 0) for total costs.

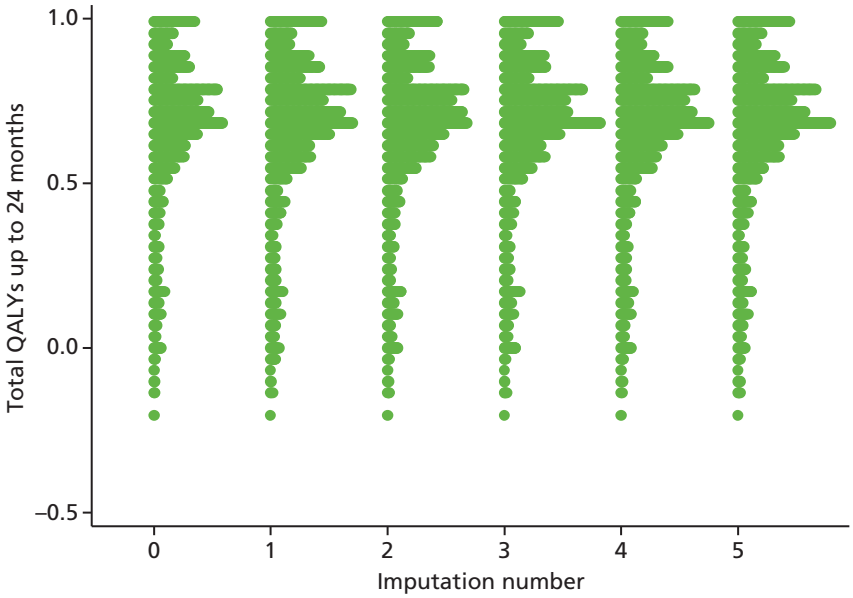

FIGURE 7 Comparison of the distribution of imputed values (imputations 1–5) with the observed data (imputation 0) for total QALYs.

TABLE 39 Health-related quality of life: number of questionnaires returned, completed EQ-5D scores and corresponding proportion of missing data by treatment group and follow-up time point

	Treatment group, *n* (%)			
	Intervention (*N* = 493)		Usual care (*N* = 517)	
Time point	Completed EQ-5D	Missing EQ-5D	Completed EQ-5D	Missing EQ-5D
Baseline	468 (94.9)	25 (5.1)	497 (96.1)	20 (3.9)
6 months	422 (85.6)	71 (14.4)	448 (86.7)	69 (13.4)
12 months	405 (82.2)	88 (17.9)	440 (85.1)	77 (14.9)
Total trial duration	369 (74.9)	113 (21.9)	404 (78.1)	113 (21.9)

TABLE 40 Numbers and proportions reporting levels within EQ-5D-3L dimensions by treatment group at baseline (0 months) and at 12 months

	Dimension																	
	Mobility				Self-care				Usual activities				Pain/discomfort				Anxiety/depression			
	Usual care		Intervention		Usual care		Intervention		Usual care		Intervention		Usual care		Intervention		Usual care		Intervention	
Description	Baseline	12 months	Baseline	12 months	Baseline	12 months	Baseline	12 months	Baseline	12 months	Baseline	12 months	Baseline	12 months	Baseline	12 months	Baseline	12 months	Baseline	12 months
Level 1, *n* (%)	220 (43)	165 (37)	194 (40)	162 (39)	425 (85)	374 (84)	385 (81)	333 (80)	267 (53)	218 (48)	221 (46)	182 (44)	120 (24)	101 (22)	104 (22)	93 (22)	371 (73)	319 (70)	323 (67)	285 (69)
Level 2, *n* (%)	290 (57)	286 (63)	287 (60)	256 (61)	77 (15)	73 (16)	90 (19)	78 (19)	232 (46)	223 (49)	243 (51)	218 (52)	343 (68)	315 (70)	334 (69)	285 (69)	128 (25)	126 (28)	155 (32)	122 (30)
Level 3, *n* (%)	0 (0)	1 (2)	0 (0)	0 (0)	1 (2)	1 (2)	2 (4)	3 (7)	8 (16)	10 (22)	14 (29)	16 (38)	44 (87)	34 (8)	43 (9)	37 (9)	8 (2)	8 (2)	4 (1)	7 (2)
Total	510	452	481	418	503	448	477	414	507	451	478	416	507	450	481	415	507	453	482	414
Number reporting some problems, *n* (%)	290 (58)	287 (64)	287 (60)	256 (61)	78 (16)	74 (17)	92 (19)	81 (20)	240 (47)	233 (52)	257 (54)	234 (56)	387 (57)	349 (78)	377 (78)	322 (78)	136 (27)	134 (30)	159 (33)	129 (31)
Change in numbers reporting problems	–3		–31		–4		–11		–7		–23		62		–55		–2		–30	
% change in numbers reporting problems	–1		–11		–5		–12		–3		–9		–10		–15		–1.5		–19	
Rank of dimensions in terms of changes	4		4		1		3		2		5		5		2		3		1	

Similarly, the intervention improved pain (15% reduction in participants reporting problems in the intervention group compared with 10% change in the usual-care group).

The likelihood of remaining in perfect health decreased with time (*Tables 41* and *42*). However, the reduction in the number of participants in perfect health is lower in the intervention group (7.4%) than in the usual-care group (17.7%). The data also suggested that improvement in anxiety/depression is proportionally even greater than the improvement in other dimensions, especially among participants in the intervention group (19% reduction in numbers reporting anxiety problems).

Utility values were generated by valuing health status (using a social tariff) as measured using the EQ-5D system. The analysis of utilities (*Table 43*) shows that participants in the intervention group start from a lower baseline utility, on average (0.67 for the intervention group vs. 0.69 for usual care). The data also

TABLE 41 Proportion of participants reporting perfect health or problems (level 2 + level 3) by time point

	Treatment group	
Description	Usual care (%)	Intervention (%)
Baseline		
Perfect health	15.3	13.6
Problems	84.7	86.4
6 months		
Perfect health	12.8	11.6
Problems	87.2	88.4
12 months		
Perfect health	12.6	12.6
Problems	87.4	87.4

TABLE 42 Variation in proportion of participants reporting perfect health or problems (level 2 + level 3) from baseline to 12 months per treatment group

	Treatment group	
Description	Usual care (%)	Intervention (%)
Variation in perfect health	–17.7	–7.4
Variation in problems	3.2	1.2

TABLE 43 Health-related quality of life: EQ-5D mean (SD) scores and unadjusted and adjusted mean difference (95% CI) at baseline and follow-up assessments up to 12 months according to ITT

	Treatment group, EQ-5D score					
	Intervention		Usual care			
Time point	*n*	Mean score (SD)	*n*	Mean score (SD)	Unadjusted mean difference (intervention – usual care) (95% CI)[a]	Mean difference adjusted for baseline utility (intervention – usual care) (95% CI)[a]
Baseline	468	0.67 (0.24)	467	0.70 (0.23)	–0.023 (–0.053 to 0.008)	–0.023 (–0.053 to 0.008)
6 months	426	0.65 (0.27)	455	0.65 (0.27)	–0.005 (–0.041 to 0.031)	0.013 (–0.016 to 0.041)
12 months	414	0.66 (0.27)	455	0.66 (0.26)	–0.005 (–0.041 to 0.031)	0.015 (–0.013 to 0.043)

a CIs estimated using OLS regression.

showed that participants in the intervention group had, on average, 0.14 [standard deviation (SD) 0.38] admissions to the hospital during the 6 months before randomisation, whereas participants in the usual-care group had, on average, 0.12 (SD 0.45) admissions. This emphasises the need to adjust the utilities gained for baseline utility level. When considering this baseline imbalance, the data show that by the end of the trial participants allocated to intervention obtained, on average, a marginally higher HRQoL gain than participants allocated to usual care.

The overall distribution of EQ-5D scores (utilities) for the different follow-up time points is illustrated by treatment group in *Figure 8*. Utilities at baseline ranged from –0.181 to 1 for both groups; at the end of the trial, utilities ranged from –0.239 to 1 for both groups.

The distribution of mean utilities across the 12-month follow-up for the two groups is shown in *Figure 9*. The usual care participants reported higher HRQoL at baseline and at 6 and 12 months. All of the differences were small, and the 95% CIs overlap at each time point.

The mean QALYs were estimated based on individual participants' utilities. *Table 44* summarises the mean QALYs and the difference between treatment groups for all available cases. At the end of the trial, participants allocated to the intervention obtained, on average, a marginally higher QALY gain than participants allocated to usual care (*Figure 10*) when adjusted for baseline utility (0.010 QALY gain). The difference is 0.083 when adjusted for all covariates.

Health-care resource use and costs

The mean levels of resource use over the trial based on all available data are shown for the two treatment groups in *Table 45*. Although participants in the intervention group had, on average, fewer hospital day cases and used the patient transportation service fewer times, they had, on average, more hospital admissions, more outpatient visits and more A&E attendances than usual care participants over the trial duration.

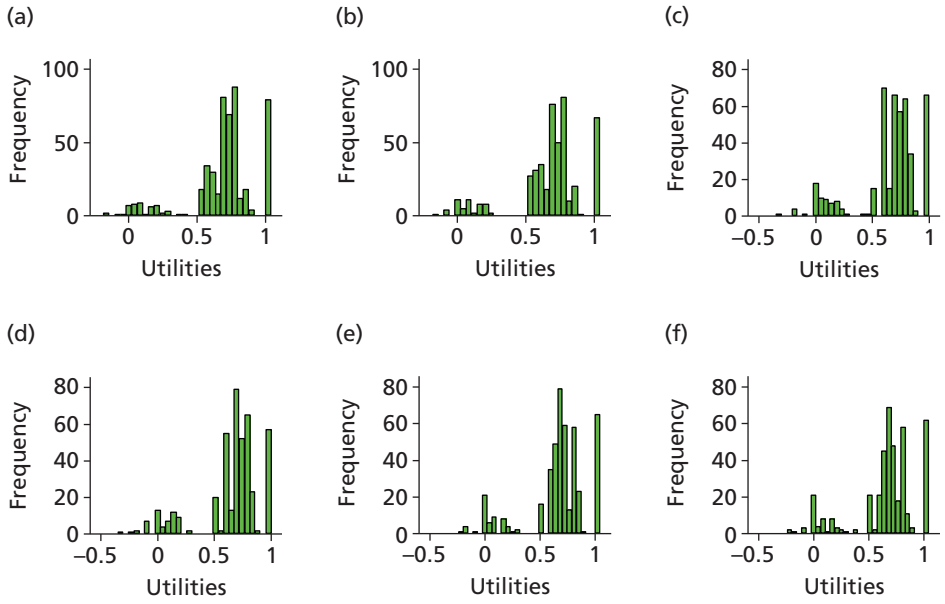

FIGURE 8 Distribution of EQ-5D scores by treatment allocation and time point. (a) Baseline: usual care; (b) baseline: intervention; (c) 6 months: usual care; (d) 6 months: intervention; (e) 12 months: usual care; and (f) 12 months: intervention.

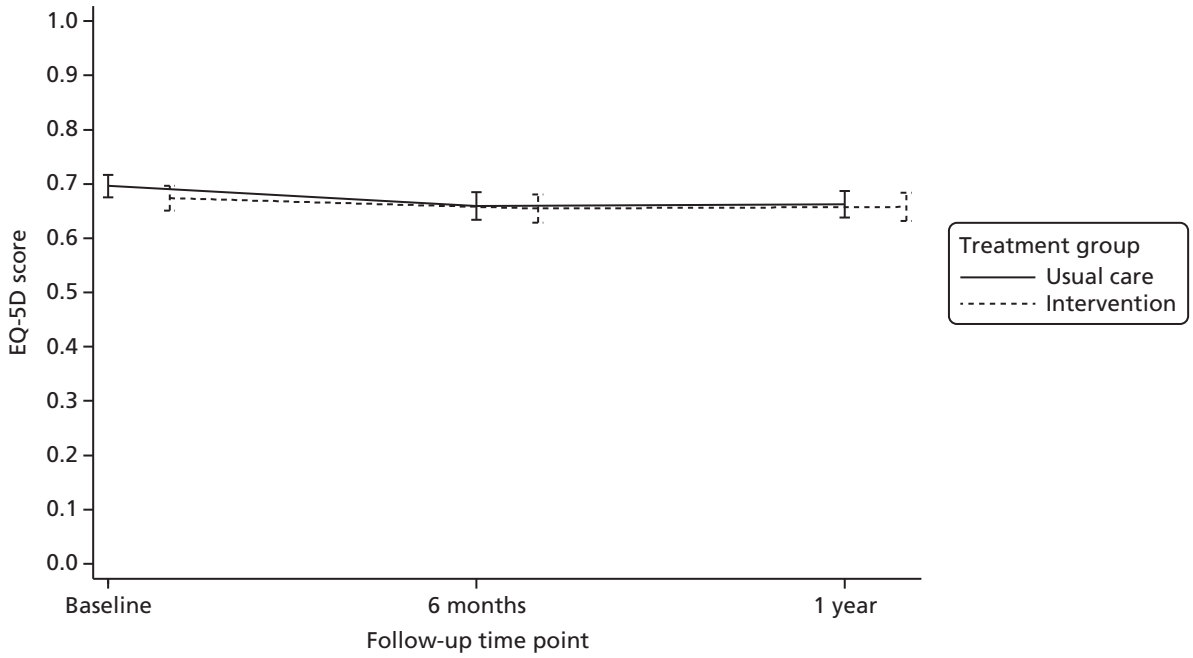

FIGURE 9 Mean EQ-5D scores at baseline and follow-up time points by treatment group.

TABLE 44 Health-related quality of life: total QALYs for all available cases by treatment group over trial duration (12 months) and difference in mean QALYs (95% CI) (estimated using OLS)

Treatment group	Total	Mean (SD) QALYs	Difference (intervention – usual care) (95% CI)[a]	Difference (intervention – usual care) (95% CI)[b]
Intervention	377	0.67 (0.24)	0.010 (–0.010 to 0.031)	0.008 (–0.009 to 0.026)
Usual care	415	0.68 (0.23)		

a Adjusted for baseline utility.
b Adjusted for all covariates (baseline utility, total falls, sex, age, fall history and centre).

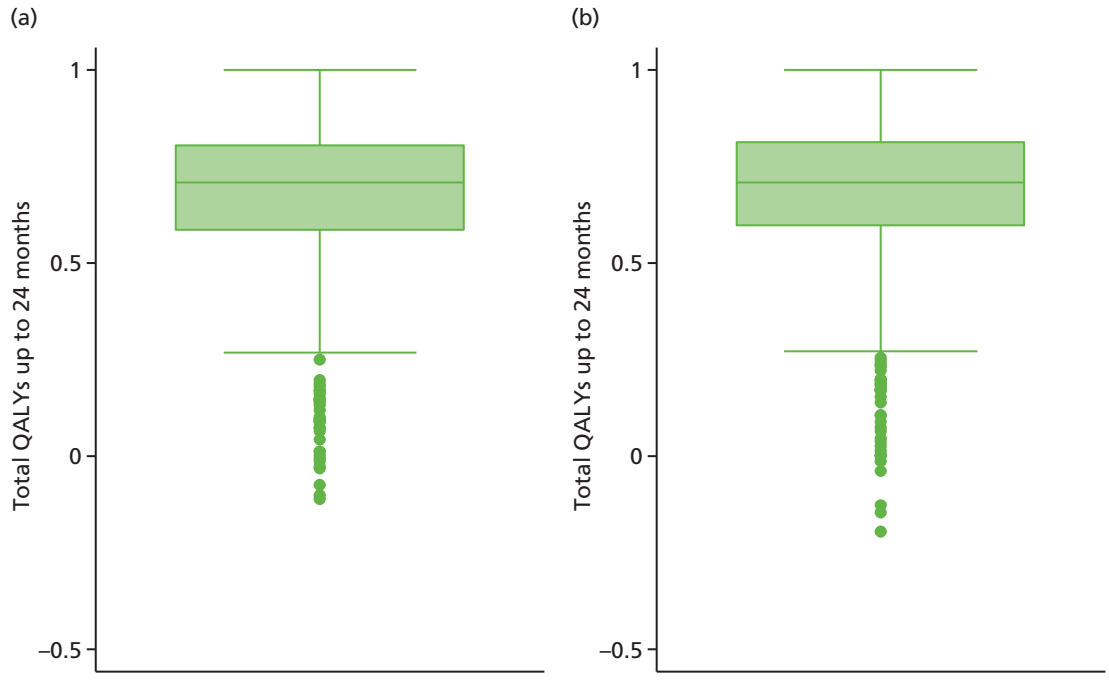

FIGURE 10 Mean total QALYs for the intervention and usual-care groups.

TABLE 45 Average hospital resource use per treatment group (all fall-related resource use except hospital admissions, which includes both fall- and non-fall-related stays)

Type of resource use	Treatment group	
	Intervention ($N = 493$)	Usual care ($N = 517$)
Hospital admissions		
At 6 months		
n	444	475
Mean (SD)	0.20 (0.50)	0.16 (0.46)
Median (minimum, maximum)	0 (0, 3)	0 (0, 3)
Missing (%)	49 (9.94)	42 (8.12)
At 12 months		
n	425	467
Mean (SD)	0.14 (0.45)	0.13 (0.41)
Median (minimum, maximum)	0 (0, 4)	0 (0, 3)
Missing (%)	68 (13.79)	50 (9.67)
Over the trial		
n	418	452
Mean (SD)	0.34 (0.81)	0.30 (0.71)
Median (minimum, maximum)	0 (0, 7)	0 (0, 6)
Missing (%)	75 (15.21)	65 (12.57)
Hospital outpatient visits		
At 6 months		
n	341	359
Mean (SD)	0.17 (0.92)	0.12 (0.52)
Median (minimum, maximum)	0 (0, 13)	0 (0, 5)
Missing (%)	152 (30.83)	158 (30.56)
At 12 months		
n	315	362
Mean (SD)	0.15 (1.11)	0.12 (0.50)
Median (minimum, maximum)	0 (0, 18)	0 (0, 4)
Missing (%)	178 (36.11)	155 (29.88)
Over the trial		
n	259	292
Mean (SD)	0.32 (1.66)	0.23 (0.73)
Median (minimum, maximum)	0 (0, 20)	0 (0, 4)
Missing (%)	234 (47.46)	225 (43.52)

continued

TABLE 45 Average hospital resource use per treatment group (all fall-related resource use except hospital admissions, which includes both fall- and non-fall-related stays) (*continued*)

Type of resource use	Treatment group	
	Intervention ($N = 493$)	Usual care ($N = 517$)
Hospital day case *At 6 months*		
n	331	354
Mean (SD)	0.04 (0.26)	0.07 (0.43)
Median (minimum, maximum)	0 (0, 3)	0 (0, 5)
Missing (%)	162 (32.86)	163 (31.53)
At 12 months		
n	313	363
Mean (SD)	0.07 (0.57)	0.11 (1.10)
Median (minimum, maximum)	0 (0, 7)	0 (0, 20)
Missing (%)	180 (36.51)	154 (29.79)
Over the trial		
n	245	287
Mean (SD)	0.11 (0.80)	0.12 (1.33)
Median (minimum, maximum)	0 (0, 10)	0 (0, 22)
Missing (%)	248 (50.30)	230 (44.49)
Hospital A&E *At 6 months*		
n	346	375
Mean (SD)	0.13 (0.56)	0.10 (0.38)
Median (minimum, maximum)	0 (0, 6)	0 (0, 3)
Missing (%)	147 (29.82)	142 (27.47)
At 12 months		
n	328	373
Mean (SD)	0.07 (0.32)	0.09 (0.37)
Median (minimum, maximum)	0 (0, 3)	0 (0, 4)
Missing (%)	165 (33.47)	144 (27.85)
Over the trial		
N	268	309
Mean (SD)	0.22 (0.73)	0.19 (0.58)
Median (minimum, maximum)	0 (0, 6)	0 (0, 4)
Missing (%)	225 (45.64)	208 (40.23)
Emergency service call *At 6 months*		
n	365	384
Mean (SD)	0.06 (0.30)	0.05 (0.39)
Median (minimum, maximum)	0 (0, 3)	0 (0, 6)
Missing (%)	128 (25.96)	133 (25.73)

TABLE 45 Average hospital resource use per treatment group (all fall-related resource use except hospital admissions, which includes both fall- and non-fall-related stays) (*continued*)

Type of resource use	Treatment group	
	Intervention ($N = 493$)	Usual care ($N = 517$)
At 12 months		
n	338	381
Mean (SD)	0.02 (0.26)	0.03 (0.19)
Median (minimum, maximum)	0 (0, 4)	0 (0, 2)
Missing (%)	156 (31.64)	136 (26.31)
Over the trial		
n	287	321
Mean (SD)	0.08 (0.43)	0.09 (0.48)
Median (minimum, maximum)	0 (0, 6)	0 (0, 6)
Missing (%)	206 (41.78)	196 (37.91)
Patient transportation *At 6 months*		
n	360	382
Mean (SD)	0.013 (0.13)	0.031 (0.30)
Median (minimum, maximum)	0 (0, 2)	0 (0, 5)
Missing (%)	133 (26.98%)	136 (26.31%)
At 12 months		
n	337	381
Mean (SD)	0.053 (0.58)	0.015 (0.21)
Median (minimum, maximum)	0 (0, 10)	0 (0, 4)
Missing (%)	156 (31.64)	136 (26.31)
Over the trial		
Patient transportation (*N*)	283	319
Mean (SD)	0.021 (0.20)	0.015 (0.14)
Median (minimum, maximum)	0 (0, 3)	0 (0, 2)
Missing (%)	210 (42.60)	198 (38.30)

Participants in the intervention group had, on average, fewer visits to the GP than the usual-care group (*Table 46*); however, they had, on average, more visits to the practice nurse and the occupational therapist. Participants in the intervention group undertook more podiatrist visits in total than the usual-care group, as this group received this service as part of the intervention.

Table 47 summarises the mean cost by item of resource use based on all available cases and according to treatment group. Costs associated with hospital inpatient stay and the intervention itself were the major cost drivers for the participants in the intervention group.

Twenty-eight participants (intervention, $n = 14$; usual care, $n = 14$) reported that they had to spend a night in hospital as a result of a fall. The average cost per inpatient stay was £7121.00 (SD £1535.83) in the intervention group and £6666.50 (SD £1156.84) in the usual-care group. Therefore, inpatient stay based on fall calendars was £454.50 more expensive for participants in the intervention group (95% CI –£601.80

TABLE 46 Average primary and community care resource use by treatment group over the 12-month follow-up (fall-related resource use only)

Type of resource use	Treatment group	
	Intervention ($N = 493$)	Usual care ($N = 517$)
GP visit at GP practice		
At 6 months		
n	328	364
Mean (SD)	0.17 (1.17)	0.15 (0.55)
Median (minimum, maximum)	0 (0, 20)	0 (0, 5)
Missing (%)	165 (33.47%)	153 (29.59%)
At 12 months		
n	323	364
Mean (SD)	0.11 (0.47)	0.14 (0.57)
Median (minimum, maximum)	0 (0, 4)	0 (0, 5)
Missing (%)	170 (34.48)	153 (29.59)
Over the trial		
n	250	295
Mean (SD)	0.25 (1.53)	0.30 (0.95)
Median (minimum, maximum)	0 (0, 23)	0 (0, 10)
Missing (%)	243 (49.29)	222 (42.94)
Nurse visit at GP practice		
At 6 months		
n	324	360
Mean (SD)	0.12 (0.62)	0.25 (1.48)
Median (minimum, maximum)	0 (0, 6)	0 (0, 20)
Missing (%)	169 (34.28)	157 (30.37%)
At 12 months		
n	309	359
Mean (SD)	0.23 (2.89)	0.13 (0.86)
Median (minimum, maximum)	0 (0, 50)	0 (0, 10)
Missing (%)	184 (32.32)	158 (30.56)
Over the trial		
n	241	287
Mean (SD)	0.37 (3.54)	0.35 (1.88)
Median (minimum, maximum)	0 (0, 54)	0 (0, 20)
Missing (%)	252 (51.12)	230 (44.49)
Occupational therapist visit		
At 6 months		
n	342	376
Mean (SD)	0.10 (0.71)	0.04 (0.46)
Median (minimum, maximum)	0 (0, 10)	0 (0, 6)
Missing (%)	151 (30.63)	141 (27.27)

TABLE 46 Average primary and community care resource use by treatment group over the 12-month follow-up (fall-related resource use only) (*continued*)

Type of resource use	Treatment group	
	Intervention (*N* = 493)	Usual care (*N* = 517)
At 12 months		
n	334	370
Mean (SD)	0.04 (0.31)	0.07 (0.53)
Median (minimum, maximum)	0 (0, 4)	0 (0, 7)
Missing (%)	159 (32.25)	147 (28.43)
Over the trial		
n	268	304
Mean (SD)	0.12 (0.65)	0.11 (0.67)
Median (minimum, maximum)	0 (0, 7)	0 (0, 6)
Missing (%)	225 (45.64)	213 (41.20)
Podiatrist visits *Not intervention related*		
n[a]	355	380
Mean (SD)	2.09 (3.84)	4.01 (2.63)
Median (minimum, maximum)	1 (0, 46)	3 (0, 20)
Missing (%)	138 (27.99)	137 (26.50)
Intervention related		
n	413	N/A
Mean (SD)	2.52 (0.88)	N/A
Median (minimum, maximum)	0 (0, 7)	N/A
Missing (%)	0 (0%)	N/A

N/A, not applicable.
a This includes only those podiatry visits received by participants in the intervention group that were not directly related to the trial intervention itself.

to £1510.80). Given the small sample size, it was decided to estimate inpatient stay based on data from the participant questionnaires. The only limitation of this is that the participant questionnaire did not differentiate inpatient stay as fall- and non-fall-related, although the rest of hospital stay (outpatient, day case and A&E) did differentiate between these.

Costing the intervention

The protocol stated that participants allocated to the intervention would receive at least one baseline visit to the podiatrist plus at least one follow-up appointment. In total, 413 out of 493 (83.8%) participants allocated to the intervention had at least one visit to the podiatry clinic and 183 (37.1%) had at least two. The first appointment was assumed to last for 1 hour, the second appointment for 30 minutes and all the rest were assumed to be the same duration as a GP clinic consultation (11.7 minutes). The cost for the visits was estimated according to NHS pay scales on the Agenda for Change (https://healthcareers.nhs.uk/glossary#Agenda_for_Change) for NHS podiatrist staff in England, Wales, Scotland and Northern Ireland from 1 April 2015. Podiatrists delivering the intervention ranged from band 6 to band 8. The annual and unit costs per podiatry visit were estimated, excluding qualifications but including overheads on a community basis.

TABLE 47 Total mean costs based on all available cases, up to 12 months' follow-up

Cost item	Total mean cost, £ (SD)		Mean difference (intervention – usual care) (95% CI)
	Intervention ($N = 493$)	Usual care ($N = 517$)	
Hospital inpatient length of stay[a]	1314.29 (3290.81)	1089.96 (2791.51)	224.3 (–181.0 to 629.6)
Hospital outpatient visits	37.57 (190.09)	26.66 (84.41)	10.91 (–13.24 to 35.06)
Hospital day case	85.22 (578.58)	90.31 (962.86)	–5.08 (–143.31 to 133.13)
A&E visit	30.95 (103.97)	27.75 (82.85)	3.19 (–12.09 to 18.48)
Podiatry visits	73.35 (134.43)	140.64 (92.35)	–67.29 (–83.90 to –50.68)
GP visit at GP practice	11.24 (64.47)	13.42 (42.01)	–2.15 (–11.47 to 7.15)
Nurse visit at GP practice	9.43 (88.51)	8.88 (47.06)	0.55 (–11.31 to 12.42)
Occupational therapist	5.58 (28.71)	4.92 (29.71)	0.66 (–4.15 to 5.47)
Emergency service call	12.34 (67.62)	14.87 (74.05)	–2.53 (–13.87 to 8.81)
Patient transportation	21.80 (116.51)	24.20 (132.79)	–2.39 (–22.47 to 17.68)
Cost of intervention[b]	155.79 (55.02)	N/A	N/A
Podiatry visits	104.74 (32.14)	N/A	N/A
Shoes	40.29 (30.94)	N/A	N/A
Insoles	3.60 (3.33)	N/A	N/A
Exercise therabands	2.32 (1.17)	N/A	N/A
Exercise ball	1.00 (0.58)	N/A	N/A
Exercise DVD	3.82 (0)	N/A	N/A

N/A, not applicable.
a Length of stay.
b This is the average cost for the 413 participants in the intervention group who actually received the podiatry intervention.

A total of 260 participants received a new pair of shoes. The price of the shoes ranged between £39 and £89. There was insufficient information to determine the exact make and model of shoe received by the participant; hence, an average shoe price of £64 was assumed for the analysis. As the NHS will not cover the cost of the provision of new footwear, this was not considered for the base-case analysis. A sensitivity analysis on the societal perspective looked at the impact of the shoe price on the cost-effectiveness results. A total of 241 participants also received a pair of insoles: X-Line red ($n = 23$), X-Line blue ($n = 209$) or Formthotics insoles ($n = 9$). They also received resistive therapy bands and therapy balls for the exercises.

The intervention cost on average was £155.79 (SD £55.02) for the 413 participants who received the intervention when we include the price of the shoes (societal perspective) and £115.5 (SD £33.06) when we exclude the price of the shoes.

Cost–utility analysis and uncertainty

The base-case analysis (*Table 48*) shows that the participants who were randomised to the intervention experienced (marginally) improved health outcomes. At the end of the trial, the intervention group had experienced 0.0129 (95% CI –0.0050 to 0.0314) more QALYs. However, the intervention is more costly than usual care [on average £252.17 more per participant than usual care (95% CI –£69.48 to £589.38)] when adjusted for all covariates (including baseline utility). ICERs ranged between £19,494 and £20,593 (societal perspective adjusted for all covariates) per additional QALY. For both the base-case and secondary

TABLE 48 Summary for incremental analysis (ITT), cost-effectiveness results and uncertainty for the base-case analysis (highlighted) and sensitivity analyses

Analysis	Difference in costs[a] (95% CI)	Difference in QALYs[a] (95% CI)	ICER for the intervention (£ per QALY)	Probability intervention was cost-effective £30,000/QALY (%)
Base case (MI), NHS perspective	252.17 (–69.48 to 589.38)	0.0129 (–0.00 to 0.03)	19,494.35	65.58
Sensitivity 1 (complete case)	272.86 (–349.6 to 916.56)	–0.0091 (–0.04 to 0.02)	Intervention dominated	17
Sensitivity 2	222.34 (–156.6 to 605.1)	0.0109 (–0.007 to 0.029)	20,385.75	61
Sensitivity 3	441.88 (–273.1 to 1052.4)	0.0150 (–0.002 to 0.033)	29,454.34	49
Sensitivity 4	327.17 (–65.17 to 451.09)	0.0140 (–0.003 to 0.032)	23,341.72	60

a Difference between groups (intervention – usual care) and 95% CIs were estimated from a bivariate model using SUR. The covariates used to adjust for in the model were age, sex, treatment group, baseline utility and history of falling.

analysis (societal perspective), the probability of the intervention being the more cost-effective option is > 0.60 for the incremental analysis adjusted for baseline EQ-5D, and > 0.65 when incremental QALYs are adjusted for all covariates. The NMB associated with the intervention is positive, indicating that the intervention is cost-effective, as the resources to be displaced would be less than the benefit to be gained if the intervention was implemented in the NHS. However, these results were calculated from the point estimate of the difference in QALYs; the lower-bound confidence limit for the 95% CI was negative, and, therefore, there is the potential for a negative QALY gain.

The incremental cost-effectiveness plane (*Figure 11*) demonstrates the uncertainty associated with the mean difference in costs and QALYs between both intervention groups by plotting the non-parametric bootstrapping results. A total of 5000 bootstrapped replicates of differences in costs and QALYs are shown. The majority of the replicates falls within the north-east quadrant, indicating that the intervention is more effective but more costly.

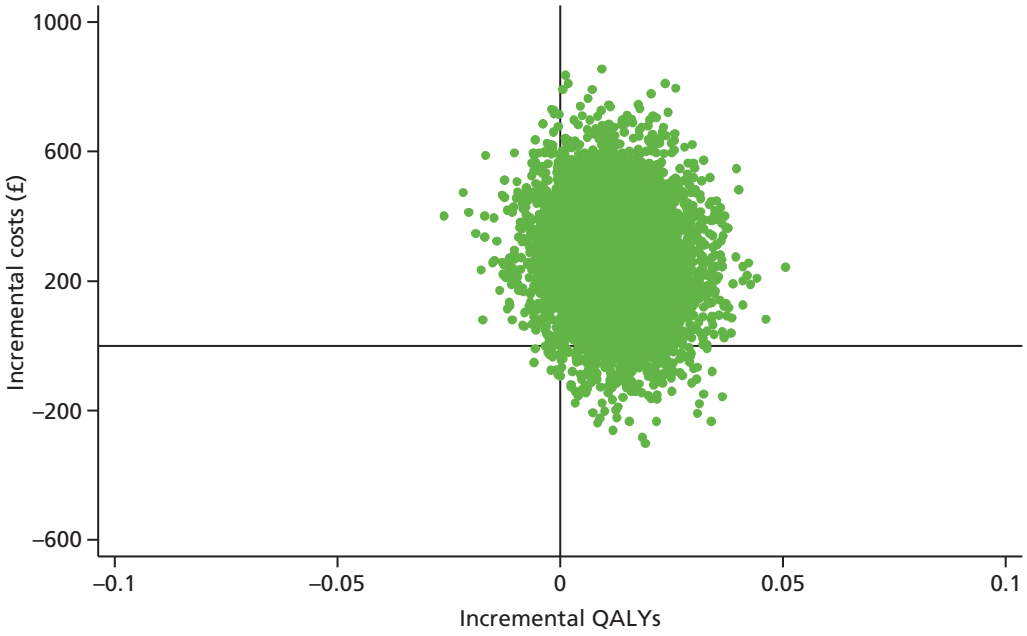

FIGURE 11 Cost-effectiveness plane (ITT analysis) for the base-case analysis: base-case NHS perspective (MI adjusted for baseline utility).

The CEAC derived from the joint distribution of costs and effects is represented in *Figure 12*. The curve was constructed by plotting the proportion of incremental cost–effect pairs that are cost-effective for a range of thresholds. The horizontal interrupted line indicates a 50% probability of the intervention representing value for money for the NHS. The probability of the intervention being cost-effective is > 60% given the current NICE WTP threshold of £30,000 per additional QALY.

Cost-effectiveness analysis and uncertainty

A cost-effectiveness analysis, in which the outcome is expressed in terms of number of falls averted, may be more intuitive to interpret for health-care professionals. However, there is no established WTP threshold for an additional fall averted. Therefore, the cost per fall averted was assessed for comparison, as allocation decisions can be made based only on cost per QALY estimates. In the base case, the podiatry intervention was both more costly (mean incremental cost £241.64, 95% CI £–98.08 to £581.37) and more effective (mean incremental effect 0.19 falls averted per person year, 95% CI –0.05 to 0.44 falls averted per person year), with an incremental cost per fall averted of £1253.82 (ICER); however, for both of these parameters the lower 95% confidence limit is negative, and so this does not exclude the possibility of a negative result. *Figure 13* shows the incremental costs and incremental effects on the form of a cost-effectiveness plane. There is significant uncertainty in the effectiveness estimates, as the estimates fall on both sides of the *x*-axis. *Figure 14* shows the CEAC per fall averted.

Sensitivity analysis

Handling missing data

The complete-case analysis was tested as an alternative method to MI for handling missing data. The complete-case scenario comprised 286 (28.3%) participants, of whom 129 (26.2%) were in the intervention group and 157 (30.4%) were in the usual-care group. The complete-case analysis shows that the intervention group accumulated greater costs and reported lower HRQoL than participants randomised to usual care. The intervention costs were, on average, £272.86 more per participant than usual care (95% CI –£349.63 to £916.56), although accumulated total QALYs are smaller than those for usual care (mean difference –0.0091, 95% CI –0.0396 to 0.0196). Therefore, complete-case results indicate that the

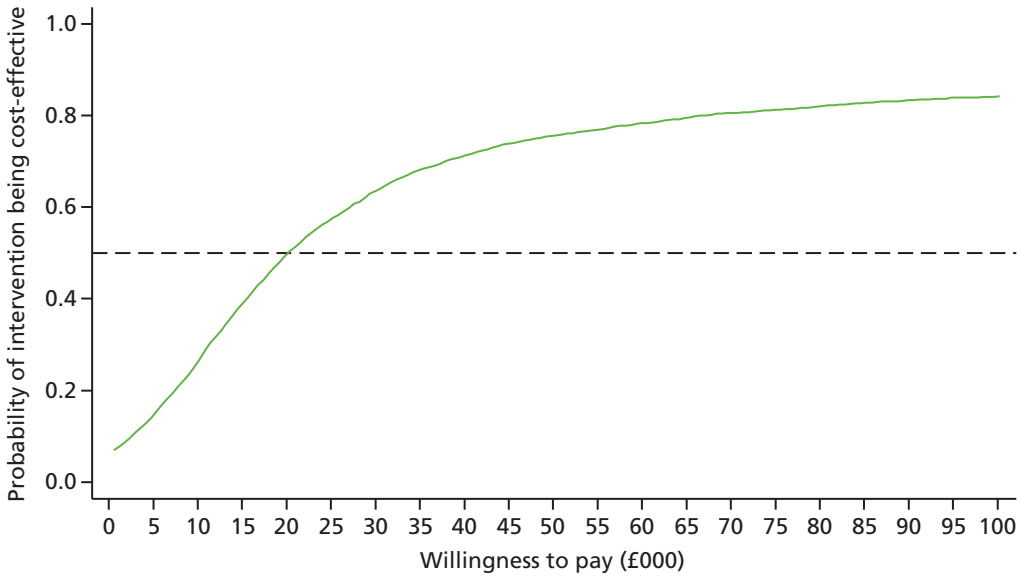

FIGURE 12 Cost-effectiveness acceptability curve (ITT analysis) for the base-case analysis: base-case NHS perspective (MI adjusted for baseline utility).

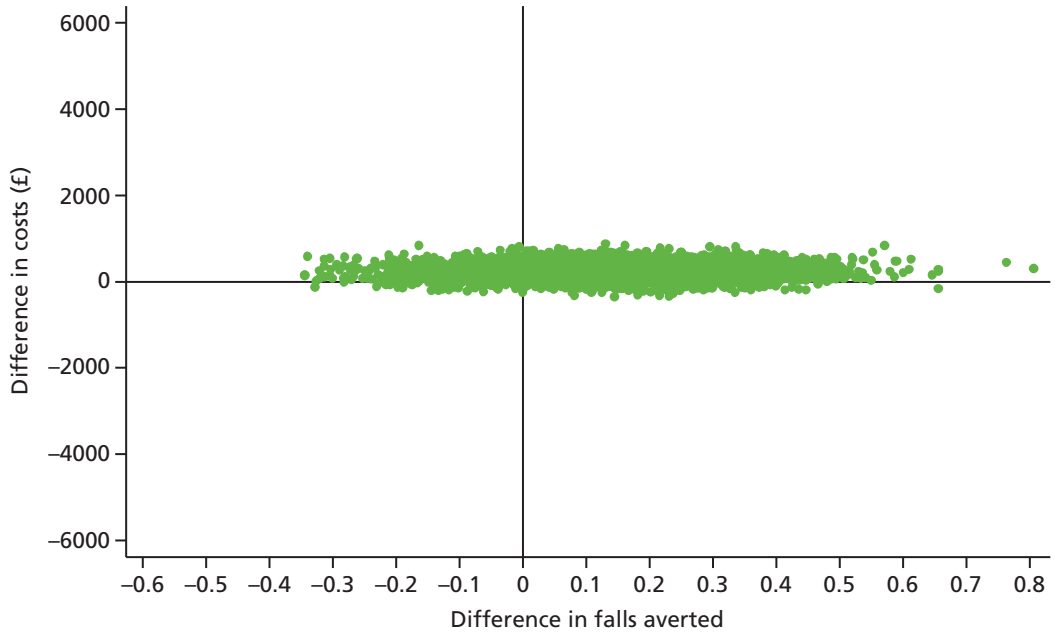

FIGURE 13 Cost-effectiveness plane (ITT analysis) per fall averted.

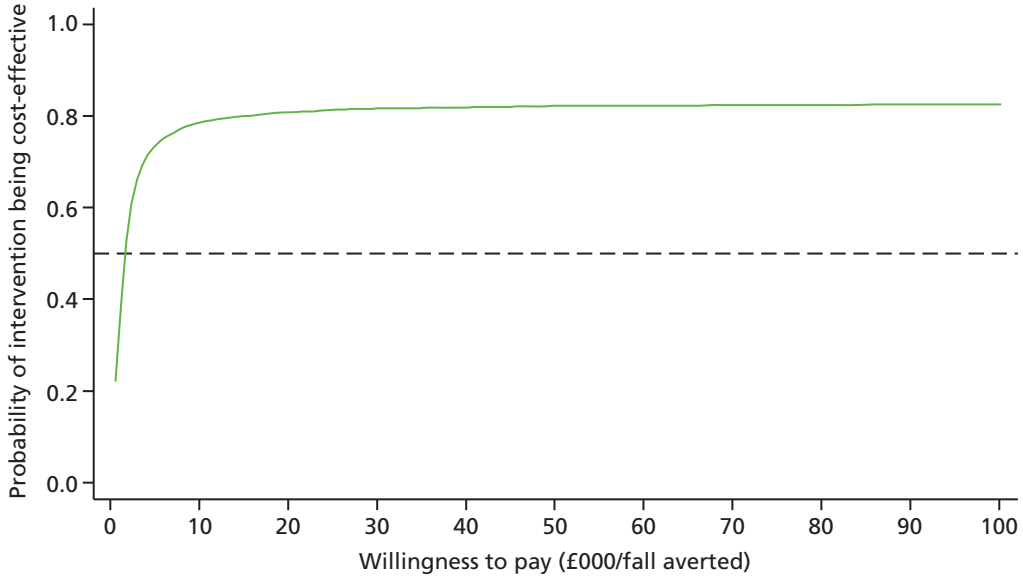

FIGURE 14 Cost-effectiveness acceptability curve (ITT analysis) per fall averted.

intervention is dominated by usual care (*Figure 15*). The NMB associated with the intervention indicates that the resources to be displaced would be greater than the benefit to be gained if the intervention were implemented in the NHS. *Figure 16* represents the CEACs for the complete case when adjusted for all covariates. The probability of the intervention being cost-effective is < 20% given the WTP for an additional QALY up to £30,000; therefore, the intervention is unlikely to be cost-effective based on a complete-case analysis.

Given the accumulative nature of costs and QALYs, these variables can be dealt with at different levels of aggregation. The base-case analysis estimated QALYs by imputing missing utilities (e.g. disaggregated level). A sensitivity analysis was conducted for the base case on the imputed data set in which we explored the impact of imputing HRQoL at QALY level (e.g. aggregated level). Imputing HRQoL at an aggregated level has no impact on the cost-effectiveness of the intervention).

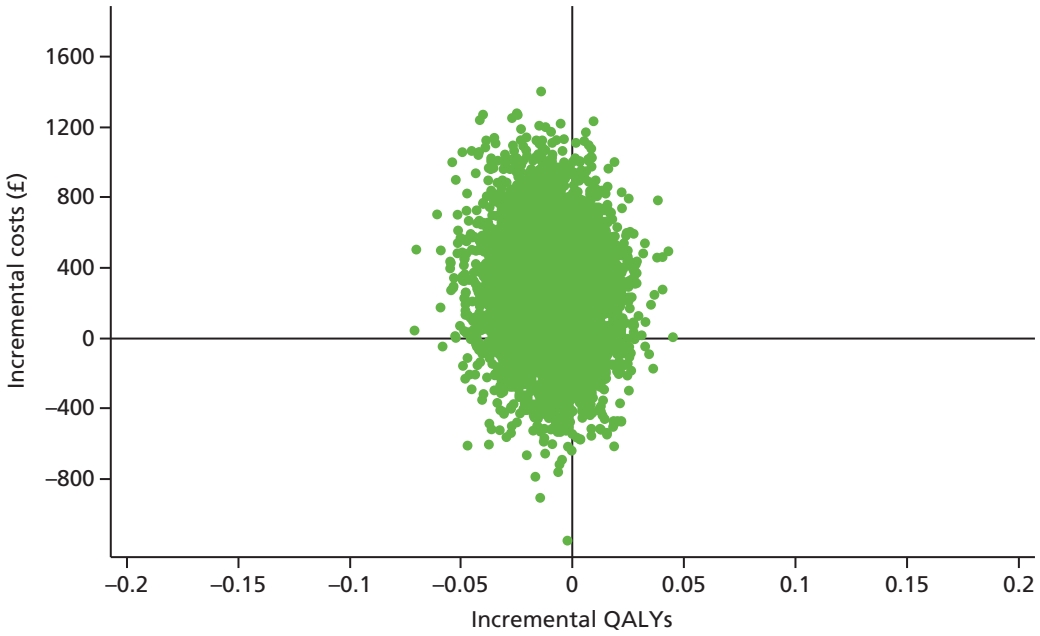

FIGURE 15 Cost-effectiveness plane (ITT analysis) for the complete-case analysis (NHS perspective, adjusted for covariates).

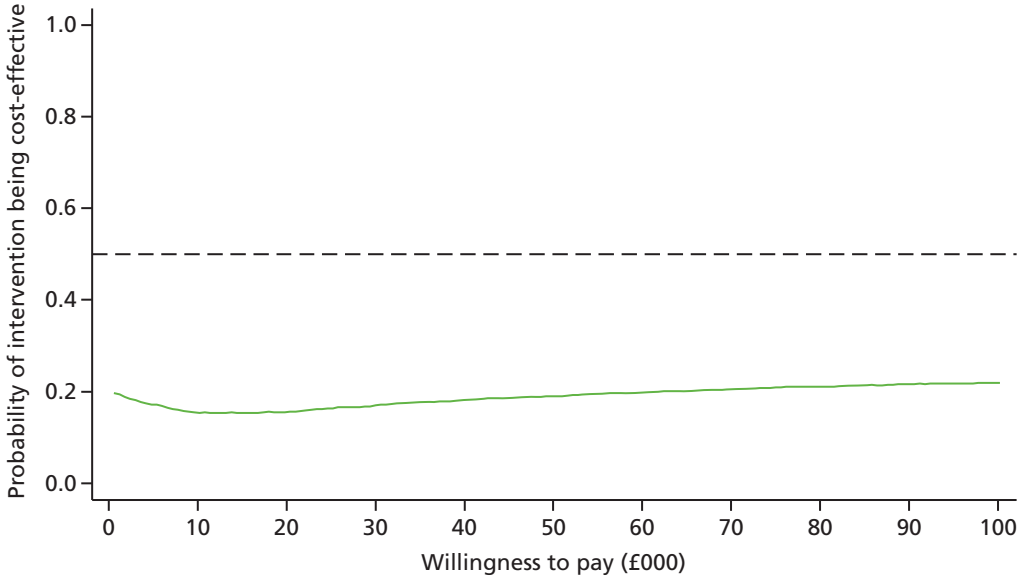

FIGURE 16 Cost-effectiveness acceptability curve (ITT analysis) for the complete-case analysis (NHS perspective, adjusted for covariates).

Resource use

A one-way sensitivity analysis was conducted to test the impact of including both fall- and non-fall-related resource use. There is no major impact in the results when we investigate the impact of considering all resource use in the assessment. The intervention is still cost-effective at the £30,000 per QALY gained threshold.

Exploration of the need for a long-term model

The economic evaluation conducted alongside REFORM found that the podiatry intervention was likely to be cost-effective over a 1-year time horizon. A sufficient condition for surgery to be definitely cost-effective over a longer term is that in each year after 12 months, HRQoL is lower (and costs are the same or increasing faster) in the usual-care group than in the intervention group. This section develops an exploratory model to explore how the differences in QALYs evolve beyond the study. A straightforward way of projecting QALYs beyond the trial is to assume that the difference in HRQoL observed at 1 year remains unchanged. To compare the cost-effectiveness estimates, we defined two health states (alive and dead). The podiatry intervention, when displacing usual care, is expected to bring gains of 0.0129 QALYs per patient (per year). In addition, it was assumed that patients undergoing the podiatry intervention incur costs of £251 more per year when alive. When looking at the first 5 years, the results of the model show that adopting the podiatry intervention over usual care provides a higher HRQoL over a 5-year time horizon. Although the difference in HRQoL between the intervention and usual-care groups decreases over time (e.g. 0.0126 at year 2 vs. 0.0117 at year 5), it remains higher for patients who received the intervention. The expected ICER related to the adoption of the podiatry intervention ranged between £19,950 (year 2) and £21,460 (year 5) per QALY gained. Nonetheless, the value for money of the intervention is decreasing with time. We consider that this exploratory projection is likely to be conservative, as it excludes potential costs savings associated with the intervention. Therefore, from this exploratory analysis we can conclude that this relatively low-cost intervention appears to improve health outcomes within the short term. We are currently conducting a long-term model to validate these preliminary results. The findings of this model will be published in a peer-reviewed journal.

Chapter 6 Qualitative results

Participants

Qualitative semistructured interviews were conducted with 15 podiatrists: 14 who delivered the REFORM intervention and one PI from a site who was not involved in delivering the intervention but who assisted with the day-to-day management of the study at the site. All trial podiatrists were invited to take part in the qualitative interviews. The sample consisted of five men and 10 women, representing seven NHS trusts and a university podiatry school in Ireland. Participating podiatrists had between 6 and 32 years' experience. Various grades of podiatrist were represented: one at band 5, six at band 6, six at band 7 and two at band 8. All podiatrists worked predominantly with patients from the community and were skilled in providing footwear advice, exercises and insole therapy for the management of foot and ankle pathology and biomechanical imbalance. The sample included podiatrists with postgraduate training at master's (three podiatrists) and doctoral (two podiatrists) level.

Further details of the REFORM podiatrists are provided in *Table 49*.

Twenty-one participants from the REFORM trial were interviewed. The sample comprised 10 men and 11 women aged between 65 and 87 years. Fifteen participants said that they lived with their spouse and/or other family members and the remaining six lived alone. Further details of the REFORM trial participants are provided in *Table 50*.

The qualitative interviews with trial participants and podiatrists discussed experiences of receiving and delivering the REFORM podiatry intervention, respectively. The findings are reported according to the three

TABLE 49 Demographic characteristics of podiatrists in qualitative study

Podiatrist identifier	Sex	Years' experience	Qualification
1P	Male	27	BSc and MSc
2P	Male	10	BSc and MSc
3P	Female	11	BSc
4P	Male	10	BSc
5P	Male	6	BSc
6P	Female	8	BSc
7P	Female	10	BSc
8P	Female	32	MSc
9P	Female	13	BSc
10P	Female	22	BSc
11P	Female	9	BSc
12P	Male	28	DPodM
13P	Female	18	BSc
14P	Female	10	PhD and BSc
15P	Female	9	PhD and BSc

BSc, bachelor of science; DpodM, diploma In podiatric medicine; MSc, master of science; PhD, doctor of philosophy.

TABLE 50 Demographic characteristics of participants in qualitative study

Participant	Age at randomisation (years)	Sex	Reported fear of falling at baseline	Fallen during the 12 months after randomisation
1	70	Male	Some of the time	No
2	75	Male	Some of the time	No
3	77	Male	A little of the time	No
4	80	Female	None of the time	Yes
5	81	Female	Most of the time	Yes
6	77	Female	A little of the time	No
7	67	Female	Some of the time	No
8	65	Male	A little of the time	No
9	80	Female	All of the time	Yes
10	84	Male	A little of the time	No
11	80	Female	A little of the time	No
12	67	Female	Some of the time	Yes
13	87	Female	None of the time	Yes
14	79	Male	All of the time	No
15	79	Female	A little of the time	No
16	84	Male	A little of the time	Yes
17	69	Male	A good bit of the time	Yes
18	78	Male	Some of the time	Yes
19	86	Male	None of the time	Yes
20	79	Female	Some of the time	Yes
21	79	Female	A good bit of the time	No

components of the REFORM trial intervention in turn: (1) footwear assessment, advice and provision, (2) orthoses and (3) exercises. For each intervention component, three main themes are discussed: (1) current usual practice, (2) acceptability and barriers to implementation among service providers and (3) acceptability and adherence among service users. Within the adherence subsection, quantitative data from the whole of the trial intervention group are included as appropriate.

Footwear assessment, advice and provision

Assessing and ordering footwear during usual practice

Podiatrists reported how patients frequently wore inappropriate footwear and cited common issues seen during practice as narrow shoes, inappropriate heel height or shoe style and a lack of appropriate fastening. Although some issues with men's footwear were reported (e.g. fastening and inappropriate slippers), it was the perception of the podiatrists that the majority of issues were with women's footwear:

> *It tended to be the women that weren't wearing the sort of shoes that would balance and that were comfortable, they tended to wear, I don't know, more fashionable shoes forgetting about what sort of age they were and they hadn't thought about the fact that the shoes were possibly causing their instability.*
>
> *Podiatrist 7*

All podiatrists discussed how general footwear advice was provided as part of their usual practice, with a small number of podiatrists basing this advice on falls prevention. Routinely, footwear advice involved discussions around the types and styles of shoes and placed a particular emphasis on the importance of indoor shoes. Central to these discussions was the need to enhance the patient's understanding of 'good footwear'. To facilitate this, podiatrists described how they often directed patients to cheaper footwear alternatives or specific companies, to demonstrate that a good shoe was not necessarily reflected by its price. In addition, podiatrists spoke of using prompts such as shoe catalogues, leaflets and sample shoes that were compared with patients' current footwear, in order to further patients' understanding.

Variation in the criteria to assess patients' footwear was reported within routine practice; for instance, some podiatrists described how they made assessments by glancing at the patients' footwear or how the assessment was 'second nature'. The characteristics of footwear commonly assessed during routine practice tended to include fastening, length, width, heel height, sole and fabric. Podiatrists confirmed that there is currently no formal checklist used within routine practice for footwear assessment:

> *Yes it's in your head and then you tick a box on SystmOne to say appropriate footwear worn . . . it's second nature.*
>
> *Podiatrist 5*

Podiatrists reported that footwear was not routinely provided, with only one podiatrist (podiatrist 5) referring to fitting 'stock hospital shoes' when there was a clinical need.

Experiences of assessing and ordering footwear during the REFORM trial

For the purposes of the REFORM trial, participants were asked to bring samples of their indoor and outdoor footwear to the clinic for assessment. As described in *Chapter 2*, podiatrists were asked to assess participants' footwear against a checklist provided by the research team of characteristics of suitable footwear identified in the literature[12] (see *Appendix 21*). If trial participants failed to bring samples of their footwear, the assessment was based on a description. The majority of the podiatrists found the trial criteria for assessing footwear straightforward to follow and described the checklist as clear and logical:

> *It [the checklist] was very similar to what I would normally do and it actually reiterated all the things that I was doing before so it was, you know, clarified everything that I was doing and thinking yep that it was [what] I would do anyway, so I mean that was quite useful because it took me back to basics to actually think about it a bit more.*
>
> *Podiatrist 7*

However, a few podiatrists mentioned that the current electronic medical record did not have sufficient data fields for the more detailed footwear checklist; therefore, alternative ways of capturing these data would have to be found:

> *In our paperwork we have whether it's a good fitting shoe, whether it was too big or too small, whether it's a slipper or bespoke orthopaedic aid and then we have an optional heel height and what kind of fastening they have and we do have a comment box as well. So that's our kind of footwear assessment of what we can document.*
>
> *Podiatrist 10*

The REFORM trial also enabled podiatrists to order footwear for participants, which is something that is not currently provided in usual podiatry care. Prior to ordering shoes, podiatrists were required to measure participants' feet. The measuring guide was a laminated picture of a foot, annotated with different shoe sizes. Participants stood on the guide and their corresponding shoe size was read. The width of shoe was determined by measuring the circumference of the foot using a tape measure and referring to a chart to find the required width (www.dbshoes.co.uk/measuring_chart.php, accessed 2 October 2012; www.hotter.com/gb/en/info/Hotter-Shoes-Fitting-Guide, accessed 2 October 2012). Although the majority

of podiatrists described the measuring process as straightforward, a number of difficulties were reported, especially among those who did not have training in shoe fitting outside the trial (the trial did not provide additional training on this). Some podiatrists commented that the measuring guide on which participants stood during the measuring process would sometimes slip unless it was taped to the floor. Challenges for less mobile patients were also reported, as they found it hard to stand on the measure, which had to be placed against a wall.

Despite some difficulties, the majority of podiatrists felt that footwear assessment and advice was generally straightforward and a central element of their clinical role; however, some expressed concerns that in routine practice there would be insufficient time to undertake a full footwear assessment:

> *It is time-consuming but we were given enough time to do it, so in an ordinary clinic if you had 20 minutes to do a routine treatment and educate them on footwear and have a discussion around it, it would really eat into the time but for the study we had enough time to do that.*
>
> *Podiatrist 1*

Given these time pressures within usual practice, a number of the podiatrists did suggest that this element of the intervention could potentially be conducted by a podiatry assistant or technician:

> *. . . probably our technicians or podiatry assistants are probably very, very competent at doing that type of thing.*
>
> *Podiatrist 7*

In contrast, however, one podiatrist (podiatrist 4) felt very strongly that footwear measurement was outside the role of podiatrist and should be conducted by an orthotist, working as part of a multidisciplinary team.

Additional issues with the measuring process included the accuracy of the sizing guide, fitting slippers that were available only in full sizes (not half sizes), the lack of footwear under size two and the time required to fit footwear:

> *That was out of frustration because of the backwards and forwards process of ordering, fitting and finding out that the shoe wasn't right.*
>
> *Podiatrist 3*

A minority of podiatrists also found the shoe ordering process very time-consuming, something that was attributed mainly to patients spending large amounts of time selecting footwear from what some podiatrists considered an excessive number of options.

Experiences of and adherence to footwear advice/trial purchased shoes

As would be expected, adherence to footwear advice varied among participants. From the 12-month follow-up questionnaire administered to the whole of the trial intervention group, we observed that nearly two-thirds ($n = 137$, 63.7%) of the participants who reported that they had their shoes checked said that their podiatrist gave them advice about their footwear or suggested that they should wear a different style of shoe, of whom 104 (77.0%) reported that they followed this advice (80.8% of men and 74.7% of women).

It was the view of both podiatrists and trial participants that it can be difficult to action footwear advice and change shoes/slippers, as high-street shops do not always stock footwear that is a suitable fit, and in some areas there is a lack of stockists:

> *But you see they say what makes an everyday shoe unsafe . . . what they mean about secure fastenings but they're not easy to find either . . . That's what I need, depth for my toes and they have depth but you don't get a great deal of choice and I believe there's a shop down [name of street*

where shop is] that deals in, just a little shop and they deal in shoes, I haven't been in. I've just looked in the window as I've passed by.

Trial participant 8

Several podiatrists highlighted that, for many service users, the cost of the appropriate footwear recommended could be prohibitive:

Obviously these brands that you recommended, you know, in the shops they can be 70 to 80 pounds, so you know, unfortunately some people just can't afford to get more specialised footwear.

Podiatrist 6

The availability of shoes through the trial had provided respondents with access to appropriate footwear by overcoming these barriers. In addition, podiatrists were at pains to discuss with service users that, although many shoes were expensive, ultimately the cost of the shoe did not always reflect whether or not it was appropriate for them:

. . . so I think [the service providing shoes] is a great idea in theory but I think it's probably quite costly and maybe, you know, you can buy, you know, if you've got to buy a pair of shoes there's a lot of shoes you can buy that aren't as expensive but still have those good qualities, you know, like a cheaper pair of trainers really.

Podiatrist 12

The response to the footwear advice/footwear provided was mixed. Many participants reported that they wore their 'appropriate' outdoor shoes all the time and were really satisfied with the fit and choice of shoe:

I think I'll always wear Hotter shoes now because they're so good.

Trial participant 2

Other participants described how they stopped wearing the footwear, largely because the shoes did not fit properly and were uncomfortable; in some cases, even the recommended shoe suppliers did not have shoes that were a good comfortable fit for people who are older (some of whom had various foot problems including arthritis, bunions or corns). In addition, there were also pragmatic reasons why appropriate shoes were more difficult to identify for some service users, such as difficulty in putting shoes on among this age group:

The age group of the patients in the REFORM trial were very elderly, or a lot of them were, and for that reason they had difficulty getting down to their feet, so they tend to go for slip-on shoes for ease of fitting them whereas a lace-up or Velcro-fastening shoe created additional problems.

Podiatrist 3

Despite participants demonstrating a good general understanding of 'appropriate footwear', there were still a number of examples of inappropriate footwear being worn, reflecting the pragmatic solutions the participants had found in order to incorporate the advice into their daily routines and practices:

I think if you wear sensible shoes, I think that's the big thing. I mean I'm past all these stiletto heels now. I used to wear them once but no, I do wear a little heel sometimes when I go out. I like these flip-flops in the summer because they've got the heighted heel at the back and I find that very comfortable. I'm not very keen on dead flat but because of my neck I don't like a very flat shoe. Yeah I think sensible shoes.

Trial participant 6

Although not particularly supported by the quantitative data, podiatrists perceived that women were less likely to action the footwear advice and that this needed to be taken into account when such advice was being provided:

> *It's about the complete loss of identity . . . you have to try and see if from the patient's point of view because it's very cut and dry for us. This is what you need, this is what's going to be really good for you and that's what you're going to get and sometimes you have to work a little bit more around the patient and I think, you know, going back to the original discussion about footwear, I think women have an idea about how they want to present themselves to the world and if say that foot support or orthotic is not going to fit in that shoe or the shoe is not going to support the function of the device, it can be very difficult.*
>
> *Podiatrist 4*

Orthoses

Using orthoses during routine practice

The majority of podiatrists described how they had prescribed some form of orthosis in their usual practice, predominantly for clinical conditions such as Achilles tendon problems or plantar fasciitis; however, one podiatrist (podiatrist 1) reported that they had prescribed an orthosis for a participant who had fallen. Of the podiatrists who had prescribed orthoses, the majority had prescribed the trial orthosis (X-Line) or a similar orthosis. Issues encountered when routinely prescribing orthoses were reported and included complaints that they were uncomfortable or too bulky to fit in participants' shoes:

> *Sometimes they [the participants]find them a bit too bulky, so they can't get their foot in as well as the insole and just to be able to get them in the shoes themselves.*
>
> *Podiatrist 2*

Experiences of the X-Line orthosis during the REFORM trial

The majority of podiatrists and trial participants reported positive experiences of using the X-Line orthosis and described the X-Line as a good, cost-effective orthosis. Podiatrists also explained how the X-Line was good for participants who had arthritis or deformities, as the orthosis was slim and so could easily fit into footwear. The arch support, control on the heel and met dome support were also cited along with the fact that the X-Line was not overly corrective and so was not expected to cause problems such as lesions or balance problems. Direct comparisons with other routinely prescribed orthoses were also made, with podiatrists often stating a preference for the trial orthosis. Podiatrists' positive experiences of the X-Line orthosis were also demonstrated when one site reported that it may consider changing its routinely prescribed orthosis to the X-Line, although this would ultimately depend on the cost of the device and whether or not those who purchased equipment in the trust would agree to order this type of device:

> *These weren't bad at all because they're quite thin on the front as well, that's another problem we usually have of patients especially if they've got arthritis in their toes, claw toes that type of thing but even the slight raise sort of lifts the foot up and then the shoes are pressing on the toes. But no I was quite impressed with those.*
>
> *Podiatrist 8*

On a practical level, the majority of podiatrists found the X-Line insoles easy to fit into participants' footwear. Trimming the insole was generally not found to be an issue, as this could mainly be done at the clinic with scissors. If required, the insole could also be trimmed to three-quarter length, to aid fitting into participants' footwear. Attaching postings and additions was also not perceived to be a problem,

as they were self-adhesive. This meant that they could be attached in the clinic and so did not require special equipment or to be sent to the laboratory, as is sometimes the case:

> *The additions we just had the peel back, so like the sticky on the back and you just peel it off and away you go whereas the ones we use at the minute, they have to go to the lab and like be glued on. So obviously this is easy because you've got them in clinic and you can put them on there and then and off they go.*
>
> *Podiatrist 2*

However, although the majority of podiatrists related positive experiences, theere were some difficulties reported with fitting and trimming the X-Line. For instance, one podiatrist (podiatrist 3) stated that trying to fit the orthosis into a participant's footwear made the shoes too tight and inappropriate:

> *The only difficulty came in with trying to fit an orthotic [insole] to what was an appropriate shoe and if the shoe then became too tight then it was no longer an appropriate shoe.*
>
> *Podiatrist 3*

At study set-up, some sites raised concerns about the possibility of the trial identifying patients with an unmet clinical need, who would require a full biomechanics assessment. Sites were apprehensive about the impact that this would have on their clinics. These concerns were not represented within the interviews; the majority of podiatrists were willing to prescribe the insole without a full assessment, as they considered the device unlikely to cause participants any problems. However, three podiatrists reported giving participants an assessment to check that it was clinically appropriate to prescribe the orthosis:

> *Yeah I mean it was a slight assessment with checking muscle strength and basic things but I wouldn't say it was a full complex biomechanical assessment.*
>
> *Podiatrist 8*

Experiences of and adherence to the orthosis prescribed during the REFORM trial

For those in the trial as a whole, *Table 51* presents responses to the adherence questions for the intervention participants who received an orthotic insole and responded to this question. At 12 months, 66.4% of participants reported wearing their orthosis most or all of the time, and 85.0% reported wearing it at least a little of the time.

It is clear that wearing orthoses was generally acceptable; however, the podiatrists adapted their use to the individual circumstances of the participant, for example by adapting the insole to accommodate foot

TABLE 51 Adherence to the orthoses for intervention participants who received the intervention

	Time point (month)		
	3	6	12
Number of questionnaires received	457	427	408
Of which received intervention	393	372	357
Of which received an orthosis	237	224	215
In the past month, typically how often was foot orthosis (insole) worn in shoes, *n* (%)			
All of the time	89 (38.5)	75 (33.9)	87 (40.7)
Most of the time	61 (26.4)	73 (33.0)	55 (25.7)
Some of the time	34 (14.7)	29 (13.1)	30 (14.0)
A little of the time	10 (4.3)	15 (6.8)	10 (4.7)
None of the time	37 (16.0)	29 (13.1)	32 (15.0)

deformities. As might be expected, how comfortable the participant found the insole was a significant determinant in whether or not it was worn with any regularity:

> *They're comfortable and that's the main thing as well, if they weren't comfortable they would have been chucked out.*
>
> *Trial participant 7*

However, those who felt that the orthosis was likely to have a benefit, through either previous experiences of using orthoses or anecdotes from family or friends, seemed to be prepared to endure some discomfort, at least initially. Some participants were also willing to persevere with the orthotic, despite some initial discomfort, because it had been recommended by the podiatrist and they felt that it was likely to be of benefit. Several reported that they considered the insoles to be a good idea, especially as they had either fallen several times or because they wanted to find something to help improve their walking, and demonstrated a willingness to try:

> *Well it took several weeks to get accustomed to the insoles, it was quite painful but I was determined to persevere.*
>
> *Trial participant 4*

Although in some cases the perseverance paid off, others ceased to wear the orthosis completely:

> *I used the orthotics, I had some from before, and they are not comfortable with my back. I mean there's nothing much the matter with my back but I ended up with a sore back, with wearing them.*
>
> *Trial participant 13*

A contributing factor in the resultant comfort was whether or not appropriate footwear was available. Although the trial had attempted to accommodate the requirement for footwear when necessary, for some participants, even with this option, the orthosis was still not a comfortable fit. This was especially the case for individuals who had pre-existing problems with their feet, which made it difficult to cope with the inserts, or who had to adapt the use of the inserts to make them tolerable:

> *Yes but on one foot I could wear them but not on the other because I've got very high arch, I broke this foot when I was very, very young and it just made a difference. It made the shoe too tight.*
>
> *Trial participant 3*

However, for many the whole package of obtaining the appropriate footwear and orthosis worked well and participants could feel the benefit from the increased support. Positive experiences were mainly associated with comfort and support, for example improvement in posture or shoes fitting better and being more comfortable to wear. This was in addition to the perceived effect it had on participants' balance, the number of falls they had and their confidence:

> *. . . [the podiatrist] decided the shoes, although they were Clarks [C&J Clark Ltd, Somerset, UK] the shoes I was wearing, they weren't as good so she measured me for some shoe inserts and I got a pair of Hotter shoes and a pair of Hotter slippers and these shoes and the inserts they've made a dramatic difference, you know, to me walking and lifting; because I think my arches have probably fallen a bit, so it gives me support in that way.*
>
> *Trial participant 2*

Those who were experiencing a noticeable benefit tended to wear the orthoses all the time:

> *I've got one set for these shoes and then another set I use if I go out anywhere or leisure, I just slip them into whatever shoes I'm using.*
>
> *Trial participant 2*

However, others, who did not feel such a palpable benefit or who did not have the expectation that orthoses were likely to affect their risk of falls, tended to use the inserts in a more pragmatic way, and adapted their use to what was practical and feasible:

> *I've got them in one of the pairs of shoes that I wear most of the time . . . [I wear them] probably four times a week, because I can't get them in, like I say, I've got a problem with my toe, so if I can't put them into any of my other shoes because there's not enough room in there for my toes and that in sole . . . I can't say that I've really felt a difference, do you know what I mean – I've got used to wearing them so they're very comfortable.*
>
> *Trial participant 7*

Exercises

Prescribing exercises in routine practice

Some podiatrists reported prescribing exercises in their routine practice, largely for conditions such as plantar fasciitis or Achilles tendon injuries. The podiatrists were not currently prescribing exercises for falls prevention in routine care. They acknowledged issues associated with prescribing exercises, which included the potential for the exercises to cause injury:

> *Yeah but with older people a lot of the exercises you've got to be really careful with that you don't cause further problems. Some of the exercises I think the patients go a bit too far with them and would actually sort of damage tendons if they overstretch.*
>
> *Podiatrist 8*

Exercises prescribed during routine practice differed from those in the REFORM trial. Although podiatrists reported having prescribed some, if not all, of the exercises provided during the trial, these exercises had not been prescribed as a 'package' or in combination with each other. In terms of the individual exercises, resistive bands and foot therapy balls were rarely provided but may have been prescribed in biomechanics clinics. Some podiatrists raised the issue of professional domains, remarking that, in current practice, prescribing exercises is the responsibility of physiotherapists rather than podiatrists:

> Podiatrist 9: *. . . but we've never had therabands within podiatry stock.*
>
> Interviewer: *I think some of it is expensive, is that the reason?*
>
> Podiatrist 9: *I think that would be, yeah the main reason I would think and it just seems to be for our trust, it seems to be the role of the physiotherapist. So we maybe refer patients to physiotherapy for that part of an exercise programme but we haven't done it within the podiatry clinics.*

To negate the need for specialist equipment in routine practice, podiatrists would suggest alternative ways of conducting exercises; for example, they might advise patients to use a dressing gown cord instead of a resistive band. In addition, over half of the podiatrists reported that they had prescribed exercises using alternatives to a therapy ball that required patients to roll their feet over a can, or to pick up pencils or golf or tennis balls.

Experiences of the exercises during the REFORM trial

Podiatrists mostly spoke positively of the trial exercises. Indeed, two podiatrists reported having changed their routine practice to prescribe exercises when appropriate. However, some practical issues were reported, including the difficulty with prescribing exercises for elderly and frail patients, especially given the number of exercises that were included and the length of time it took to explain them. Podiatrists took a

pragmatic approach and modified the trial exercise package to adapt the regime for people with comorbidities, to reduce the number of exercises or to suggest that particular exercises were not undertaken:

> Podiatrist 3: *Yes when we were finding exercises for the very elderly patients, a lot of them struggled to actually be able to go on tiptoe, stand on one foot because they were quite frail. Some patients also had other health problems which made exercise a lot more difficult such as osteoarthritis of the feet, so they would often phone up and say, I've tried very hard to do these exercises but they're causing me a lot of pain.*
>
> Interviewer: *Right and so in those cases what was the advice you gave them?*
>
> Podiatrist 3: *We asked them to modify their approach and to do as many of the exercises as they could do but not feel too bad if they had to reduce the frequency of the exercise or maybe even miss one exercise out, for instance, if they had osteoarthritis of the first MTP [metatarsophalangeal], big toe joint, we would say to them, don't worry about getting on tiptoe but do and try and do the other ones.*

To facilitate trial participants' understanding of and adherence to the exercises, a booklet and a DVD were provided. Podiatrists and trial participants spoke positively of the booklet, describing it as well written and easy to follow, with clear instructions and a good combination of pictures and text. The booklet was viewed as a useful resource that helped podiatrists to remind and explain to patients how to do the exercises, something that was considered particularly important given the amount of information patients received at their first appointment. During the trial, podiatrists used the booklet as a guide when delivering the whole intervention and also worked through the booklet with patients, using the pictures to aid their description of the exercises during clinic. Although one podiatrist (podiatrist 3) felt that some participants viewed the information in the booklet as too simplistic, others saw its simplicity as a strength, stating that it could have been issued without additional instructions. The positive feedback provided by podiatrists is exemplified by the fact that a few sites asked if they could give out the booklet in their routine practice prior to the end of the trial, with one podiatrist (podiatrist 10) also presenting the booklet at a staff meeting:

> *I thought it was very good. It was very well written. It was very easy to follow and because it had the pictures, the people could, you know, go back to it and have a look and it did make sense. It was written well.*
>
> *Podiatrist 7*

In light of podiatrists' initial concerns regarding the amount of information given to trial participants at the start of the study, both the DVD and the booklet were considered helpful reminders. However, only a small proportion of trial participants reported having watched the DVD. The podiatrists provided some insight into this during their interviews, as they reported that patients had difficulty playing the DVD or, in some cases, did not have a DVD player. In addition, one podiatrist (podiatrist 3) suggested that the DVD may be more suitable for younger people and felt that those in the age group taking part in the trial would prefer written information:

> *Some of the DVDs did not work and not every patient had access to a DVD player and the patients tended to report back that while they found the booklet very helpful because that generation tends to like to read things rather than play things, if you're dealing with a younger generation the DVD would have been more useful.*
>
> *Podiatrist 3*

Podiatrists felt that a follow-up appointment was important to ensure that the exercises were being conducted correctly:

> *. . . showing the patient how to do them correctly and getting them to do them correctly, because occasionally when they came back to the clinic for their review appointment and you asked them to demonstrate the exercises again, some of them hadn't been doing them correctly, so it just needed a bit of re-education really.*
>
> *Podiatrist 1*

Experiences of and adherence to the exercises prescribed during the REFORM trial

At 12 months, 28.9% of participants in the intervention group reported performing the exercises at least three times per week and 74.5% reported performing them at least once per week (*Table 52*).

In the interviews, participants reported varying levels of adherence to the exercises, with some reporting undertaking them every day, some reporting undertaking them three times a week and some reporting that they did not do them at all. The length of time that participants complied for also varied, with some reporting trying the exercises for a short time before stopping (e.g. 1 month), although others persevered because of their desire to prevent falls.

In the main, the trial participants spoke positively about the trial exercises, although, in a similar vein to the podiatrist interviews, the number and challenging nature of some exercises was discussed. Trial participants and podiatrists expressed varying opinions regarding the resistive band and therapy ball exercises, which are outlined in *Table 53*.

Although some participants reported that they had not noticed any differences since undertaking the exercises, for many participants the exercises had led to perceived benefits, such as improvements in their walking, balance, confidence and body awareness:

> *I didn't do them every day to start with but I did them at least three times a week and within several weeks I felt the benefit. I did feel the benefit from, you know. In my walking and in my balance and the ability to get to stand up.*
>
> *Trial participant 2*

Whether or not participants perceived the exercises to be beneficial may have influenced their adherence. For example, one participant commented that they had continued to undertake the exercises even when they were tired, as their perception of improvements had given them an incentive to continue.

TABLE 52 Adherence to the exercises for intervention participants who received the intervention

	Time point (month)		
	3	6	12
Number of questionnaires received	457	427	408
Of which received intervention	393	372	357
In the past month, typically how many times a week were foot and ankle exercises undertaken, *n* (%)			
More than three times a week	51 (13.4)	43 (11.8)	45 (12.9)
Three times a week	90 (23.7)	66 (18.1)	56 (16.1)
Twice a week	89 (23.4)	86 (23.6)	71 (20.3)
Once a week	75 (19.7)	79 (21.7)	88 (25.2)
Not undertaken	75 (19.7)	90 (24.7)	89 (25.5)

TABLE 53 Trial participant and podiatrist opinions on resistive band and therapy ball exercises

Type of exercise	Trial participant and podiatrist opinions
Resistive band exercises	
Some podiatrists thought that the exercises were good but expressed concerns over whether or not the participant could site the band properly and undertake the exercises correctly	*The place at where they put the theraband over the foot, so sometimes it might have been more along the arches of the foot rather than across the forefoot, so just where to place the theraband. Sometimes they were trying to move their whole leg with the theraband* — *Podiatrist 13*
Some trial participants reported difficulties in siting the band and others developed strategies to site the band correctly	*Mainly because I don't think I have furniture that lends itself to it but it just kept sliding off and we tried and tried* — *Trial participant 1* *I used to put like the big elastic band around the table leg and move my leg* — *Trial participant 8*
Therapy ball exercises	
The majority of podiatrists liked the exercise and found it easy to determine which size of ball to prescribe, although patients with foot deformities encountered difficulties in performing the exercises	*It was quite useful idea, get the intrinsic muscles working a little bit, help with the stability a good idea* — *Podiatrist 1* *There were a few patients who couldn't do it but just due to their foot deformity they've got like arthritis of the toes or they couldn't actually bend, you know* — *Podiatrist 10*
Most of the trial participants liked these exercises. Not all could pick up the ball but those who did often reported a sense of achievement	*I did find them very good and I felt very pleased with myself when I could grip the ball. I used to say [name] come and see what I can do now, you know, it's an achievement because again you get to a certain age and you don't do, you know, generally you don't do exercises really* — *Trial participant 9* *I find the ones with the ball I find it very good to do that and I can more or less, at first I couldn't lift it, you know, but I am getting more flexibility in my toes now with that* — *Trial participant 3*

A number of participants also described strategies that they had adopted to make the exercises easier to fit into their daily lives, for example goal-setting (e.g. wanting to stand up easily), splitting the exercises throughout the day, and doing the exercises 'first thing in the morning' or while watching television, which may have improved adherence:

> *I do them three times a week all at once, one after the other. Monday, Wednesday and Friday and I've done them this morning before 7 o'clock. Well I make sure because I do it at a time that suits me that doesn't interfere with my life, you know, because I'm out of the house by quarter to nine every morning, so you know, that's the time it's done.*
>
> *Trial participant 1*

For participants who did not regularly undertake the exercises, a range of reasons for non-adherence were provided, including the length of time required to undertake them. Medical conditions such as heart problems or arthritis also made performing the exercises difficult or painful for a number of participants:

> *. . . because I've got a bad heart, it doesn't take me long to get out of breath, so I found them hard work, very hard work.*
>
> *Trial participant 7*

Others had to adapt the exercise package to accommodate their own physical limitations:

> *One I couldn't do. The one where you had to stand up with your back up against a wall. I couldn't do that because I couldn't balance on one leg because this knee is so bad. There is no way I could stand and put all my weight on one leg, so I tried that one once and thought wow.*
>
> *Trial participant 7*

For others, the exercises were not a priority either because they were not motivated to do them or because they had other priorities such as being a full-time carer for a relative.

The REFORM package of care

Of the 211 participants who received an orthosis as part of the intervention and who provided a response to both questions relating to adherence to the insole and to the exercises at 12 months, 68.7% ($n = 145$) reported having worn their orthotic and preformed the exercises in the previous 4 weeks, 5.2% ($n = 11$) reported no adherence to either aspect and the remaining 55 reported that they either only wore the orthotic ($n = 35$) or only undertook the exercises ($n = 20$).

Given the multifaceted nature of the REFORM intervention, coupled with the often complex health issues of the population group, the majority of participants were able to complete only some aspects of the care package and had to adapt what was available to suit their own circumstances and perceptions of impact. A similar pragmatic approach was taken by the podiatrists, who were able to see how they could incorporate the basis of the intervention into routine practice:

> *I mean the majority I think I would probably give a few exercises and an insole to.*
>
> *Podiatrist 7*

Although podiatrists found the intervention acceptable and were, in principle, willing to administer all of the elements, some did question how the intervention could be incorporated into routine care, given the way that services were currently configured:

> *I think just, I suppose it just reminded me more of what I should be doing, what our roles should involve because the way we work in [centre], we're all quite fragmented I suppose. So I would not normally have a patient in a clinic, in a routine clinic for a 20-minute appointment slot and so, if you've got a caseload of patients and they're coming in to see you every 4 months, if they've had a fall, you're just not going to start taking them through a falls exercise programme and there isn't any other specialised clinic that you book them into to have that time to do it. So we have falls, so you know if somebody has a fall, our service accesses the falls clinic and the GP would refer onto the falls clinic and that's nothing to do with podiatry.*
>
> *Podiatrist 13*

Some highlighted that, for the exercise element in particular, there may be more appropriate contexts in which this could be delivered:

> *Yeah because we have got dedicated biomechanics clinics, so I think it would sort of fit in well within that area of our service.*
>
> *Podiatrist 9*

Given the probable time restraints in routine care, some podiatrists suggested delivering certain elements of the package of care in group sessions to save time and money; however, opinion was split on whether or not this would be the best mode of delivery from the patients' point of view:

> *Something that we could use later as maybe a group session and getting patients in to talk them through as a group session and showing them the different exercises and the type of shoe that they should be wearing.*
>
> *Podiatrist 7*

> *I think on a one-to-one basis it is better. If you have them in a class, you'll have people who are self-conscious or not really willing to try things just out of fear and I think one-on-one situations they feel comfortable, in a safe environment and it's a better way to deliver it.*
>
> *Podiatrist 1*

Summary

Footwear

Podiatrists provide footwear advice in routine practice and are well versed in doing so. The trial footwear checklist was detailed, provided a more formal evidence-based tool with which to assess footwear and was acceptable to podiatrists. For the checklist to be used in routine practice, attention would have to be paid to how the information on the checklist was recorded in the current electronic patient record systems.

Although most podiatrists found measuring for shoes straightforward, this could be time-consuming and may be difficult within the constraints of normal clinic appointments. It was suggested that this aspect could be conducted by technicians, podiatry assistant or orthotists rather than podiatrists as part of a multidisciplinary team.

It is questionable whether appropriate footwear would be provided within current NHS budgets. Outside the trial it may be more difficult to achieve adherence to footwear advice, given the financial constraints of many of the service users. In addition, there is a subgroup of service users who will be unable to access shoe retailers, who will not be able to achieve a good fit owing to existing foot problems, or who will be resistant to wearing the footwear options available.

Orthotics

Podiatrists do not routinely prescribe orthotics for falls prevention. However, they were positive about the trial orthotic and found it easy and acceptable to implement without the need for more complex biometrics assessment. Appropriate footwear is required to achieve a good fit for the orthotic; this will be less achievable for a wide range of service users outside the context of the trial if footwear is not being provided. Service users will find a pragmatic solution to incorporating wearing an orthotic, if comfortable to do so, into their everyday lives.

Exercises

Podiatrists do not currently prescribe exercise packages such as those in the REFORM intervention. They did find it acceptable to do so, in particular with the aid of the trial booklet. However, explaining the exercises properly was time-consuming and would be difficult to fit into a routine podiatry appointment. Podiatrists also felt that a follow-up appointment would be necessary to check that the exercises were being conducted appropriately to avoid injury.

The equipment necessary for the REFORM exercises was not always routinely available in podiatry clinics, meaning that additional resources would be required or that alternatives to the formal equipment would have to be suggested. Although podiatrists were happy to implement the exercise component of the intervention, this was more commonly seen as being the domain of physiotherapy or biomechanics, and in routine practice a way of incorporating the intervention into the current configuration of podiatry/falls services would have to be developed. For example, it was suggested the exercises and footwear advice could be explained in a group setting, perhaps in the context of a multidisciplinary falls clinic.

Chapter 7 Discussion

Here we report the results of a large RCT assessing the clinical effectiveness and cost-effectiveness of a multifaceted podiatric intervention for the prevention of falls among podiatry patients within a NHS setting and one international site in Ireland. Previous reviews, including the most recent Cochrane review, have identified only one previous RCT of a similar intervention in an Australian setting.[23] A meta-analysis of eight RCTs using foot and ankle exercises noted improvements in surrogate measures of outcomes, such as balance.[19] In this discussion, we summarise our key findings, compare these with previous studies and discuss the strengths and limitations of our study.

Key findings

The REFORM trial is the largest study of a podiatric programme that includes a foot and ankle exercise programme to reduce the risk of falling. A total of 1010 participants were randomised. Our sample size allowed for a 10% loss to follow-up. The actual overall loss to follow-up observed at 12 months was 12.4% [in total, a 12-month questionnaire was returned for 885/1010 (87.6%) randomised participants]. Although this loss was higher than expected, we still had sufficient numbers relative to the target sample size of 890, as the trial over-recruited to 1010 participants. The primary clinical outcome for the trial was the incidence rate of falls reported on monthly falls calendars in the 12 months following randomisation. In practice, it is difficult to calculate the required sample size for a regression model, such as a Poisson or negative binomial regression model, to analyse count data. This requires an estimate of the measure of overdispersion and a justifiable treatment effect to detect. There were a limited number of data on which to base these parameters and so the decision was made to power the trial to detect a difference in the percentage of participants who reported at least one fall over the 12-month follow-up.

In total, 992 (98.2%) trial participants returned at least one falls calendar following randomisation, with similar proportions across the two groups [484 (98.2%) participants in the intervention group and 508 (98.3%) participants in the usual-care group]. We found a reduction in the rate of falls per person-year (IRR 0.88, 95% CI 0.73 to 1.05) and in the proportion of participants who had one or more falls over the 12 months from randomisation (OR 0.78, 95% CI 0.60 to 1.00). The difference was not statistically significant in our prespecified primary outcome of rate of falls ($p = 0.16$); however, the difference in the proportion of participants who had at least one fall (54.9% and 49.7% for usual care and intervention groups, respectively), a key secondary outcome, was of borderline statistical significance ($p = 0.05$). In our sample size calculation, we assumed that 50% of the usual-care group would fall during the 12-month follow-up, and we powered to detect a fall to 40% in the intervention group. In fact, 55% of the usual-care group experienced a fall. With the numbers recruited, we had 80% power to detect a fall to 46%, and approximately 36% power to detect the difference of 5% observed. Although a 5% decrease in the number of participants falling is of borderline statistical significance, it is difficult to say whether or not it is clinically meaningful. The estimated number of participants to whom we would need to offer the intervention to prevent one person from experiencing a fall is 20, which is relatively low.

A small, and similar, proportion of participants reported at baseline that they had been referred to a falls clinic or service in the previous 12 months in the two groups. At the end of the 12-month follow-up, we asked this question again: 30 out of 416 (7.2%) intervention participants and 22 out of 452 (4.9%) usual care participants said that they had been referred to a falls clinic or service in the previous 12 months. It is possible that participants in the intervention group interpreted this question as referring to their trial appointments at the podiatry clinic. If participants in the usual-care group received some form of intervention shortly before or during the trial follow-up, this could potentially have diluted the treatment effect. However, with only small numbers reporting this, we do not believe that this could have significantly influenced the results, and in any case we ran this as a pragmatic trial and so the results will reflect usual practice.

Time to first fall was reduced in the intervention group but this was not statistically significantly (hazard ratio 0.88, 95% CI 0.74 to 1.04; $p = 0.14$). No statistically significant differences between the two groups were observed at 6 or 12 months in the fear of falling question, the Short Falls Efficacy Scale-International, the FAI, the GDS or the CD-RISC2. The intervention group did, however, report higher levels of foot pain at 12 months on a 10-cm visual analogue scale from 0 (no pain) to 10 (worst pain possible). The mean pain in the intervention group was 3.1, compared with 2.6 in the usual-care group (adjusted mean difference 0.43, 95% CI 0.06, 0.80; $p = 0.02$); however, although statistically significant, a difference of 4.3 mm may not be clinically meaningful. It is unclear why participants in the intervention group reported higher pain scores. Evidence from the qualitative study suggests that, in some cases, increased foot pain could have been a result of insoles reducing the space in footwear. In other cases it may be that intervention participants were simply more aware and more critical of (problems with) their feet, or they were using their feet more while performing the exercises. Alternatively, this could be a chance finding.

Cost-effectiveness

The results of the economic evaluation conducted alongside the REFORM trial suggest that the multifaceted intervention could be a cost-effective option for falls prevention in terms of QALYs gained calculated using the EQ-5D. The ICER for the ITT approach in the imputed data set ranged between £19,494 and £20,593 per additional QALY. The probability of being cost-effective for the base-case analysis is > 60%. The results are robust to the sensitivity analyses testing the assumptions regarding resource use, perspective of analysis and level of imputation regarding missing data on HRQoL. With the one exception of when the missing data mechanism is tested, the complete-case analysis suggests that the multifaceted podiatry intervention is expected to be more costly and slightly less beneficial than usual care. However, the complete case in REFORM is not without limitations. In addition to the much reduced sample size of the original data (28.3%), missing data patterns showed that incomplete data followed a non-monotonic pattern, which suggests that the complete-case assessment would be inefficient, as it would discard observed data from individuals who have some missing outcomes. A logistic regression analysis showed that advancing age and lower EQ-5D at baseline are associated with missing QALY data. This suggests that the data are unlikely to be MCAR; consequently, the results from the multiple imputed data set are likely to be more accurate and more reliable than complete care results.

The main limitation of this economic evaluation, conducted alongside the REFORM trial, is that it does not account for any differences in costs and QALYs that may be expected over the longer term (> 12 months post randomisation). The HRQoL data showed that the reduction in the number of participants in perfect health in the intervention group is lower than that in the usual-care group (17.7%); the increase in the number of participants having problems is also lower in the intervention group. The effectiveness analysis also indicated a reduction, albeit a non-statistically significant one, in fall rate in the intervention group relative to usual care. Cost-effectiveness did not noticeably differ when we projected HRQoL beyond the trial duration (up to 5 years). However, we consider this exploratory projection likely to be conservative, and it would be important to explore the long-term impact of reducing the number of falls, as this might also lead to a reduction in the number of fractures, which in turn will make it more likely that the intervention yields long-term cost savings in the NHS.

Qualitative findings

The qualitative study explored issues of acceptability and implementation from the perspectives of both patients and podiatrists. It found that most podiatrists could implement some elements of the programme, such as the footwear advice and the provision of the orthotic, as part of their normal clinic practice, with some podiatrists continuing to offer the intervention outside the trial. Some concerns were raised about the ability of podiatrists to effectively deliver the exercise component within the time constraints of a

routine clinical appointment. Although the podiatrists generally felt confident in doing so, time (and equipment) would have to be allocated for this purpose, alongside any necessary follow-up appointments. Given the way in which most falls prevention services are set up, some podiatrists felt that the intervention may be well suited to a multidisciplinary falls service, which would include podiatry alongside physiotherapy input for the exercise intervention, particularly in a group setting.

The trial participants were largely content with the intervention, and adherence was generally good. Some trial participants, especially those with comorbidities, found some of the exercises challenging; however, generally, both podiatrists and participants were able to adapt the exercises to suit individual circumstances. Some participants noticed a benefit of the exercise training after several weeks and felt more confident as a result. The trial participants found pragmatic ways to incorporate wearing an orthotic, when it was comfortable to do so. Some participants, however, were not able to adhere to the footwear advice/orthotic, as they were unable to achieve a good fit owing to existing foot problems or they were resistant to wearing the footwear options available.

Comparison with other studies

Our results to some extent support the earlier findings by Spink *et al.*[23] In this Australian trial, among 305 community-dwelling men and women (mean age 74 years) who were suffering from disabling foot pain and who had an elevated risk of falling, a reduction in the incidence rate of falls was observed (IRR 0.64, 95% CI 0.45 to 0.91). The Australian population was similar to ours in that they were all receiving routine podiatry care and were recruited from podiatry patient lists. However, participants had to be suffering from disabling foot pain, which was not the case for our population; patients may have had foot pathology but they did not necessarily have significant foot pain. Our population had a higher risk of falling; the usual-care group sustained an average of 1.5 falls per year, compared with 1.06 for the Australian patient group. Similarly, 55% of our usual care participants sustained one or more falls, compared with 49% in the Spink *et al.*[23] study.

The key elements of the interventions were similar, comprising foot and ankle exercises, an orthosis and an assessment for poor footwear. Both studies were carried out among patients who were receiving 'standard' podiatry. However, there were some differences. We did not use exactly the same orthosis as that used in the Australian study, and the foot and ankle exercises were modified partly in light of lessons learned from the Australian study. In our study, when possible, new footwear was provided to participants in the intervention group whose own current footwear was inappropriate. In the Spink *et al.*[23] trial, participants were provided with a subsidy for new footwear in the form of a voucher. Furthermore, the participants in our study did not need to have 'disabling foot pain', as was the case in the Australian study. Forest plots to compare the results of the two studies graphically are presented in *Figures 17* and *18*. An analysis of the

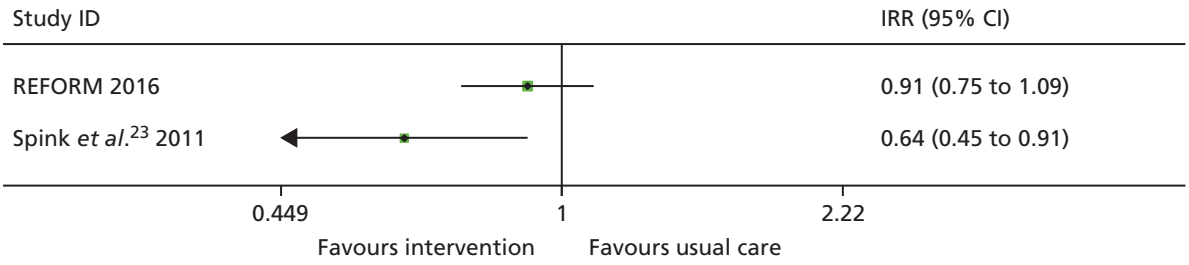

FIGURE 17 Impact of multifaceted podiatry intervention on the incidence rate of falls over 12 months in older adults. Reproduced from Spink *et al.*[23] This is an open-access article distributed under the terms of the Creative Commons Attribution Non-commercial License (CC BY-NC 2.0), which permits use, distribution, and reproduction in any medium, provided the original work is properly cited, the use is non commercial and is otherwise in compliance with the license (http://creativecommons.org/licenses/by-nc/2.0/ and http://creativecommons.org/licenses/by-nc/2.0/legalcode).

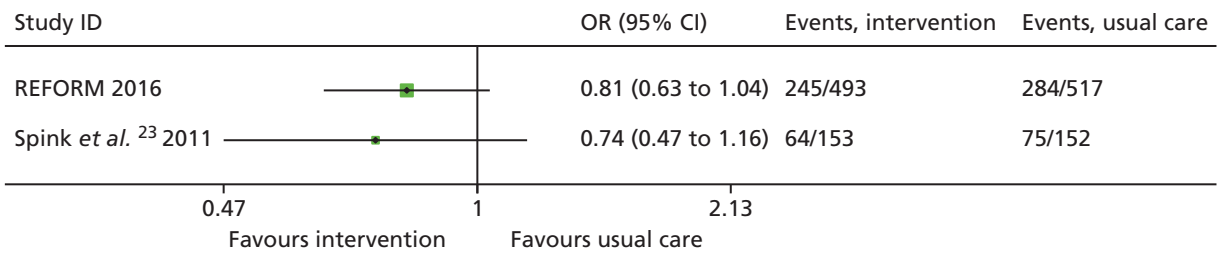

FIGURE 18 Impact of multifaceted podiatry intervention on proportion of participants who fall at least once over 12 months. Reproduced from Spink *et al.*[23] This is an open-access article distributed under the terms of the Creative Commons Attribution Non-commercial License (CC BY-NC 2.0), which permits use, distribution, and reproduction in any medium, provided the original work is properly cited, the use is non commercial and is otherwise in compliance with the license (http://creativecommons.org/licenses/by-nc/2.0/).

REFORM data was repeated including only treatment groups in the models for comparability with the Spink *et al.*[23] trial. Individual patient data were provided by the authors of the Spink *et al.* trial, and so, whereas results for the proportion of fallers are presented as a risk ratio in the publication, here we were able to present these as an OR.

Strengths and limitations of the study

This was a large pragmatic trial, and we used a novel design, namely a cohort randomised trial, to evaluate this podiatric intervention. The design had several strengths: the use of a run-in period with outcome data collection could have reduced the incidence of post-randomisation attrition; those in the usual-care group were unaware of the exact time at which they were randomised, and, in theory, this should have limited resentful demoralisation. The design also allowed us to recruit participants who initially were ineligible because they had not fallen but later became eligible because they had fallen while part of the observational cohort. The initial engagement of participants with the intervention was high; 84% of intervention participants attended a trial appointment. Compliance with the exercise component was reasonable (at 12 months, 29% of intervention participants reported performing the exercises at least three times per week and 75% reported doing them at least once per week). However, in the qualitative interviews, some podiatrists stated that they felt that this could have been higher if they had had additional contact with the participants. Another limitation of the study is that the sample size was based on detecting a difference not in the primary outcome of incidence rate of falls but in the proportion of participants reporting at least one fall in 12 months. This was because of the difficulty in calculating a sample size for a count outcome, as discussed in *Key findings*. It is not possible, therefore, to confirm that the trial was sufficiently powered for the primary outcome. In addition, participants were recruited from podiatry clinics; therefore, the estimated impact of the intervention among people who do not regularly see a NHS podiatrist or who receive care from a private podiatrist may be different. Using a run-in period may also have biased the sample towards volunteers with a heightened interest and commitment to the intervention. Furthermore, the intervention is a 'complex' one, and our design does not allow us to estimate the different contributions of changes in footwear, the addition of an orthotic insole or the undertaking of foot and ankle exercises to the observed effect. It may well be that one or more of the interventions included in the 'package of care' is ineffective. There is also the possibility that some participants in the usual-care group had enrolled in another falls prevention programme as part of their NHS care, which could have diluted the treatment effect. This dilution effect is likely to be minimal, however, given that only a small proportion of participants in the usual-care group reported being referred to a falls clinic or service during the trial.

Generalisability of the results

The REFORM intervention was a pragmatic RCT across nine sites in the UK and one site in Ireland. All participants were recruited from podiatry clinic lists. This was to ensure that we could identify an additional effect of the intervention not confounded by routine podiatric care. Consequently, the trial cannot answer the question of whether or not the intervention is effective among patients who do not have routine podiatry care. However, approximately one in six people aged > 65 years receives NHS podiatry care and, therefore, our results are applicable to a significant proportion of the older population.

The trial results may also not be generalisable to patients who would not fulfil the eligibility criteria, that is, those with lower limb amputations, neuropathy, dementia or other neurological conditions; those unable to walk household distances without the help of a walking aid; those living in residential or nursing care homes; and those aged < 65 years. The views of the podiatrists interviewed in the qualitative part of the study were mixed on whether or not people with neuropathy or amputations could have benefited from the intervention, and the majority agreed that a more intensive follow-up would have been required in order to ensure patient safety.

Implications for health care

Our results suggest that there is a role for NHS podiatrists in reducing the risk of falling among their patients. Although cost-effectiveness was demonstrated based on QALYs gained calculated via the EQ-5D and not necessarily on reducing falls, falls could potentially have a negative effect of patients' quality of life and any intervention to improve this is valid. However, in terms of the current intervention, some of the podiatrists felt that additional podiatry contact was required to maximise compliance with the individual intervention components. There is the potential for the cost of the intervention to be further reduced if a podiatry assistant rather than the podiatrist undertook the assessment of participants' footwear and the measuring, ordering and fitting of new footwear.

Implications for research

The impact of falls risk among these patients was relatively modest. As falls are a major source of morbidity in an older population, research into combining different interventions to develop a more effective overall strategy might be worth pursuing. Further research could also examine the risk and cost of falls in other populations or settings (e.g. people with neuropathy or residential aged care facilities). Additionally, the intervention could be tested in populations deemed to be at high risk of falling.

There is evidence to suggest that exercise is an effective falls prevention strategy, and it may be the case that it is equally, or possibly more, effective when demonstrated to patients in group sessions, as opposed to one on one. This would have the additional benefit of being cheaper to deliver and, therefore, being more cost-effective. Further research could be undertaken to test the clinical effectiveness and cost-effectiveness of a group exercise programme, which could also investigate whether or not the intervention could be delivered equally effectively across the professional boundaries of podiatry and physiotherapy. Alternatively, further research into the intensity of the exercise could be undertaken to see how much is actually needed.

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Contributions of authors

Sarah Cockayne (Research Fellow, Health Sciences) was a coinvestigator and the REFORM study manager. She contributed to the development of the grant application, trial protocol and was the lead for study management. She undertook the qualitative interviews and analysis and was involved in writing the report. She also was responsible for co-ordinating the compilation, formatting, proofreading and final approval of the report.

Sara Rodgers (Research Fellow Health Sciences) was a trial co-ordinator, assisted with the day-to-day management of the study and contributed to writing the report.

Lorraine Green (Research Podiatrist) contributed to the development of the protocol, trained the podiatrists delivering the intervention and assisted with the day-to-day management of the study.

Caroline Fairhurst (Statistician, Health Sciences) wrote the statistical analysis plan, conducted the statistical data analysis and contributed to writing the report.

Joy Adamson (Senior Research Fellow, Health Sciences) was a coinvestigator and contributed to the development of the grant application and trial protocol. She supervised the conduct of qualitative research and was involved in the qualitative analysis and writing the report.

Arabella Scantlebury (Research Fellow, Health Sciences) undertook the qualitative interviews and analysis and wrote sections of the report.

Belen Corbacho (Research Fellow, Health Sciences) wrote the health economics analysis plan, conducted the health economics analysis and wrote the health economics section of the report.

Catherine E Hewitt (Professor in Statistics, Health Sciences) was a coinvestigator and contributed to the overall study design and implementation, supervised the statistical analyses and approved the final version of the report.

Kate Hicks (Research Fellow, Health Sciences) was a trial co-ordinator, assisted with the day-to-day management of the study and proofread the final report.

Robin Hull (General Manager Acute and Cancer Care and Podiatrist) was a coinvestigator and contributed to the overall study design.

Anne-Maree Keenan (Professor, Assistant Director, NIHR Leeds Musculoskeletal Biomedical Research Unit and Musculoskeletal Research Lead for the Leeds Teaching Hospitals Trust) was a coinvestigator and contributed to the overall study design and protocol, provided podiatry advice and supervised the research podiatrist.

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Caroline McIntosh (Established Professor and Head of Podiatric Medicine) was a coinvestigator and contributed to the overall study design and provided podiatry expertise.

Hylton B Menz (Professor, National Health and Medical Research Council Senior Research Fellow) was a coinvestigator and contributed to the overall study design and protocol, provided podiatry advice and critically reviewed drafts of the report and approved the final version.

Anthony Redmond (Professor, Head of Section of Clinical Biomechanics and Physical Medicine) was a coinvestigator and contributed to the overall study design and provided podiatry expertise and supervised the research podiatrist.

Zoe Richardson (Trials Support Officer) assisted with the day-to-day management of the trial.

Wesley Vernon (Professor in Podiatric Medicine) was a coinvestigator and contributed to the overall study design and provided podiatry expertise.

Judith Watson (Research Fellow Health Sciences) was a coinvestigator and contributed to the overall study design and protocol, gave advice on study management and critically reviewed drafts of the report and approved the final version.

David J Torgerson (Professor, Director of the YTU, University of York) was the lead applicant and Chief Investigator for the REFORM study. He had overall responsibility for the design and implementation of the study and the writing of the report with final approval of the report submission.

All authors were invited to comment on the final manuscript.

Publications from REFORM podiatry intervention

Cockayne S, Adamson J, Hewitt C, Hull R, Keenan AM, Redmond A, *et al.* The reform study: a cohort multiple randomised controlled trial. *Trials* 2013;**14**(Suppl. 1):44.

Arundel C, Torgerson D, Jefferson L, Cockayne S. A nested randomised controlled trial of a leaflet, containing information on research, to increase the recruitment rate of reform (reducing falls with orthoses and a multifaceted podiatry) trial participants. *Trials* 2013;**14**(Suppl. 1):109.

Cockayne S, Adamson J, Corbacho, Martin B, *et al.* The REFORM study protocol: a cohort randomised controlled trial of a multifaceted podiatry intervention for the prevention of falls in older people. *BMJ Open* 2014;**4**:e006977.

Cockayne S, Adamson J, Bower P, Corbacho B, Fairhurst C, Farndon L, *et al.* The reform patient information sheet sub study – an embedded trial evaluating the enhancement of patient information sheets to improve recruitment. *Trials* 2015;**16**(Suppl. 2):87.

Cockayne S, Adamson J, Corbacho B, Fairhurst C, Farndon L, Hicks K, *et al.* The reform study: a case study of embedded trials. *Trials* 2015;**16**(Suppl. 2):174.

Tong JWK, Kong VP, Sze L, Gale S, Veto J, McArdle C, *et al.* The College of Podiatry Annual Conference 2015: meeting abstracts. *J Foot Ankle Res* 2016;**9**:1–14.

Cockayne S, Adamson J, Clarke A, Corbacho B, Fairhurst C, Green L, *et al.* Cohort randomised controlled trial of a multifaceted podiatry intervention for the prevention of falls in older people (the REFORM trial). *PLOS ONE* 2017;**12**:e0168712.

Data sharing statement

Requests to access REFORM data can be made to the corresponding author and will be considered on a case-by-case basis by the Trial Management Group. All data requests will be managed in accordance with YTU, University of York, processes and procedures.

References

1. Iglesias CP, Manca A, Torgerson DJ. The health-related quality of life and cost implications of falls in elderly women. *Osteoporos Int* 2009;**20**:869–78. http://dx.doi.org/10.1007/s00198-008-0753-5
2. Bischoff-Ferrari HA. The role of falls in fracture prediction. *Curr Osteoporos Rep* 2011;**9**:116–21. http://dx.doi.org/10.1007/s11914-011-0059-y
3. Lord SR, Sherrington C, Menz HB, Close JCT. *Falls in Older People: Risk Factors and Strategies for Prevention*. Cambridge: Cambridge University Press; 2007. https://doi.org/10.1017/CBO9780511722233
4. O'Loughlin JL, Robitaille Y, Boivin JF, Suissa S. Incidence of and risk factors for falls and injurious falls among the community-dwelling elderly. *Am J Epidemiol* 1993;**137**:342–54. https://doi.org/10.1093/oxfordjournals.aje.a116681
5. Vetter NJ, Lewis PA, Ford D. Can health visitors prevent fractures in elderly people? *BMJ* 1992;**304**:888–90. https://doi.org/10.1136/bmj.304.6831.888
6. British Orthopaedic Association. *The Care of Patients with Fragility Fracture*. London: British Orthopaedic Association; 2007.
7. Department of Health (DH). *National Service Framework for Older People*. London: DH; 2001.
8. Dunn JE, Link CL, Felson DT, Crincoli MG, Keysor JJ, McKinlay JB. Prevalence of foot and ankle conditions in a multiethnic community sample of older adults. *Am J Epidemiol* 2004;**159**:491–8. https://doi.org/10.1093/aje/kwh071
9. Menz HB, Morris ME, Lord SR. Foot and ankle risk factors for falls in older people: a prospective study. *J Gerontol A Biol Sci Med Sci* 2006;**61**:866–70. https://doi.org/10.1093/gerona/61.8.866
10. Mickle KJ, Munro BJ, Lord SR, Menz HB, Steele JR. Foot pain, plantar pressures, and falls in older people: a prospective study. *J Am Geriatr Soc* 2010;**58**:1936–40. http://dx.doi.org/10.1111/j.1532-5415.2010.03061.x
11. Hatton AL, Rome K, Dixon J, Martin DJ, McKeon PO. Footwear interventions: a review of their sensorimotor and mechanical effects on balance performance and gait in older adults. *J Am Podiatr Med Assoc* 2013;**103**:516–33. https://doi.org/10.7547/1030516
12. Menant JC, Steele JR, Menz HB, Munro BJ, Lord SR. Optimizing footwear for older people at risk of falls. *J Rehabil Res Dev* 2008;**45**:1167–81. https://doi.org/10.1682/JRRD.2007.10.0168
13. Koepsell TD, Wolf ME, Buchner DM, Kukull WA, LaCroix AZ, Tencer AF, *et al.* Footwear style and risk of falls in older adults. *J Am Geriatr Soc* 2004;**52**:1495–501. http://dx.doi.org/10.1111/j.1532-5415.2004.52412.x
14. Kelsey JL, Procter-Gray E, Nguyen US, Li W, Kiel DP, Hannan MT. Footwear and falls in the home among older individuals in the MOBILIZE Boston study. *Footwear Sci* 2010;**2**:123–9. http://dx.doi.org/10.1080/19424280.2010.491074
15. American Geriatrics Society, British Geriatrics Society and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. Guideline for the prevention of falls in older persons. *J Am Geriatr Soc* 2001;**49**:664–72. https://doi.org/10.1046/j.1532-5415.2001.49115.x
16. Australian Commission on Safety and Quality in Healthcare. *Preventing Falls and Harm from Falls in Older People: Best Practice Guidelines for Australian Community Care*. Sydney, NSW: Australian Commission on Safety and Quality in Healthcare; 2009.

17. Balanowski KR, Flynn LM. Effect of painful keratoses debridement on foot pain, balance and function in older adults. *Gait Posture* 2005;**22**:302–7. https://doi.org/10.1016/j.gaitpost.2004.10.006

18. Hijmans JM, Geertzen JHB, Dijkstra PU, Postema K. A systematic review of the effects of shoes and other ankle or foot appliances on balance in older people and people with peripheral nervous system disorders. *Gait Posture* 2007;**25**:316–23. https://doi.org/10.1016/j.gaitpost.2006.03.010

19. Schwenk M, Jordan ED, Honarvararaghi B, Mohler J, Armstrong DG, Najafi B. Effectiveness of foot and ankle exercise programs on reducing the risk of falling in older adults: a systematic review and meta-analysis of randomized controlled trials. *J Am Podiatr Med Assoc* 2013;**103**:534–47. https://doi.org/10.7547/1030534

20. Kobayashi R, Hosoda M, Minematsu A, Sasaki H, Maejima H, Tanaka S, *et al.* Effects of toe grasp training for the aged on spontaneous postural sway. *J Phys Ther Sci* 1999;**11**:31–4. https://doi.org/10.1589/jpts.11.31

21. Gillespie LD, Robertson MC, Gillespie WJ, Lamb SE, Gates S, Cumming RG, *et al.* Interventions for preventing falls in older people living in the community. *Cochrane Database Syst Rev* 2009;**2**:CD007146. https://doi.org/10.1002/14651858.cd007146.pub2

22. Cameron ID, Murray GR, Gillespie LD, Robertson MC, Hill KD, Cumming RG, *et al.* Interventions for preventing falls in older people in nursing care facilities and hospitals. *Cochrane Database Syst Rev* 2010;**1**:CD005465. https://doi.org/10.1002/14651858.cd005465.pub2

23. Spink MJ, Menz HB, Fotoohabadi MR, Wee E, Landorf KB, Hill KD, Lord SR. Effectiveness of a multifaceted podiatry intervention to prevent falls in community dwelling older people with disabling foot pain: randomised controlled trial. *BMJ* 2011;**342**:d3411. http://dx.doi.org/10.1136/bmj.d3411

24. Relton C, Torgerson D, O'Cathain A, Nicholl J. Rethinking pragmatic randomised controlled trials: introducing the 'cohort multiple randomised controlled trial' design. *BMJ* 2010;**340**:c1066. http://dx.doi.org/10.1136/bmj.c1066

25. Pighills AC, Torgerson DJ, Sheldon TA, Drummond AE, Bland JM. Environmental assessment and modification to prevent falls in older people. *J Am Geriatr Soc* 2011;**59**:26–33. http://dx.doi.org/10.1111/j.1532-5415.2010.03221.x

26. Vernon W. The healthy footwear guide. *Podiatry Now* 2009;**5**:35.

27. Age UK. *Staying Steady. Improving Your Strength and Balance*. URL: http://psnc.org.uk/doncaster-lpc/wp-content/uploads/sites/51/2013/07/Appendix-4-staying-sready-leaflet.pdf (accessed 10 August 2011).

28. Irish Osteoporosis Society. *Fall Prevention*. URL: www.irishosteoporosis.ie/downloads/Fall_Prevention.pdf (accessed 11 February 2013).

29. Mitchell N, Hewitt CE, Lenaghan E, Platt E, Shepstone L, Torgerson DJ, SCOOP study team. Prior notification of trial participants by newsletter increased response rates: a randomized controlled trial. *J Clin Epidemiol* 2012;**65**:1348–52. http://dx.doi.org/10.1016/j.jclinepi.2012.05.008

30. Lamb SE, Jørstad-Stein EC, Hauer K, Becker C, Prevention of Falls Network Europe and Outcomes Consensus Group. Development of a common outcome data set for fall injury prevention trials: the Prevention of Falls Network Europe consensus. *J Am Geriatr Soc* 2005;**53**:1618–22. https://doi.org/10.1111/j.1532-5415.2005.53455.x

31. Kempen GI, Yardley L, van Haastregt JC, Zijlstra GA, Beyer N, Hauer K, Todd C. The Short FES-I: a shortened version of the falls efficacy scale-international to assess fear of falling. *Age Ageing* 2008;**37**:45–50. https://doi.org/10.1093/ageing/afm157

32. Schuling J, de Haan R, Limburg M, Groenier KH. The Frenchay Activities Index. Assessment of functional status in stroke patients. *Stroke* 1993;**24**:1173–7. https://doi.org/10.1161/01.STR.24.8.1173

33. Brink TL, Yesavage JA, Lum O, Heersema PH, Adey M, Rose TL. Screening tests for geriatric depression. *Clin Gerontol* 1982;**1**:37–43. https://doi.org/10.1300/J018v01n01_06

34. Vaishnavi S, Connor K, Davidson JR. An abbreviated version of the Connor-Davidson Resilience Scale (CD-RISC), the CD-RISC2: psychometric properties and applications in psychopharmacological trials. *Psychiatry Res* 2007;**152**:293–7. https://doi.org/10.1016/j.psychres.2007.01.006

35. Kind P. *The EuroQoL Instrument: An Index of Health-Related Quality of Life. Quality of Life and Pharmacoeconomics in Clinical Trials*. 2nd edn. Philadelphia, PA: Lippincott-Raven; 1996. pp. 191–201.

36. Sheikh JI, JA Y. *Geriatric Depression Scale (GDS): Recent Evidence and Development of a Shorter Version. A Guide to Assessment and Intervention*. New York, NY: The Haworth Press; 1986. pp. 165–73.

37. Kahan BC. Accounting for centre-effects in multicentre trials with a binary outcome – when, why, and how? *BMC Med Res Methodol* 2014;**14**:20. http://dx.doi.org/10.1186/1471-2288-14-20

38. Glidden DV, Vittinghoff E. Modelling clustered survival data from multicentre clinical trials. *Stat Med* 2004;**23**:369–88. http://dx.doi.org/10.1002/sim.1599

39. Akaike H. A new look at the statistical model identification. *IEEE T Automat Contr* 1974;**19**:716–23.

40. Sandelowski M. Sample size in qualitative research. *Res Nurs Health* 1995;**18**:179–83. http://dx.doi.org/10.1002/nur.4770180211

41. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;**3**:77–101. https://doi.org/10.1191/1478088706qp063oa

42. Lincoln YS, Guba EG. *Naturalistic Inquiry*. Newbury Park, CA: Sage; 1985.

43. Birks YF, Porthouse J, Addie C, Loughney K, Saxon L, Baverstock M, *et al.* Randomized controlled trial of hip protectors among women living in the community. *Osteoporos Int* 2004;**15**:701–6. http://dx.doi.org/10.1007/s00198-004-1599-0

44. Cockayne S, Adamson J, Clarke A, Corbacho B, Fairhurst C, Green L, *et al*. Cohort randomised controlled trial of a multifaceted podiatry intervention for the prevention of falls in older people (the REFORM trial). *PLOS ONE* 2017;**12**:e0168712. http://dx.doi.org/10.1371/journal.pone.0168712

45. Gill TM, Pahor M, Guralnik JM, McDermott MM, King AC, Buford TW, *et al.* Effect of structured physical activity on prevention of serious fall injuries in adults aged 70–89: randomized clinical trial (LIFE Study). *BMJ* 2016;**352**:i245. http://dx.doi.org/10.1136/bmj.i245

46. Drummond M, Sculpher MJ, Torrance GW, O'Brien BJ, Stoddart GL. *Methods for the Economic Evaluation of Health Care Programmes*. 3rd edn. Oxford: Oxford University Press; 2005.

47. Torgerson DJ, Torgerson C. *Designing Randomised Trials in Health, Education and the Social Sciences: An Introduction*. Basingstoke: Palgrave Macmillan; 2008. https://doi.org/10.1057/9780230583993

48. Manca A, Palmer S. Handling missing data in patient-level cost-effectiveness analysis alongside randomised clinical trials. *Appl Health Econ Health Policy* 2005;**4**:65–75. https://doi.org/10.2165/00148365-200504020-00001

49. National Institute for Health and Care Excellence (NICE). *Guide to the Methods of Technology Appraisal*. London: NICE; 2013.

50. Brooks R. EuroQoL: the current state of play. *Health Policy* 1996;**37**:53–72. https://doi.org/10.1016/0168-8510(96)00822-6

51. Haywood KL, Garratt AM, Fitzpatrick R. Quality of life in older people: a structured review of generic self-assessed health instruments. *Qual Life Res* 2005;**14**:1651–68. https://doi.org/10.1007/s11136-005-1743-0

52. Billingham LJ, Abrams KR, Jones DR. Methods for the analysis of quality-of-life and survival data in health technology assessment. *Health Technol Assess* 1999;**3**(10).

53. Manca A, Hawkins N, Sculpher MJ. Estimating mean QALYs in trial-based cost-effectiveness analysis: the importance of controlling for baseline utility. *Health Econ* 2005;**14**:487–96. http://dx.doi.org/10.1002/hec.944

54. Curtis L. *Unit Costs of Health and Social Care 2015*. Canterbury: Personal Social Services Research Unit, University of Kent; 2015.

55. Department of Health (DH). *NHS Reference Costs 2014–15*. London: DH; 2015.

56. Faria R, Gomes M, Epstein D, White IR. A guide to handling missing data in cost-effectiveness analysis conducted within randomised controlled trials. *PharmacoEconomics* 2014;**32**:1157–70. http://dx.doi.org/10.1007/s40273-014-0193-3

57. White IR, Horton NJ, Carpenter J, Pocock SJ. Strategy for intention to treat analysis in randomised trials with missing outcome data. *BMJ* 2011;**342**:d40. http://dx.doi.org/10.1136/bmj.d40

58. White IR, Royston P, Wood AM. Multiple imputation using chained equations: issues and guidance for practice. *Stat Med* 2011;**30**:377–99. http://dx.doi.org/10.1002/sim.4067

59. Rubin DB. Multiple imputation after 18+ years. *J Am Stat Assoc* 1996;**91**:473–89. https://doi.org/10.1080/01621459.1996.10476908

60. Rubin DB. *Multiple Imputation for Nonresponse in Surveys*. Hoboken, NJ: John Wiley & Sons; 2004.

61. Royston P. Multiple imputation of missing values. *Stata Tech J* 2005;**5**:527–36.

62. Ramsey S, Willke R, Briggs A, Brown R, Buxton M, Chawla A, *et al.* Good research practices for cost-effectiveness analysis alongside clinical trials: the ISPOR RCT-CEA Task Force report. *Value Health* 2005;**8**:521–33. https://doi.org/10.1111/j.1524-4733.2005.00045.x

63. Efron B, Tibshirani RJ. *An Introduction to the Bootstrap*. Boca Raton, FL: CRC Press; 1994.

64. Glick HA, Doshi JA, Sonnad SS, Polsky D. *Economic Evaluation in Clinical Trials*. Oxford: Oxford University Press; 2014. https://doi.org/10.1093/med/9780199685028.001.0001

65. Gomes M, Grieve R, Nixon R, Ng ES, Carpenter J, Thompson SG. Methods for covariate adjustment in cost-effectiveness analysis that use cluster randomised trials. *Health Econ* 2012;**21**:1101–18. http://dx.doi.org/10.1002/hec.2812

66. Manca A, Lambert PC, Sculpher M, Rice N. Cost-effectiveness analysis using data from multinational trials: the use of bivariate hierarchical modeling. *Med Decis Making* 2007;**27**:471–90. https://doi.org/10.1177/0272989X07302132

67. Claxton K. *Methods for the Estimation of the NICE Cost Effectiveness Threshold*. York: University of York, Centre for Health Economics; 2013.

68. Stinnett AA, Mullahy J. Net health benefits: a new framework for the analysis of uncertainty in cost-effectiveness analysis. *Med Decis Making* 1998;**18**(Suppl. 2):68–80. https://doi.org/10.1177/0272989X98018002S09

69. Claxton K. Exploring uncertainty in cost-effectiveness analysis. *PharmacoEconomics* 2008;**26**:781–98. https://doi.org/10.2165/00019053-200826090-00008

70. Briggs AH. A Bayesian approach to stochastic cost-effectiveness analysis. *Health Econ* 1999;**8**:257–61. https://doi.org/10.1002/(SICI)1099-1050(199905)8:3<257::AID-HEC427?3.0.CO;2-E

Appendix 1 Regulatory approvals

Research site	Date of research and development approval
Sheffield Teaching Hospitals NHS Foundation Trust	19 September 2012
Harrogate and District NHS Foundation Trust	2 July 2012
Leeds Community Healthcare NHS Trust	7 March 2013
National University of Ireland, Galway	26 April 2013
Humber NHS Foundation Trust	13 May 2013
Solent NHS Trust	29 October 2013
North Lincolnshire and Goole Hospitals NHS Foundation Trust	11 November 2013
Kent Community Health NHS Foundation Trust	11 February 2014
South Tyneside NHS Foundation Trust	1 April 2014
North Tees and Hartlepool Hospitals NHS Foundation Trust	9 May 2014

Approval was gained at two additional sites; neither was able to start recruitment.

Appendix 2 REFORM invitation letter

Insert Trust logo
Insert podiatry clinic details

Date as postmarked

Dear Patient

An invitation to participate in a research project about the prevention of falls

You may be aware that falls are a common problem, especially amongst older adults. Our podiatry service is working with the University of York, to conduct a research study which aims to look at ways of reducing the number of falls people have.

Our Podiatry service is sending this letter to all patients over the age of 65, to find out who would be willing and suitable to take part in the study. Staff at the University of York do not have access to your name and address unless you fill in the enclosed consent form and questionnaire and return them to the University of York.

Before you decide whether or not to take part in the study, it is important for you to understand why this research is being done and what it will involve. The enclosed information leaflet explains the study in detail. Please feel free to discuss the study with others. Your participation in this study is voluntary.

You do not need to attend the University of York to take part in this study. If you agree to take part, and are offered extra podiatry care, the additional two appointments will be arranged at your usual podiatry clinic.

If you wish to take part, please complete the following enclosed forms and return them both to the research team at the University of York in the prepaid envelope provided (no stamp needed):

- The yellow consent form
- The white questionnaire

For study related questions please contact Mrs Sarah Cockayne at the University of York on XXXX or XXXX. For questions in relation to your podiatry care and the study, please contact our research podiatrist Miss Lorraine Loughrey on the same number. If there is no-one available, please leave a message and someone will contact you as soon as possible.

Thank you for taking the time to read this information.

Yours faithfully

(PI electronic signature)
PI name
Podiatrist and REFORM Principal Investigator
Version 5 9.7.13

Appendix 3 REFORM consent form

[redacted] Trial ID number ☐☐☐☐☐

PARTICIPANT CONSENT FORM

If you wish to take part in the ***REFORM*** study, **please place your initials in each of the boxes below, sign and date this form, and complete the attached questions. Please return these forms in the pre-paid envelope provided.** If you (or a relative or friend) would like to ask more questions about this study before deciding whether to take part, please do not hesitate to contact [Name of Trial coordinator], the trial co-ordinator on [insert telephone number].

All the information on this form will be kept confidential and won't be released to anyone outside the research team

	Please initial each box
1. I confirm that I have read and understand the information sheet version [no] dated [date] for the above study and have had the opportunity to ask questions by phoning the contact number provided. **I agree to take part in the *REFORM* study.**	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, and without my medical care or legal rights being affected.	☐
3. I understand that sections of my health care records may be looked at by researchers from the University of York or the NHS Trust where the study is being conducted.	☐
4. I agree to my GP being informed of my participation in the study and of any health concerns the REFORM study team may become aware of during my participation.	☐
5. I agree to researchers from the University of York contacting my GP if I have had a fall to collect further information about the event if required.	☐
6. I agree to the University of York's Trials Unit holding my contact details and consent form to allow them to send me questionnaires and other REFORM study related documents.	☐
7. I am willing to receive emails/texts (please delete as necessary) about the REFORM study.	☐
8. We may offer some patients extra podiatry visits at their local clinic. If offered, I agree to attend my local podiatry clinic at a day and time convenient for me.	☐

_____ _____ _____

Name of patient *Date* *Signature*

Other research studies

Researchers from the *REFORM* team would like to contact men and women who agree to take part in the main *REFORM* study to see if they would be interested in helping with other related studies these are entirely optional. If you would **not** like to be sent information about related studies, please tick this box. ☐

REFORM Patient consent form Version 2.0 20th July 2012

Appendix 4 REFORM patient information sheet

Your invitation to participate in a research study.
Can you help?

We would like to invite you to take part in our research study. Before you decide whether to take part, it is important for you to understand why the study is being done and what it will involve. Please take time to read this information sheet carefully and discuss it with your podiatrist, family or friends if you wish. Ask us if there is anything that is not clear, if you would like more information or if you would like help with completing the forms – our contact details are given at the end of this leaflet.

What is the purpose of the study?
As you know, falling is a common problem among people over the age of 65 years. It has been estimated that up to half of people aged over 80 fall each year. People may fall for a variety of reasons, including problems with balance or due to poor vision. Unfortunately, some of these falls will cause serious injury, such as a broken bone.

People often think that falls are an unavoidable result of getting older and that little can be done to stop them. It may not be possible to prevent falls completely, however, there are many different ways to help reduce the number of falls someone has for example undertaking exercises, checking your eyesight and reviewing your medication.

In this study we are looking at the health of people over the age of 65. We are also interested in finding out the likelihood of people falling and ways of reducing the number of falls older people have. For example we would like to know if foot and ankle exercises and wearing insoles in appropriate shoes prevent falls.

Why have I been approached?
The York University is working together with the NHS podiatry clinics across the UK to help conduct this research study. People aged over 65, who have attended an NHS podiatry clinic are being sent information about the study and an invitation to take part.

Because this information has been sent to you by the podiatry clinic your name and address is not available to the University of York researchers unless you choose to give it to them by agreeing to take part in the study.

We hope about 1,700 people will agree to take part in this study from across the UK. Even if you haven't fallen, you may still be able to take part

Unfortunately on this occasion, we are unable to include people who have the following:
(1) have had a lower limb amputation
(2) suffer from certain conditions such as Parkinson's, Multiple Sclerosis and Alzheimer's
(3) people with neuropathy in their feet
(4) people who are unable to walk 32 yards without the help of a Zimmer frame, walker or wheelchair

Do I have to take part?

No, it is entirely up to you whether or not you decide to take part. Participation in the trial is entirely voluntary. If you decide to take part, you are still free to withdraw at any time, without giving a reason. A decision to withdraw at any time, or a decision not take part, will not affect the standard of care you receive. If you would like more information then please feel free to contact us, our details are at the end of this leaflet. If you want to take part please keep this information sheet. You will be asked to sign a consent form, a copy will be returned to you to keep.

Expenses and payments

Unfortunately, we are not able to offer any direct expenses or payments to patients who participate in the study.

What will be involved if I agree to take part?

If you agree to take part in the study you will be asked to complete a consent form and a questionnaires about yourself and return them both to the University of York in a prepaid envelope. You will then sent an information sheet giving advice about how to reduce the possibility of having a fall, a questionnaire and a monthly falls calendar to help you keep a record of whether you've fallen or not. We will ask you to send the falls calendar back to the University of York at the end of each month (no stamp required). If you prefer, you can also choose to call us at the end of each month on the free-phone number to confirm if you have fallen or not. If you do have a fall, we will ask you some questions about this. If you have been unable to send in your calendar or phone at the end each month, someone from the University of York Trials team will aim to contact you and record this information at a time that is convenient for you.

In addition, some people may be offered some extra podiatry visits at a later date to see if a podiatry package of care can reduce falls. This visit will be at the podiatry clinic you normally attend. You will not have to travel to the University of York to see a podiatrist or to complete any forms. It will not be possible to offer everyone extra podiatry visits, so these people will be selected according to the play of chance (randomly) like using the toss of a coin. Your GP care and the routine care you receive from the podiatrist will continue as usual whether or not you are offered the additional visit.

Even if you haven't fallen, you may still be able to take part in the study. If you have fallen you may not be eligible for the study, if this is the case we will write and let you know.

You will be sent some more questionnaires approximately six and twelve months later for you to complete. We expect it will take you about 20 minutes to complete each of the questionnaires we send you.

The information you provide will allow us to follow your health and to see if it changes over time. It will also contribute to the wider study we are carrying out about the health of people over 65 and will let us look at the benefit of long term podiatry treatments.

This study will take us three and a half years to complete but if you agree to take part in the study we will only ask for your help for a maximum of 24 months.

The study results will be written up and published, a summary of which will be made available to you.

What will happen if I am offered the podiatrist package of care?
If you are offered the extra podiatry care you will be asked to see a podiatrist at your local podiatry clinic on two occasions. (You will not have to travel to the University of York at any point for the study.)The first appointment will last for about an hour and the second appointment for about 20 minutes. Your podiatrist will contact you to make appointments which are convenient for you.

At the first appointment the podiatrist will assess your everyday shoes, give you advice about your footwear and undertake routine podiatry care as required. They will then measure your feet and fit an orthotic device – a type of insole which is worn in your shoe. You will then be shown some foot and ankle exercises and asked to do these at home three times a week. You will be given an exercise diary and asked to complete this and send it back to the University of York during the course of the trial. You will also receive a patient information sheet giving advice about how to reduce the possibility of you having a fall. At your second appointment, the podiatrist will check the fitting of your orthotic device and check how you're getting on with the foot and ankle exercises. Your routine podiatry care will continue as usual.

What will happen if I am not offered extra podiatry visits?
If you are not offered extra podiatry care, your GP care will continue as usual. If you are already seeing a podiatrist for treatment which is not related to the trial, you will continue this care as usual. If you are not currently receiving treatment from a podiatrist, you will not be invited to attend the podiatry clinic. You will receive a patient information sheet giving advice about how to reduce the possibility of you having a fall and we would still ask you to complete and return the questionnaires mentioned above.

What are the possible benefits of taking part in this study?
We cannot promise that taking part in this study will help you, but the information we get from the study may help us to find out how we can help improve balance and reduce the number of falls people have.

What are the possible disadvantages of taking part in this study?
Taking part in this study will involve some of your time to complete questionnaires. If you are randomly allocated to receive the podiatry package of care, you will be contacted by a podiatrist and asked to attend the podiatry clinic. We cannot think of any other disadvantages.

Will the information in the study be confidential?
Any information you provide us with will be treated in confidence. At the beginning of the study we will record your name, address, telephone number and date of birth and keep a copy of your signed consent form. This information will be stored securely at the University of York in accordance with the Data Protection Act 1998. Your name will not be mentioned in any publications arising from the study and we will ensure that individuals cannot be identified from details in reports of the study results. If you withdraw from the study at any time, unless you inform us otherwise, the information you have already provided will be used in anonymous form for the purposes of the study.

If you consent to take part in the research, members of the REFORM research team from the University of York (for the purposes of checking data collection) may inspect

REFORM PIS sent from podiatry clinic Version 9.0 9th July 2013

your medical records. People from regulatory authorities such as the NHS Trust where the study is being conducted may also look at your records to check that the study is being carried out correctly.

Will I be approached about taking part in any other studies?
If you agree to take part in this research, if you consent you may be invited to join other research studies about how to improve balance and reduce the number of falls being carried out by researchers in the REFORM team. For example, we may contact you to ask if you would like to take part in an interview with one of our researchers to discuss your views about how we can improve balance and reduce the number of falls people have and about taking part in the study. This is voluntary and you do not need to do this to be part of the main study.

You do not have to take part in any related studies, and you will be sent more information about them before you decide. If you do agree to us contacting you about other studies we will keep all personal and anonymised data for a total of 5 years to allow us to do this.

Will my GP be involved?
If you consent we will inform your GP if you agree to participate in this research. If you consent we will also contact your GP if we have any concerns about your health during your participation. If you do have a fall, if you agree we may contact your GP to find out some further information.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the trial co-ordinator who will do their best to answer your questions, their details are at the end of this leaflet. If you do not want to speak to the trial co-ordinator you can contact the local principal investigator ([PI name and contact telephone]) or your local Patient Advice and Liaison Service (PAL). [Insert site specific PALS details here.]

While we anticipate no harm or distress to anyone as a result of this study it is important to state that there are no special compensation arrangements. If you are harmed due to someone's negligence, then you have ground for legal action but you may have to pay for it. Regardless of this if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you.

Yes, I would like to take part in the study – what do I need to do now?
Please complete and sign the enclosed yellow consent form and background information form and return them in the prepaid envelope provided. If you need any help with completing the forms, please phone us and we'll be happy to help. We will write to you again in a few weeks time to ask you to complete some simple questionnaires. If you have decided to participate in the study, if you agree we will let you and your GP know how you are involved in the study.

I'm not sure about taking part – where can I get more information about the study?
We would be very pleased to answer any questions you may have. Please contact either the study coordinator [insert name and telephone number] or your local podiatrist [Name of local podiatrist contact at podiatry clinic delivering intervention], on

[telephone number].

Is there anyone else I can talk to about the study?
For further general information and advice about taking part in research, you can contact the Patient Advice and Liaison Service (PAL). [Insert site specific PALS details here.]

How can I find out about the results of the study?
This study is due to finish in summer 2015. All patients who have consented to take part in the research will be sent a summary of the results. Participants can request copies of any published data by contacting the study coordinator.

If you decide not to take part in the study but would like to receive a copy of the results you can contact the York Trials Unit directly. Our contact details are at the end of this leaflet.

Who is involved in organising and funding this study?
This study is being organised by the University of York. The research has been funded by the Department of Health, National Institute of Health Research Health Technology Assessment programme. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This research has been reviewed and approved by NRES Committee East of England – Cambridge East Research Ethics Committee.

Thank you for reading this information sheet

If you require any further information please contact us. A friend or relative may speak to us on your behalf if you wish. There is an answering machine available 24 hours a day, so please leave a message and one of the research team will contact you as soon as possible.

The REFORM study also has a website at
http://www.york.ac.uk/healthsciences/trials-unit/reform/study/

Contact details:-
Study coordinator:
Tel:
Address:

Podiatrist contact:
Tel:
Address:

REFORM PIS sent from podiatry clinic Version 9.0 9th July 2013

Appendix 5 REFORM background information form

[redacted] Centre number: ☐☐

Trial ID number: ☐☐☐☐☐

BACKGROUND INFORMATION

Please answer the following questions:

1. What is your date of birth? ☐☐ / ☐☐ / 1 9 ☐☐
   Day *Month* *Year*
2. Are you? Male ☐ Female ☐
3a. Have you fallen in the last 12 months? Yes ☐ No ☒
   (Please cross one box only)
3b. If 'Yes', how many times have you fallen? ☐☐
4a. Have you fallen in the last 24 months? Yes ☐ No ☐
   (Please cross one box only)
4b. If 'Yes', did any of the falls in the last 24 months require hospital attention? Yes ☐ No ☐
5. Can you walk for 10 yards without the use of a zimmer frame, walker or wheelchair? Yes ☐ No ☒
6. Have you had any lower limb surgery in the last three months? Yes ☒ No ☐
7. Do you have any lower limb surgery planned in the next six months? Yes ☒ No ☐
8. Have you had any toe or lower limb amputations (e.g. toes removed)? Yes ☒ No ☐
9a. Do you currently require modifications to your shoes in order to wear them? Yes ☐ No ☐
9b. If 'Yes', what modifications are made to your shoes?
   (Please specify) _____
10. Are you currently wearing an insole or orthotic in your shoe (either one you have bought over the counter or one given to you by a podiatrist)? Yes ☐ No ☐

REFORM Patient background information form Version 4.0 9th July 2013 Admin code: ☐☐☐ 9750178906

11. Do you experience any of the following health problems?
(Please cross all that apply)

ALS / Lou Gehrig's disease ☐ | Alzheimer's disease ☐ | Arthritis ☐ | Dementia ☐ | Depression ☐

Diabetes ☐ | Dizziness / Vertigo ☐ | Huntington's ☐ | Meniere's disease / conditions affecting balance ☐ | Multiple sclerosis ☐

Numbness or tingling in your feet or lower limbs ☐ | Osteoporosis ☐ | Parkinson's ☐

12. Have you broken any bones in the past 12 months? Yes ☐ No ☐

13. If 'Yes', which bone(s) did you break?

Bone 1: _____

Bone 2: _____

Bone 3: _____

14. During the past 4 weeks have you worried about having a fall?
(Please cross one box only)

All of the time ☐ | Most of the time ☐ | A good bit of the time ☐ | Some of the time ☐ | A little of the time ☐ | None of the time ☐

15. To which of these ethnic groups do you belong?
(Please cross one box only)

White ☐ | Asian or Asian British ☐ | Black or Black British ☐

Other ethnic group ☐ | If 'Other', Please describe: _____

4707178903

Centre number: ☐☐

Trial ID number: ☐☐☐☐☐

Please enter the date you are completing this form: ☐☐ / ☐☐ / 2 0 ☐☐

Day *Month* *Year*

CONTACT SHEET

If you would like to take part in the REFORM trial please can you tell us your:

Title:

Forename:

Surname

Address

Post code

Telephone number:

Your mobile number:

Your email address:

GP name:

GP Address

If you do not wish to take part you do not need to complete your contact details

Thank you for taking the time to complete these questions.
Please return these forms in the pre-paid envelope provided to the York Trials Unit.

REFORM Patient background information form Version 4.0 9th July 2013 Admin code: ☐☐☐ 1784096656

Appendix 6 REFORM decline form

[redacted]

Centre number: ☐☐

Trial ID number: ☐☐☐☐☐

PARTICIPANT DECLINE FORM

We would find it really helpful to have a wide range of men and women over the age of 70 joining this study.

However, we quite understand if you do not wish to take part. If this is the case, we would be grateful if you could tell us the reason(s) why by placing a cross in as many boxes as apply to you from the list below: -

I am not interested in taking part in this study. ☐

I feel too unwell to take part in this study. ☐

I do not have time to take part in this study. ☐

Other reason ☐

Please give more details here if you would like to: -

It would be very helpful if you would be willing to give us some brief details about yourself. **We will not be able to identify you from this form, and we will not contact you again**. We will use the anonymous information that you provide to help us see if there are any differences between those who agree to take part and those who decline. **If you wish, please complete the background information questions and return these forms in the pre-paid envelope provided. Thank you very much.**

REFORM Patient decline form Version 1.0 12th August 2011

Admin code: ☐☐☐ 9809554066

Appendix 7 REFORM baseline questionnaire

CONFIDENTIAL

REFORM Study

Reducing falls with ORthosis and a Multifaceted podiatry intervention

Participant Baseline Questionnaire

For office use only

Centre number: | | |

Participant's trial ID number: | | | | | |

Date questionnaire sent: | | | / | | | / | 2 | 0 | | |

Day *Month* *Year*

[redacted]

[redacted]

REFORM Participant baseline questionnaire version 4.0a 28 August 2013 1606458246

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to take part in this study. The responses you give in this questionnaire will help us find out the best way to stop people who are over 65 years old from having a fall.

Please answer ALL the questions. Although some of the questions may not seem relevant to yourself or may appear similar, they do give us valuable information.

If you find it difficult to answer the question, please give the best answer you can.

Please follow the instructions for each section carefully.

For each section, if you are asked to put a cross in the box, please use a cross rather than a tick, as if you were filling out a ballot paper.

For example in the following question, if your answer to the question is 'yes', you should place a cross firmly in the box next to yes.

Do you drive a car? Yes ☒

No ☐

If you are asked to write your answer, please do so by entering your answer in the box provided, for example:

How old are you? | 7 | 5 | years

Please use a black or blue pen for all the questions.

Please do not use a pencil or any other coloured pen.

If you have any queries or problems completing this questionnaire please contact the trial co-ordinator, Sarah Cockayne, telephone number XXXX, email XXXX.

7268458246

SECTION 1

This section asks about any falls you have had in the **past 6 months** and about some general information about you.

Please enter the date you are completing this questionnaire: ☐☐ / ☐☐ / 2 0 ☐☐

Day *Month* *Year*

1. Have you fallen in the **past 6 months**?
(Please cross one box only)

☐ Yes ☐ No ☐ Don't know

1a. If 'Yes', how many falls did you have in the **past 6 months**? ☐☐

2. During the **past 4 weeks** have you worried about having a fall?
(Please cross one box only)

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐	☐

3a. Please tell us your height ☐ feet ☐☐ inches **or** ☐☐☐ cm

3b. Please tell us your weight ☐☐ stone ☐☐ lbs **or** ☐☐☐.☐ kgs

4. Are you taking more than four medications prescribed by a doctor?
(Please cross one box only)

☐ Yes ☐ No

5. Have you been referred to a falls clinic / falls service?
(Please cross one box only)

☐ Yes ☐ No

0344458244

SECTION 2

This section asks about your health in general.

By placing a cross in one box in each group below, please indicate which statements best decribes your own health **today**.

Mobility

I have no problems in walking about ❑

I have some problems in walking about ❑

I am confined to bed ❑

Self-Care

I have no problems with self-care ❑

I have some problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

Usual Activities *(e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ❑

I have some problems with performing my usual activities ❑

I am unable to perform my usual activities ❑

Pain / Discomfort

I have no pain or discomfort ❑

I have moderate pain or discomfort ❑

I have extreme pain or discomfort ❑

Anxiety / Depression

I am not anxious or depressed ❑

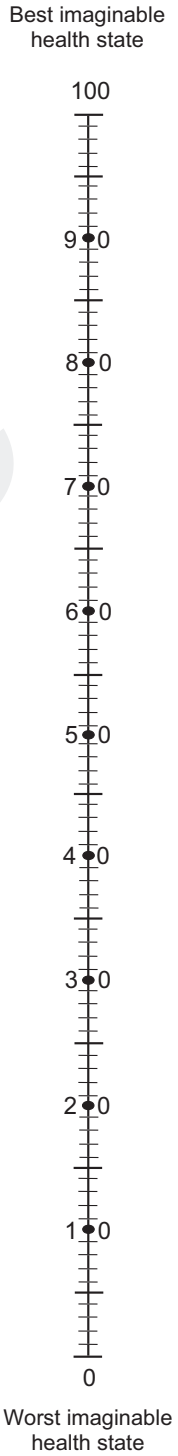
I am moderately anxious or depressed ❑

I am extremely anxious or depressed ❑

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



SECTION 3

Now we would like to ask some questions about how concerned you are about the possibility of falling.

Please reply thinking how you usually do the activity. If you currently do not do the activity, please answer to show whether you think you would be concerned about falling IF you did the activity.

For each of the following activities, please cross the box which is closest to you own opinion to show how concerned you are that you might fall if you did the activity.

	Not at all concerned	Somewhat concerned	Fairly concerned	Very concerned
Getting dressed or undressed	☐	☐	☐	☐
Taking a bath or shower	☐	☐	☐	☐
Getting in or out of a chair	☐	☐	☐	☐
Reaching for something above your head or on the ground	☐	☐	☐	☐
Walking up or down a slope	☐	☐	☐	☐
Going out to a social event (eg, religious service, family gathering or club meeting)	☐	☐	☐	☐

SECTION 4

This section asks about how you've been feeling. Answer each question by placing a cross in the box that best describes your answer.

1a. I tend to bounce back after illness or hardship

Not true at all	Rarely true	Sometimes true	Often true	True nearly all of the time
☐	☐	☐	☐	☐

1b. I am able to adapt to change

Not true at all	Rarely true	Sometimes true	Often true	True nearly all of the time
☐	☐	☐	☐	☐

6136458249

SECTION 5

We are interested in finding out how often you carry out some activities. Please cross one box for each question.

1. **In the last 3 months**, how often have you carried out these activities?

	Never	Less than once per week	1 or 2 times a week	Most days
Preparing main meals	☐	☐	☐	☐
Washing up	☐	☐	☐	☐

2. **Over the last 3 months**, how often have you carried out the following?

	Never	1-2 times in 3 months	3-12 times in 3 months	At least weekly
Washing clothes	☐	☐	☐	☐
Light housework	☐	☐	☐	☐
Heavy housework	☐	☐	☐	☐
Local shopping	☐	☐	☐	☐
Social outings	☐	☐	☐	☐
Walking outside for over 15 minutes	☐	☐	☐	☐
Actively pursuing a hobby	☐	☐	☐	☐
Driving a car/travel on a bus	☐	☐	☐	☐

3. In the **last 6 months**, how often have you undertaken:

	Never	1-2 times in 6 months	3-12 times in 6 months	At least weekly
Travel outing / car ride	☐	☐	☐	☐

	Never	Light	Moderate	Heavy / All necessary
Gardening	☐	☐	☐	☐
Household maintenance	☐	☐	☐	☐

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In the **last 6 months**, how often have you undertaken:

	None	1 in 6 months	Less than 1 in 2 weeks	More than 1 every 2 weeks
Reading books	☐	☐	☐	☐

	None	Up to 10 hours/week	10 - 30 hours/week	Over 30 hours/week
Gainful work	☐	☐	☐	☐

SECTION 6

This section is about visits you have had to a NHS hospital as a patient **for any reason**.

Answer each question by placing a cross in the box that best describes your answer.

Attending hospital

1a. During the **last six months** have you stayed overnight in an NHS hospital?

☐ Yes ☐ No (go to section 7)

1b. If 'Yes', on how many separate occasions did you stay overnight in hospital? ☐☐

1c. For each stay please complete the information below:

	Number of nights in hospital	Reason for admittance
e.g.	3	ANGINA

2867458246

SECTION 7

This section is about other services you have used in the **past six months** as a patient **for any reason**. If the health care you received was related to a fall, record this in the 'about a fall' column. If the health care was for any other reason, enter this in the 'other reason' column.

Please fill in all of the boxes even if you have not had any visits. This information is really important for us.

	About a fall	Other reason
For example, if you have not used a service for any reason then put a '0' in both boxes:	0 0	0 0
If you have used a service three times about a fall and once for another reason then you would write:	0 3	0 1

1. Over the **past six months,** how many times have you:

Other visits to NHS hospital	About a fall *(If None enter '00')*	Other reason *(If None enter '00')*
a. Visited hospital for an out-patient appointment?		
b. Visited hospital for a day case / procedure (not overnight)?		
c. Attended Accident and Emergency?		

Other care from the NHS	About a fall *(If None enter '00')*	Other reason *(If None enter '00')*
d. Seen your GP at the surgery or at home?		
e. Seen a nurse at your GP practice or the district or community nurse?		
f. Seen an occupational therapist and/or physiotherapist at home?		

Transportation	About a fall *(If None enter '00')*	Other reason *(If None enter '00')*
g. Used a '999' emergency ambulance?		
h. Used the Patient Transport Service?		

5367458244

Support services

2a. Have you received any help or care (e.g. dressing, tasks around the home, providing meals, shopping from a relative or a friend) in the **last 6 months**?
(Please cross one box only)

☐ Yes ☐ No (go to 3a)

2b. If 'Yes', thinking about the **last 6 months**, typically how many hours per week did someone help you?

☐☐☐

3a. Does a paid care worker visit you at home?
(Please cross one box only)

☐ Yes ☐ No (go to 4a)

3b. If 'Yes', thinking about the **last 6 months**, typically how many days per week did a care worker visit?

☐

4a. Do you use meals on wheels?
(Please cross one box only)

☐ Yes ☐ No

4b. If 'Yes', thinking about the **last 6 months**, typically how many times a week did you use meals on wheels?

☐☐

0294458248

SECTION 8

This section asks about any extra costs you have had in the **past six months**.

1a. In the **last 6 months**, have you had to buy any new equipment (e.g. a bed), or paid to have any changes made to your house (e.g. installed a stairlift) due to ill health?
(Please cross one box only)

☐ Yes ☐ No (go to section 9)

1b. If 'Yes', please tell us the item and how much it cost.
(Please enter the cost to the nearest pound)

Item bought	Cost
	£
	£
	£

SECTION 9

This section asks about your living arrangements and some general information about you.

1. Do you?
(Please cross all that apply)

- Live alone ☐
- Live with a partner or spouse? ☐
- Live with a friend or relative? ☐
- Live in sheltered accommodation? ☐

2a. Did your education continue after the minimum school leaving age? ☐ Yes ☐ No

2b. Do you have a degree or equivalent professional qualification? ☐ Yes ☐ No

7045458249

SECTION 10

This section asks about your mood. Choose the best answer for how you have felt this past week by placing a cross in the appropriate box.

		Yes	No
1.	Are you basically satisfied with your life?	☐	☐
2.	Have you dropped many of your activities and interests?	☐	☐
3.	Do you feel that your life is empty?	☐	☐
4.	Do you often get bored?	☐	☐
5.	Are you in good spirits most of the time?	☐	☐
6.	Are you afraid that something bad is going to happen to you?	☐	☐
7.	Do you feel happy most of the time?	☐	☐
8.	Do you often feel helpless?	☐	☐
9.	Do you prefer to stay at home, rather than going out and doing new things?	☐	☐
10.	Do you feel you have more problems with memory than most?	☐	☐
11.	Do you think it is wonderful to be alive now?	☐	☐
12.	Do you feel pretty worthless the way you are now?	☐	☐
13.	Do you feel full of energy?	☐	☐
14.	Do you feel that your situation is hopeless?	☐	☐
15.	Do you think that most people are better off than you are?	☐	☐

For office use only: Insert total score ☐☐

Thank you for taking the time to complete this questionnaire. Please return it to the York Trials Unit at the University of York in the pre-paid envelope provided.

2131458240

Appendix 8 REFORM sample falls calendar

September 2011

REFORM Trial FALLS CALENDAR

Centre number ☐☐ Participant's trial ID number ☐☐☐☐☐

If you have a fall, even if it was minor, place a cross (X) in the date box on the day it occurred and call us. If you did not have a fall on any day this month, put a cross in the box next to the statement at the bottom.

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

If you didn't have any falls at all this month please place a cross in this box. ☐

Please call the researchers on XXXX if

- You have a fall, even if it was minor
- You have any queries

At the end of the month when this card is complete, please separate and post it back to us. There is no need for you to add your name or any postage.

Pre-paid post card with return postal address

Appendix 9 Falls telephone data collection sheet

REFORM

REFORM: FALLS TELEPHONE DATA COLLECTION SHEET

Thank you for ringing us to let us know you have had a fall. I would like to ask you some questions to find out more about your fall please.

Centre number: ☐☐

Participant's trial ID number: ☐☐☐☐☐

Participant's name: _____

Participant's telephone number: _____

1. Date of phone call ☐☐ / ☐☐ / 2 0 ☐☐
   Day *Month* *Year*

2. Date of fall ☐☐ / ☐☐ / 2 0 ☐☐
   Day *Month* *Year*

3. What was the cause/reason for your fall?

Trip	Slip	Turning	Legs gave way	Dizzy
☐	☐	☐	☐	☐

Other _____

4a. Where did you fall?

- Inside your own home? ☐
- Inside, but not in your own home? ☐
- Outside? ☐

4b. If you fell inside was it:

- On the one level ☐
- Accessing the shower/bath ☐
- Getting out of bed ☐
- Getting out of a chair ☐
- Walking up or down stairs ☐
- Accessing the toilet ☐
- Other* ☐

*Please specify if 'Other' _____

REFORM falls telephone data collection sheet version 1.0 12 August 2011 1402210369

4c. If you fell outside was it:

Car park/driveway	☐	Crossing a street	☐
Garden park/grassed area	☐	Getting into or out of a vehicle	☐
On a bus or train	☐	On a footpath	☐
On a kerb	☐	On a step/escalator	☐
On the one level	☐	Other*	☐

*Please specify if 'Other' _____

5. What footwear were you wearing when you fell?

Barefoot	Slipper	Shoe	Can't remember	Other*
☐	☐	☐	☐	☐

*Please specify if 'Other' _____

6. Were you using a walking aid when you fell? Yes ☐ No ☐

7. Were you wearing an insole/orthotic in your shoe when you fell? Yes ☐ No ☐

8. Did you suffer any injuries as a result of the fall?

No injury	☐
Had some superficial wounds eg bruising, sprain, cut, abrasion	☐
Broken bones*	☐

*Please specify type of broken bone _____

9. Did you have to stay in hospital overnight because of this fall? Yes ☐ No ☐

9a. If 'Yes', how many nights did you stay in hospital? ☐☐☐

4947210366

Appendix 10 REFORM 6-month follow-up questionnaire

CONFIDENTIAL

REFORM Study

Reducing falls with ORthosis and a Multifaceted podiatry intervention

Participant Six Month Questionnaire

For office use only

Centre number: ☐☐

Participant's trial ID number: ☐☐☐☐☐

Date questionnaire sent: ☐☐ / ☐☐ / 2 0 ☐☐

Day *Month* *Year*

[redacted]

[redacted]

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to take part in this study. The responses you give in this questionnaire will help us find out the best way to stop people who are over 65 years old from having a fall.

Please answer ALL the questions. Although some of the questions may not seem relevant to yourself or may appear similar, they do give us valuable information.

If you find it difficult to answer the question, please give the best answer you can.

Please follow the instructions for each section carefully.

For each section, if you are asked to put a cross in the box, please use a cross rather than a tick, as if you were filling out a ballot paper.

For example in the following question, if your answer to the question is 'yes', you should place a cross firmly in the box next to yes.

Do you drive a car? Yes ☒

No ☐

If you are asked to write your answer, please do so by entering your answer in the box provided, for example:

How old are you? | 7 | 5 | years

Please use a black or blue pen for all the questions.

Please do not use a pencil or any other coloured pen.

If you have any queries or problems completing this questionnaire please contact the trial co-ordinator, Sarah Cockayne, freephone XXXX or XXXX, email XXXX.

7702248077

SECTION 1

This section asks about any falls you have had in the **past 6 months** and about some general information about you.

Please enter the date you are completing this questionnaire: ☐☐ / ☐☐ / 2 0 ☐☐

Day *Month* *Year*

1. Have you fallen in the **past 6 months**?
(Please cross one box only)

☐ Yes ☐ No ☐ Don't know

1a. If 'Yes', how many falls did you have in the **past 6 months**? ☐☐

2. During the **past 4 weeks** have you worried about having a fall?
(Please cross one box only)

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐	☐

3a. Please tell us your height ☐ feet ☐☐ inches **or** ☐☐☐ cm

3b. Please tell us your weight ☐☐ stone ☐☐ lbs **or** ☐☐☐.☐ kgs

4. Are you taking more than four medications prescribed by a doctor?
(Please cross one box only)

☐ Yes ☐ No

5. Have you been referred to a falls clinic / falls service?
(Please cross one box only)

☐ Yes ☐ No

8235248079

SECTION 2

This section asks about your health in general.

By placing a cross in one box in each group below, please indicate which statements best decribes your own health **today**.

Mobility

I have no problems in walking about ❑

I have some problems in walking about ❑

I am confined to bed ❑

Self-Care

I have no problems with self-care ❑

I have some problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

Usual Activities *(e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ❑

I have some problems with performing my usual activities ❑

I am unable to perform my usual activities ❑

Pain / Discomfort

I have no pain or discomfort ❑

I have moderate pain or discomfort ❑

I have extreme pain or discomfort ❑

Anxiety / Depression

I am not anxious or depressed ❑

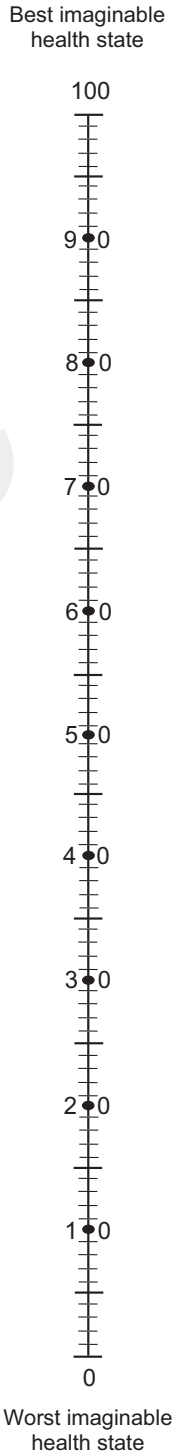
I am moderately anxious or depressed ❑

I am extremely anxious or depressed ❑

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



SECTION 3

Now we would like to ask some questions about how concerned you are about the possibility of falling.

Please reply thinking how you usually do the activity. If you currently do not do the activity, please answer to show whether you think you would be concerned about falling IF you did the activity.

For each of the following activities, please cross the box which is closest to you own opinion to show how concerned you are that you might fall if you did the activity.

	Not at all concerned	Somewhat concerned	Fairly concerned	Very concerned
Getting dressed or undressed	☐	☐	☐	☐
Taking a bath or shower	☐	☐	☐	☐
Getting in or out of a chair	☐	☐	☐	☐
Going up or down stairs	☐	☐	☐	☐
Reaching for something above your head or on the ground	☐	☐	☐	☐
Walking up or down a slope	☐	☐	☐	☐
Going out to a social event (eg, religious service, family gathering or club meeting)	☐	☐	☐	☐

SECTION 4

This section asks about how you've been feeling. Answer each question by placing a cross in the box that best describes your answer.

1a. I tend to bounce back after illness or hardship

Not true at all	Rarely true	Sometimes true	Often true	True nearly all of the time
☐	☐	☐	☐	☐

1b. I am able to adapt to change

Not true at all	Rarely true	Sometimes true	Often true	True nearly all of the time
☐	☐	☐	☐	☐

9505248070

SECTION 5

We are interested in finding out how often you carry out some activities. Please cross one box for each question.

1. **In the last 3 months**, how often have you carried out these activities?

	Never	Less than once per week	1 or 2 times a week	Most days
Preparing main meals	☐	☐	☐	☐
Washing up	☐	☐	☐	☐

2. **Over the last 3 months**, how often have you carried out the following?

	Never	1-2 times in 3 months	3-12 times in 3 months	At least weekly
Washing clothes	☐	☐	☐	☐
Light housework	☐	☐	☐	☐
Heavy housework	☐	☐	☐	☐
Local shopping	☐	☐	☐	☐
Social outings	☐	☐	☐	☐
Walking outside for over 15 minutes	☐	☐	☐	☐
Actively pursuing a hobby	☐	☐	☐	☐
Driving a car/travel on a bus	☐	☐	☐	☐

3. In the **last 6 months**, how often have you undertaken:

	Never	1-2 times in 6 months	3-12 times in 6 months	At least weekly
Travel outing / car ride	☐	☐	☐	☐

	Never	Light	Moderate	Heavy / All necessary
Gardening	☐	☐	☐	☐
Household maintenance	☐	☐	☐	☐

9230248075

In the **last 6 months**, how often have you undertaken:

	None	1 in 6 months	Less than 1 in 2 weeks	More than 1 every 2 weeks
Reading books	☐	☐	☐	☐

	None	Up to 10 hours/week	10 - 30 hours/week	Over 30 hours/week
Gainful work	☐	☐	☐	☐

SECTION 6

This section is about visits you have had to a NHS hospital as a patient **for any reason**.

Answer each question by placing a cross in the box that best describes your answer.

Attending hospital

1a. During the **last six months** have you stayed overnight in an NHS hospital?

☐ Yes ☐ No (go to section 7)

1b. If 'Yes', on how many separate occasions did you stay overnight in hospital? ☐☐

1c. For each stay please complete the information below:

	Number of nights in hospital	Reason for admittance
e.g.	3	ANGINA

6698248070

SECTION 7

This section is about other services you have used in the **past six months** as a patient **for any reason**. If the health care you received was related to a fall, record this in the 'about a fall' column. If the health care was for any other reason, enter this in the 'other reason' column.

Please fill in all of the boxes even if you have not had any visits. This information is really important for us.

	About a fall	Other reason
For example, if you have not used a service for any reason then put a '0' in both boxes:	0 0	0 0
If you have used a service three times about a fall and once for another reason then you would write:	0 3	0 1

1. Over the **past six months,** how many times have you:

Other visits to NHS hospital	About a fall *(If None enter '00')*	Other reason *(If None enter '00')*
a. Visited hospital for an out-patient appointment?		
b. Visited hospital for a day case / procedure (not overnight)?		
c. Attended Accident and Emergency?		

Other care from the NHS	About a fall *(If None enter '00')*	Other reason *(If None enter '00')*
d. Seen your GP at the surgery or at home?		
e. Seen a nurse at your GP practice or the district or community nurse?		
f. Seen an occupational therapist and/or physiotherapist at home?		

Transportation	About a fall *(If None enter '00')*	Other reason *(If None enter '00')*
g. Used a '999' emergency ambulance?		
h. Used the Patient Transport Service?		

2301248077

Support services

2a. Have you received any help or care (e.g. dressing, tasks around the home, providing meals, shopping from a relative or a friend) in the **last 6 months**?
(Please cross one box only)

☐ Yes ☐ No (go to 3a)

2b. If 'Yes', thinking about the **last 6 months**, typically how many hours per week did someone help you?

☐☐☐

3a. Does a paid care worker visit you at home?
(Please cross one box only)

☐ Yes ☐ No (go to 4a)

3b. If 'Yes', thinking about the **last 6 months**, typically how many days per week did a care worker visit?

☐

4a. Do you use meals on wheels?
(Please cross one box only)

☐ Yes ☐ No

4b. If 'Yes', thinking about the **last 6 months**, typically how many times a week did you use meals on wheels?

☐☐

9136248070

SECTION 8

This section asks about any extra costs you have had in the **past six months**.

1a. In the **last 6 months**, have you had to buy any new equipment (e.g. a bed), or paid to have any changes made to your house (e.g. installed a stairlift) due to ill health?
(Please cross one box only)

☐ Yes ☐ No (go to section 9)

1b. If 'Yes', please tell us the item and how much it cost.
(Please enter the cost to the nearest pound)

Item bought	Cost
	£
	£
	£

SECTION 9

This section asks about your living arrangements and some general information about you.

1. Do you?
(Please cross all that apply)

Live alone ☐

Live with a partner or spouse? ☐

Live with a friend or relative? ☐

Live in sheltered accommodation? ☐

2a. Did your education continue after the minimum school leaving age? ☐ Yes ☐ No

2b. Do you have a degree or equivalent professional qualification? ☐ Yes ☐ No

1266248076

SECTION 10

This section asks about your mood. Choose the best answer for how you have felt this past week by placing a cross in the appropriate box.

		Yes	No
1.	Are you basically satisfied with your life?	☐	☐
2.	Have you dropped many of your activities and interests?	☐	☐
3.	Do you feel that your life is empty?	☐	☐
4.	Do you often get bored?	☐	☐
5.	Are you in good spirits most of the time?	☐	☐
6.	Are you afraid that something bad is going to happen to you?	☐	☐
7.	Do you feel happy most of the time?	☐	☐
8.	Do you often feel helpless?	☐	☐
9.	Do you prefer to stay at home, rather than going out and doing new things?	☐	☐
10.	Do you feel you have more problems with memory than most?	☐	☐
11.	Do you think it is wonderful to be alive now?	☐	☐
12.	Do you feel pretty worthless the way you are now?	☐	☐
13.	Do you feel full of energy?	☐	☐
14.	Do you feel that your situation is hopeless?	☐	☐
15.	Do you think that most people are better off than you are?	☐	☐

For office use only: Insert total score ☐☐

6043248074

SECTION 11

If you have any general comments about the study, or this questionnaire, please write them below.

Thank you for taking the time to complete this questionnaire. Please return it to the York Trials Unit at the University of York in the pre-paid envelope provided.

6279248075

Appendix 11 REFORM 12-month follow-up questionnaire

CONFIDENTIAL

REFORM Study

Reducing falls with ORthosis and a Multifaceted podiatry intervention

Participant 12 Month Questionnaire

For office use only

Centre number: ☐☐

Participant's trial ID number: ☐☐☐☐☐

Date questionnaire sent: ☐☐ / ☐☐ / 2 0 ☐☐

Day *Month* *Year*

[redacted]

[redacted]

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to take part in this study. The responses you give in this questionnaire will help us find out the best way to stop people who are over 65 years old from having a fall.

Please answer ALL the questions. Although some of the questions may not seem relevant to yourself or may appear similar, they do give us valuable information.

If you find it difficult to answer the question, please give the best answer you can.

Please follow the instructions for each section carefully.

For each section, if you are asked to put a cross in the box, please use a cross rather than a tick, as if you were filling out a ballot paper.

For example in the following question, if your answer to the question is 'yes', you should place a cross firmly in the box next to yes.

Do you drive a car? Yes ☒

No ☐

If you are asked to write your answer, please do so by entering your answer in the box provided, for example:

How old are you? | 7 | 5 | years

Please use a black or blue pen for all the questions.

Please do not use a pencil or any other coloured pen.

If you have any queries or problems completing this questionnaire please contact the trial co-ordinator, Sarah Cockayne, telephone number XXXX, email XXXX.

4992625658

SECTION 1

This section asks about any falls you have had in the **past 6 months** and about some general information about you.

Please enter the date you are completing this questionnaire:

		/			/	2	0		
Day			*Month*			*Year*			

1. Have you fallen in the **past 6 months**?
(Please cross one box only)

☐ Yes ☐ No ☐ Don't know

1a. If 'Yes', how many falls did you have in the **past 6 months**? ☐☐

2. During the **past 4 weeks** have you worried about having a fall?
(Please cross one box only)

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐	☐

3. Are you taking more than four medications prescribed by a doctor?
(Please cross one box only)

☐ Yes ☐ No

4. Have you been referred to a falls clinic / falls service in the **past 12 months**?
(Please cross one box only)

☐ Yes ☐ No

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SECTION 2

This section asks about your health in general.

By placing a cross in one box in each group below, please indicate which statements best decribes your own health **today**.

Mobility

I have no problems in walking about ❑

I have some problems in walking about ❑

I am confined to bed ❑

Self-Care

I have no problems with self-care ❑

I have some problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

Usual Activities *(e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ❑

I have some problems with performing my usual activities ❑

I am unable to perform my usual activities ❑

Pain / Discomfort

I have no pain or discomfort ❑

I have moderate pain or discomfort ❑

I have extreme pain or discomfort ❑

Anxiety / Depression

I am not anxious or depressed ❑

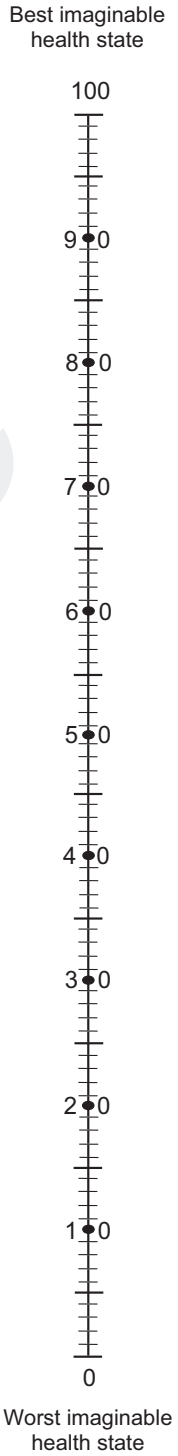
I am moderately anxious or depressed ❑

I am extremely anxious or depressed ❑

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



SECTION 3

Now we would like to ask some questions about how concerned you are about the possibility of falling.

Please reply thinking how you usually do the activity. If you currently do not do the activity, please answer to show whether you think you would be concerned about falling IF you did the activity.

For each of the following activities, please cross the box which is closest to you own opinion to show how concerned you are that you might fall if you did the activity.

	Not at all concerned	Somewhat concerned	Fairly concerned	Very concerned
Getting dressed or undressed	☐	☐	☐	☐
Taking a bath or shower	☐	☐	☐	☐
Getting in or out of a chair	☐	☐	☐	☐
Going up or down stairs	☐	☐	☐	☐
Reaching for something above your head or on the ground	☐	☐	☐	☐
Walking up or down a slope	☐	☐	☐	☐
Going out to a social event (eg, religious service, family gathering or club meeting)	☐	☐	☐	☐

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SECTION 4

We are interested in finding out how often you carry out some activities. Please cross one box for each question.

1. **In the last 3 months**, how often have you carried out these activities?

	Never	Less than once per week	1 or 2 times a week	Most days
Preparing main meals	☐	☐	☐	☐
Washing up	☐	☐	☐	☐

2. **Over the last 3 months**, how often have you carried out the following?

	Never	1-2 times in 3 months	3-12 times in 3 months	At least weekly
Washing clothes	☐	☐	☐	☐
Light housework	☐	☐	☐	☐
Heavy housework	☐	☐	☐	☐
Local shopping	☐	☐	☐	☐
Social outings	☐	☐	☐	☐
Walking outside for over 15 minutes	☐	☐	☐	☐
Actively pursuing a hobby	☐	☐	☐	☐
Driving a car/travel on a bus	☐	☐	☐	☐

3. In the **last 6 months**, how often have you undertaken:

	Never	1-2 times in 6 months	3-12 times in 6 months	At least weekly
Travel outing / car ride	☐	☐	☐	☐

	Never	Light	Moderate	Heavy / All necessary
Gardening	☐	☐	☐	☐
Household maintenance	☐	☐	☐	☐

1975625656

In the **last 6 months**, how often have you undertaken:

	None	1 in 6 months	Less than 1 in 2 weeks	More than 1 every 2 weeks
Reading books	☐	☐	☐	☐

	None	Up to 10 hours/week	10 - 30 hours/week	Over 30 hours/week
Gainful work	☐	☐	☐	☐

SECTION 5

This section is about visits you have had to a NHS hospital as a patient **for any reason**.

Answer each question by placing a cross in the box that best describes your answer.

Attending hospital

1a. During the **last six months** have you stayed overnight in an NHS hospital?

☐ Yes ☐ No (go to section 6)

1b. If 'Yes', on how many separate occasions did you stay overnight in hospital? ☐☐

1c. For each stay please complete the information below:

	Number of nights in hospital	Reason for admittance
e.g.	3	ANGINA

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SECTION 6

This section is about other services you have used in the **past six months** as a patient **for any reason**. If the health care you received was related to a fall, record this in the 'about a fall' column. If the health care was for any other reason, enter this in the 'other reason' column.

Please fill in all of the boxes even if you have not had any visits. This information is really important for us.

	About a fall	Other reason
For example, if you have not used a service for any reason then put a '0' in both boxes:	0 0	0 0
If you have used a service three times about a fall and once for another reason then you would write:	0 3	0 1

1. Over the **past six months,** how many times have you:

Other visits to NHS hospital	About a fall *(If None enter '00')*	Other reason *(If None enter '00')*
a. Visited hospital for an out-patient appointment?		
b. Visited hospital for a day case / procedure (not overnight)?		
c. Attended Accident and Emergency?		

Other care from the NHS	About a fall *(If None enter '00')*	Other reason *(If None enter '00')*
d. Seen your GP at the surgery or at home?		
e. Seen a nurse at your GP practice or the district or community nurse?		
f. Seen an occupational therapist and/or physiotherapist at home?		

Transportation	About a fall *(If None enter '00')*	Other reason *(If None enter '00')*
g. Used a '999' emergency ambulance?		
h. Used the Patient Transport Service?		

9739625652

Support services

2a. Have you received any help or care (e.g. dressing, tasks around the home, providing meals, shopping from a relative or a friend) in the **last 6 months**?
(Please cross one box only)

☐ Yes ☐ No (go to 3a)

2b. If 'Yes', thinking about the **last 6 months**, typically how many hours per week did someone help you?

☐☐☐

3a. Does a paid care worker visit you at home?
(Please cross one box only)

☐ Yes ☐ No (go to 4a)

3b. If 'Yes', thinking about the **last 6 months**, typically how many days per week did a care worker visit?

☐

4a. Do you use meals on wheels?
(Please cross one box only)

☐ Yes ☐ No

4b. If 'Yes', thinking about the **last 6 months**, typically how many times a week did you use meals on wheels?

☐☐

6335625651

SECTION 7

This section asks about any extra costs you have had in the **past six months**.

1a. In the **last 6 months**, have you had to buy any new equipment (e.g. a bed), or paid to have any changes made to your house (e.g. installed a stairlift) due to ill health?
(Please cross one box only)

☐ Yes ☐ No (go to section 9)

1b. If 'Yes', please tell us the item and how much it cost.
(Please enter the cost to the nearest pound)

Item bought	Cost
	£
	£
	£

SECTION 8

This section asks about your living arrangements and some general information about you.

1. Do you?
(Please cross all that apply)

Live alone ☐

Live with a partner or spouse? ☐

Live with a friend or relative? ☐

Live in sheltered accommodation? ☐

9706625656

SECTION 9

This section asks about your mood. Choose the best answer for how you have felt this past week by placing a cross in the appropriate box.

		Yes	No
1.	Are you basically satisfied with your life?	☐	☐
2.	Have you dropped many of your activities and interests?	☐	☐
3.	Do you feel that your life is empty?	☐	☐
4.	Do you often get bored?	☐	☐
5.	Are you in good spirits most of the time?	☐	☐
6.	Are you afraid that something bad is going to happen to you?	☐	☐
7.	Do you feel happy most of the time?	☐	☐
8.	Do you often feel helpless?	☐	☐
9.	Do you prefer to stay at home, rather than going out and doing new things?	☐	☐
10.	Do you feel you have more problems with memory than most?	☐	☐
11.	Do you think it is wonderful to be alive now?	☐	☐
12.	Do you feel pretty worthless the way you are now?	☐	☐
13.	Do you feel full of energy?	☐	☐
14.	Do you feel that your situation is hopeless?	☐	☐
15.	Do you think that most people are better off than you are?	☐	☐

For office use only: Insert total score ☐☐

9794625653

SECTION 10

This section asks about the advice you have received from the podiatry clinic over the past 12 months. We are also interested in finding out if you've been wearing insoles or orthotics in your shoes and doing any foot or ankle exercises.

These questions ask about your NHS podiatry care.

1a. Have you attended an NHS podiatry clinic in the past 12 months?
(Please cross one box only)

☐ Yes ☐ No

1b. If 'Yes', how many times have you attended the podiatry clinic in the past 12 months?

☐☐☐

These questions ask about your footwear

2a. Has your NHS podiatrist checked your everyday shoes in the past 12 months?
(Please cross one box only)

☐ Yes ☐ No ☐ Don't know

2b. If 'Yes' did your podiatrist give you advice about your footwear or suggest you should wear a different style of shoe? *(Please cross one box only)*

☐ Yes ☐ No ☐ Don't know

2c. If 'Yes' did you follow the footwear advice the podiatrist gave you?
(Please cross one box only)

☐ Yes ☐ No ☐ Partly

These questions ask if you're wearing an insole or orthotic

3a. In the past 12 months, has an NHS podiatrist given or made you an insole or orthotic to wear in your shoe? *(Please cross one box only)*

☐ Yes ☐ No

3b. If you were given an insole or orthotic, typically over the past 12 months how often have you worn them for? *(Please cross one box only)*

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

5201625652

These questions ask about what exercise you do

4a. Has your NHS podiatrist given you any foot or ankle exercises in the past 12 months? *(Please cross one box only)*

☐ Yes ☐ No

4b. If 'Yes' thinking about the past 12 months, typically how many times a week did you undertake the foot and ankle exercises? *(Please cross one box only)*

None, I did not do any	Less than once a week	Once a week	Twice a week	Three times a week	More than three times a week
☐	☐	☐	☐	☐	☐

4c. Has another healthcare professional (other than your podiatrist) given you any foot or ankle exercises to do in the past 12 months? *(Please cross one box only)*

☐ Yes ☐ No

4d. If 'Yes' thinking about the past 12 months, typically how many times a week did you undertake these exercises? *(Please cross one box only)*

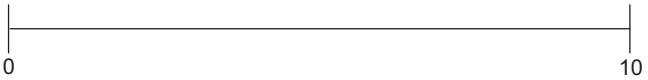
None, I did not do any	Less than once a week	Once a week	Twice a week	Three times a week	More than three times a week
☐	☐	☐	☐	☐	☐

5. Have you been involved in any other exercise activities over the past 12 months? *(Please cross one box only)*

☐ Yes ☐ No

If 'Yes' please give futher details:

6. We would like to know if you have any pain or discomfort in your feet today. Please do this by drawing a vertical mark on the line below to indicate how much pain or discomfort you have today.



No pain **Worse possible pain**

For office use only ☐☐☐ mm

0601625651

If you have any general comments about the study, or this questionnaire, please write them below:

Thank you for taking the time to complete this questionnaire. Please return it to the York Trials Unit at the University of York in the pre-paid envelope provided.

7250625658

Appendix 12 REFORM participant 6-month exercise and orthosis diary

CONFIDENTIAL

REFORM Study

Reducing falls with ORthosis and a Multifaceted podiatry intervention

Six Month
Participant exercise and orthosis diary

REFORM

For office use only

Centre number: ☐☐

Participant's trial ID number: ☐☐☐☐☐

Date questionnaire sent: ☐☐ / ☐☐ / 2 0 ☐☐
Day *Month* *Year*

[redacted]

[redacted]

REFORM Participant exercise and orthosis diary 1, 3, 6 and 12 month Version 1.0 12 August 2011 8661277568

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to take part in this study. The responses you give in this questionnaire will help us find out the best way to stop people who are over 65 years old from having a fall.

Please answer ALL the questions. Although some of the questions may not seem relevant to yourself or may appear similar, they do give us valuable information.

If you find it difficult to answer the question, please give the best answer you can.

Please follow the instructions for each section carefully.

For each section, if you are asked to put a cross in the box, please use a cross rather than a tick, as if you were filling out a ballot paper.

For example in the following question, if your answer to the question is 'yes', you should place a cross firmly in the box next to yes.

Do you drive a car? Yes ☒

No ☐

Please use a black or blue pen for all the questions.

Please do not use a pencil or any other coloured pen.

If you have any queries or problems completing this questionnaire please contact the trial co-ordinator, Sarah Cockayne, freephone XXXX or XXXX, email XXXX.

5962277569

We would like to ask you how often you have worn the orthotic (insole) in your shoe and completed the foot and ankle exercises.

Please enter the date you are completing this questionnaire: ☐☐ / ☐☐ / 2 0 ☐☐

Day *Month* *Year*

1. Thinking about the past month, typically how often have you worn your foot orthotic (insole) in your shoes?
(Please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

2. Thinking about the past month, typically how many times a week did you undertake the foot and ankle exercises?
(Please cross one box only)

None, I did not do any	Once a week	Twice a week	Three times a week	More than three times a week
☐	☐	☐	☐	☐

3. Have you had any problems wearing the orthotic or undertaking the foot and ankle exercises?
(Please specify)

Thank you for taking the time to complete this questionnaire. Please return it to the York Trials Unit at the University of York in the pre-paid envelope provided.

9663277561

Appendix 13 REFORM change of circumstance form

REFORM: A STUDY OF MUTIFACETED PODIATRY INTERVENTION FOR THE PREVENTION OF FALLS

Change of circumstances form

Please complete this form if there are any changes in the circumstances of the REFORM participant.

Centre number: ☐☐ Participant's trial ID number: ☐☐☐☐☐

Please enter the date you are completing this questionnaire: ☐☐ / ☐☐ / 2 0 ☐☐
Day *Month* *Year*

Reason for change in circumstance:

Please read the following and write the number of the MAIN reason in the box at the end of this form.

1. **The patient no longer wishes to have the study treatment**
   Please state reason, if given

2. **The patient no longer wishes to complete postal questionnaires but agrees to follow up by the health care professional.**

3. **Patient wishes to leave the study**
   Please state reason (only if given)

4. **Patient is being withdrawn by podiatrist**
   Please state reason

5. **Patient has died** (please also complete a 'Serious Adverse Event Form')
   Date of death: ☐☐ / ☐☐ / 2 0 ☐☐
   Day *Month* *Year*

6. **Patient is lost to follow up**

7. **Other reason** (Please state below)

The main reason for the change is option number ☐ (Please write option number in box)

Please give more details, if applicable:

Please send this form to the York Trials Unit in the pre-paid envelope provided

REFORM Podiatrist notification of a change of circumstances form Version 1.0 12th August 2011 0513439386

Appendix 14 REFORM adverse event form

[redacted] REFORM Adverse Event Form

Centre number: ☐☐ Participant trial ID number: ☐☐☐☐☐

Participant's date of birth ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year) Male ☐ Female ☐

Date of onset of event ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

Classification of event Serious ☐ Non-serious ☐

Serious event: Death ☐ Hospitalisation required /prolonged ☐ Life or limb threatening event ☐

Persistent or significant Disability/incapacity ☐ Other medically important condition ☐

Event related to the intervention: advised footwear, trial insoles, exercise programme, use of equipment.

Aches/pain in the lower limb for longer than 48 hours ☐ Fall ☐ Injury due to exercise equipment ☐ Soft tissue injury ☐

Skin irritation/injury (including pressure sores, new callus/corn formation, blisters, ulcers) ☐

Other ☐ Please specify: _____

Description of event:

_____

Please state outcome of event at time of this report *(cross one box only)*

Recovered fully ☐ Recovered partially ☐ On-going ☐

Died ☐ Date of death, if known: ☐☐ / ☐☐ / ☐☐☐☐

Relationship of the event to any of the research procedures *(cross one box only)*

Unrelated	Unlikely	Possibly	Probably	Definitely	Not able to assess
☐	☐	☐	☐	☐	☐

Expectedness Is this event expected? ☐ Yes ☐ No

Intensity *(cross one box only)* ☐ Mild ☐ Moderate ☐ Severe

Podiatrist's name: _____ Podiatrist's Signature: _____

Date: ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

REFORM AE Form version 1.0 4th Feb 2013 5168191674

Appendix 15 REFORM participant information sheet (qualitative)

Participant Information Sheet
Interviews with participants as part of the REFORM study

Invitation to take part in an interview

You have already kindly agreed to take part in the REFORM study which is evaluating a package of podiatry care which aims to improve balance and prevent falls in older adults.

We are now inviting you to take part in interviews which will look at your experience of being part of the study and your thoughts on preventing falls.

Before you decide whether or not to take part it is important to understand why the research is being done and what it will involve. Please read this information sheet carefully. If there is anything you wish to discuss in more detail or that is unclear please contact us.

Why am I being invited to take part?

When you were originally approached to take part in the REFORM study, you agreed that we could contact you again about other REFORM studies we were conducting.

We want to talk to a variety of older adults from the study about their views on preventing falls and their experience of being part of the study.

We hope to interview about 15 participants who are taking part in the study.

Why is it important to know what older adults think about falls prevention

In the REFORM study we are looking at a package of podiatry care to see if it will improve patient's balance and reduce the number of falls they have. We are interested in finding out what those over the age of 65 think about how we can improve balance, prevent falls and what patients thought of the treatment they received.

What will I need to do if I take part?

If you are happy to take part, you will need to give about one hour of your time for each interview. If you decide to take part you may be interviewed on two occassions. A researcher will contact you to arrange a date and time to suit you.

For the first interview, the researcher will come to your home to interview you, if that is best for you. Alternatively we can easily arrange for the interview to take place at the University of York, if you prefer. The second interview will take place over the telephone. You will be asked to sign a consent form.

There are no right and wrong answers to any questions we will ask in these interviews. We just want to find out about your thoughts on improving balance, preventing falls and your experience of taking part in the study.

The interviews will be recorded using a digital voice recorder so that we can keep an accurate record of everything you say. The recording of the interview will be copied to a secure University of York computer. The interview will then be typed-up by a secretary.

We will inform your GP if we become aware of any healthcare issues which come to light as a result of the interview.

What are the possible benefits of taking part?

The results of the interviews may help podiatrists and researchers understand how podiatry care can be delivered to patients over the age of 65 in order to help improve their balance and reduce the number of falls they have.

[redacted]

REFORM participant qualitative information sheet Version 2.0 3rd October 2011

What are the possible disadvantages of taking part?

If you take part you will need to give roughly two hours of your time.

What if something goes wrong?

While we anticipate that no harm or distress will occur to anyone as a result of taking part in this study it is important to state that there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you.

Do I have to take part?

It is entirely up to you to decide whether or not to take part. Participation in the study is voluntary. If you do decide to take part, you will be asked to sign a consent form. If you decide not to take part, no one will mind and it will not affect your participation in the REFORM study.

What happens when the interviews and observations finish?

When the interviews finish, we will write up the information and publish it in journals that will be read by health professionals and researchers. We may also present the findings at conferences, anonymised excerpts from the interview may be used as part of the presentation. We will look at the results of the interviews together with the results of the main study. We will be happy to give you a summary of the results.

If I take part, will all the information be kept confidential?

Yes, only the research team will know that you have taken part in the interview. Your name will not be written on the transcripts. You will be anonymous in any written reports of the research. We may use written quotations from the interviews in presentations and teaching. All recordings will be stored securely for a period of 5 years after the study is finished; then it will be destroyed.

Who is organising and funding the study?

This study is being organised by researchers at the University of York. The research has been funded by the Department of Health, National Institute of Health Research Health Technology Assessment programme.

Who has reviewed and checked the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This research has been reviewed and approved by NRES Committee East of England – Cambridge East Research Ethics Committee.

What do I do now?

A researcher will telephone you in the next few days to find out if you would like to take part. The researcher can give you more information if you need it and will be happy to answer any of your questions.

Thank you for taking the time to read this information.

If you have any questions about the study please contact us. A friend or relative may speak to us on your behalf if you wish. There is an answering machine available 24 hours a day, so please leave a message and a member of the research team will contact you as soon as possible.

Contact details:-

Researcher:
Tel:
Address:

Appendix 16 REFORM participant interview consent form

[redacted]

REFORM

REFORM Participant interview consent form

Title of Project: Interviews with older adults as part of the REFORM study to improve balance and help reduce falls

Contact Name: Mrs Sarah Cockayne

Contact Details: University of York, York, YO10 5DD
Tel: XXXX or XXXX Email: XXXX

Please initial each box

1. I confirm that I have read and understand the information sheet version 2 dated 03/10/2011 for this study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. ☐
3. I understand that the interview(s) will be recorded on a digital voice recorder and the sound file will be stored on a secure computer at the University of York. ☐
4. I understand that the interview transcript will be strictly confidential and that I will be anonymous in any written reports from the research. ☐
5. I understand that written quotations from the interview may be used in Presentations and teaching. ☐
6. I understand that my details (eg name, address) will be strictly confidential, stored at the University of York and will not be passed on to any individual within or outside the University. ☐
7. I agree to take part in the above study by taking part in the interview. ☐

Name of participant	Signature	/ / Date
Name of researcher	Signature	/ / Date

1 copy for the participant 1 copy for the researcher REFORM Participant consent form for qualitative sutdy Version 1.0 12th August 2011

Appendix 17 REFORM qualitative podiatrist information sheet

Podiatrist Information Sheet
Interviews with podiatrists as part of the REFORM study

Invitation to take part in an interview

You have already kindly agreed to take part in the REFORM study which is evaluating a multifaceted podiatry intervention which aims to improve balance and prevent falls in older adults.

As part of this study, we are now inviting you to take part in an interview which will look at your experience of delivering the podiatry intervention to older adults.

Before you decide whether or not to take part it is important to understand why the research is being done and what it will involve. Please read this information sheet carefully. If there is anything you wish to discuss in more detail or that is unclear please contact us.

Why am I being invited to take part?

We are inviting you to partcipate because you are delivering the multifaceted poditary intervention for falls prevention to older adults who are taking part in the REFORM trial. We want to talk to a variety of podiatrists from the study to find out about their experience of delivering the multifaceted podiatry intervetion.

We hope to interview approximately 10 podiatrists who are taking part in the study.

Why is it important to know what podiatrists think about the multifaceted podiatry intervention for older adults?

We would like to find out your views and opinions about the intervention. We are also interested in finding out about any problems you may have encountered, and things you think helped in the delivery of the intervention.

What will I need to do if I take part?

If you are happy to take part, you will need to give about one hour of your time. A researcher will contact you to arrange a date and time to suit you.

The researcher and yourself will agree a place where you can be intereviewed which could be at your place of work or at the University of York, if that is best for you.

There are no right and wrong answers to any questions we will ask in these interviews. We just want to find out about your thoughts and experience of delivering the multifaceted podiatry intervention to older adults.

The interviews will be recorded using a digital voice recorder so that we can keep an accurate record of everything you say. The recording of the interview will be copied to a secure University of York computer. The interview will then be typed-up by a secretary.

What are the possible benefits of taking part?

The results of the study may help us better understand how podiatry interventions can be delivered to patients over the age of 70 in order to help improve their balance and reduce the number of falls they have.

[redacted]

REFORM podiatrist qualitative information sheet Version 1.0 12th August 2011

What are the possible disadvantages of taking part?

If you take part in the interview, you will need to give roughly one hour of your time.

What if something goes wrong?

While we anticipate that no harm or distress will occur to anyone as a result of this study it is important to state that there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you.

Do I have to take part?

It is entirely up to you to decide whether or not to take part. Participation in the study is voluntary. If you do decide to take part, you will be asked to sign a consent form.

What happens when the interviews and observations finish?

When the interviews finish, we will write up the information and publish it in journals that will be read by health professionals and researchers. We may also present the findings at conferences, anonymised excerpts from the interview may be used as part of the presentation. We will look at the results of the interviews together with the results of the main study. We will be happy to give you a summary of the results.

If I take part, will all the information be kept confidential?

Yes, only the research team will know that you have taken part in the interview. Your name will not be written on the transcripts. You will be anonymous in any written reports of the research. We may use written quotations from the interviews in presentations and teaching. All recordings will be stored securely for a period of 5 years after the study is finished; then it will be destroyed.

Who is organising and funding the study?

This study is being organised by researchers at the University of York. The research has been funded by the Department of Health, National Institute of Health Research Health Technology Assessment programme.

Who has reviewed and checked the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This research has been reviewed and approved by NRES Committee East of England – Cambridge East Research Ethics Committee.

What do I do now?

If you would like to take part please complete the "Permission for release of podiatrist's personal details" form and give it to the Principal Investigator at your site. He/she will then give it to the qualitative researcher. They will then telephone you in the next few days to arrange to meet with you. The researcher can give you more information if you need it and will be happy to answer any of your questions.

Thank you for taking the time to read this information.

If you have any questions about the study please contact us.

Contact details:-
Researcher:
Tel:
Email:
Address:

REFORM podiatrist qualitative information sheet Version 1.0 12th August 2011

Appendix 18 REFORM podiatrist interview consent form

[redacted]

REFORM

REFORM Podiatrist interview consent form

Title of Project: REFORM: A randomised trial of a multifaceted podiatry intervention for fall prevention -

Contact Name: [Insert name of qualitative researcher]

Contact Details: University of York, York, YO10 5DD
Tel: [Insert qualitative researcher's number]; Email: [Insert qualitative researcher's email address]

Please initial each box

1. I confirm that I have read and understand the information sheet version [no], dated [date] for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. ☐
3. I understand that the interview will be recorded on a digital voice recorder and the sound file will be stored on a secure computer at the University of York. ☐
4. I understand that the interview transcript will be strictly confidential and that I will be anonymous in any written reports from the research. ☐
5. I understand that written quotations from the interview may be used in presentations and teaching. ☐
6. I understand that my details (eg name, address) will be strictly confidential, stored at the University of York and will not be passed on to any individual within or outside the University. ☐
7. I agree to take part in the above study by taking part in the interview. ☐

Name of participant	Signature	Date / /
Name of researcher	Signature	Date / /

1 copy for the participant 1 copy for the researcher REFORM Podiatrist consent form for qualitative study Version 1.0 12th August 2011

Appendix 19 REFORM participant qualitative topic guide

[redacted]

Interviews with participants as part of the REFORM study

Invitation telephone call procedure to arrange interview.

1. The qualitative researcher will introduce themselves to the participant as part of the REFORM research tear
2. The researcher will ask the participant if they received the invitation letter.
3. The researcher will explain the reason for calling ie to see if the participant would like to take part in the interview study.
4. The researcher will answer questions and/or explain the study.
5. The researcher will determine if the participant would like to take part in the study.
6. If the participant is willing to take part the researcher will thank them and arrange a convenient date and time. If the participant is not willing to take part, the researcher will thank them for their time.

Interview topic guide for REFORM participants
Approximately five participants will be interviewed.

This topic guide summarises the main areas to be explored in each interview about podiatry interventions to improve balance and to reduce the number of falls patients over the age of 70 experience. As with any qualitative interviews, these headings are intended as a starting point to ensure the primary issues are covered, whilst allowing flexibility for new issues to emerge. Preliminary analysis of data from earlier interviews will shape the topics covered in later interviews.

Introduction

- The researcher introduces themselves
- The researcher explains the background of the study
- The researcher should emphasise confidentiality, remind the participant that the interview will be tape recorded and that they can stop the interview at any time if they wish
- The researcher should remind the participant that the information from the research will be written up as a report for the HTA and other reports
- Any questions about the study or interview before we start?

Understanding improving balance and reducing the number of falls

- General background information – family circumstances, general wellbeing and their personal history of balance problems and falls. The impact of any balance problems or falls.

REFORM Participant qualitative topic guide Version 1.0 12th August 2011

- Ask about the study participant's understanding of improving balance and reducing the number of falls, where they have gained this information from (family, friends, professionals, media) how much of a problem they perceive this to be
- Ask the participant about their thoughts on the relationship between improving balance and reducing falls on any current health problems they are currently experiencing
- Explore the extent to which improving balance and reducing falls is an important issue to the participant. Eg are they steady on their feet, if they've had any fractures, worry about falling, if they would undertake any steps to reduce the possibility of them falling
- Ask the participant about their understanding of 'risk factors' what kind of things do they think might cause older adults, friends or themselves to have poor balance and fall. If they consider themselves at risk of falling
- Ask about their views and how they manage improving balance and preventing falls or why not if this is not done
- Ask about any perceived improvements in balance/falls since the start of the study

For participants allocated to the intervention group

- What did you think about the orthosis?
- Did you think they were a good idea?
- How often did you wear the orthotics?
- Did you have any problems with wearing the orthotics?
- Did you think the orthotics would help?
- Do you feel more confident when wearing the orthotics?
- Does wearing the orthotic make you worry less about falling?
- What did you think about the foot and ankle exercises?
- Did you find it easy to undertake them three times a week?
- Did you think the exercises would help?
- Did you have any problems undertaking the exercises?
- Did you manage to fill in the exercise diary?
- Did you receive any footwear advice?
- Were you given a voucher to buy new shoes? If 'yes' did you buy new shoes? If not, why not.

For participants allocated to the control group

- *Whether they have introduced any measures to address their balance problems, did they follow any advice from the falls prevention leaflet?*

Participating in the study

- Explore the participant's views on their experience of being involved in the REFORM study eg was it something that they really wanted to do? Have they ever taken part in a study before? Would they take part in a research study again?
- Views on being randomised to the intervention group eg experiences of randomisation process and understanding of this, feeling about completing questionnaires for study
- Views about value of the trial
- How did you feel about filling in the falls calendar? Did you manage to fill it in? Did you have any problems? What did you think of the layout? Could it have been improved in any way?
- What did you think about the other questionnaires we asked you to complete? How did you find these? Were they easy to understand? What was the layout like? Could they be improved in any way?
- What did you think about the falls prevention leaflet we sent out?

Any other issues

- Any other issues or questions the participant would like to raise?
- The researcher will clarify what happens next in terms of the REFORM study
- The researcher will thank the participant for their time.

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Appendix 20 REFORM podiatrist qualitative topic guide

REFORM

Interviews with podiatrists as part of the REFORM study

Invitation telephone call procedure to arrange interview.

1. The qualitative researcher will introduce themselves to the podiatrist as part of the REFORM research team.
2. The researcher will ask the podiatrist if they received the invitation letter.
3. The researcher will explain the reason for calling ie to see if the podiatrist would like to take part in the interview study.
4. The researcher will answer questions and/or explain the study.
5. The researcher will determine if the podiatrist would like to take part in the study.
6. If the podiatrist is willing to take part the researcher will thank them and arrange a convenient date and time. If the podiatrist is not willing to take part, the researcher will thank them for their time.

Interview topic guide for REFORM podiatrists
Approximately 10 podiatrists will be interviewed.

This topic guide summarises the main areas to be explored in each interview about podiatry interventions to improve balance and to reduce the number of falls patients over the age of 70 experience. As with any qualitative interviews, these headings are intended as a starting point to ensure the primary issues are covered, whilst allowing flexibility for new issues to emerge. Preliminary analysis of data from earlier interviews will shape the topics covered in later interviews.

Introduction

- The researcher introduces themselves
- The researcher explains the background of the study
- The researcher should emphasise confidentiality, remind the podiatrist that the interview will be tape recorded and that they can stop the interview at any time if they wish
- The researcher should remind the podiatrist that the information from the research will be written up as a report for the HTA and other reports
- Any questions about the study or interview before we start?

Views on delivering the intervention

- What was your overall impression of the intervention?
- Can you tell me what you liked and disliked about the multifaceted intervention?
- Has there been anything which has hindered your delivery of the intervention? Please describe these and how they could be overcome.
- Have you needed to withdraw a participant from the intervention? If so, why?
- What were your views on the exercise DVD?

[redacted]

REFORM podiatrist qualitative topic guide Version 1.0 12th August 2011

- Can you tell me how you see your role in improving balance and reducing the number of falls in elderly adults?

Participating in the study

- Views on their experience of being involved in the REFORM study
- Views about value of the trial

Training

- What did you think about the training you received on how to deliver the multifaceted intervention?
- How could the training sessions have been improved?

Any other issues

- Any other issues or questions the participant would like to raise
- Clarify what happens next in terms of the REFORM study
- Thank them for their time

Appendix 21 REFORM footwear assessment checklist

Outdoor	Yes	No
Appropriate heel height?		
Appropriate heed width?		
Appropriate fixation/fastening?		
Appropriate heel counter?		
Suitable sole?		
Correct size?		
Indoor		
Appropriate heel height?		
Appropriate heed width?		
Appropriate fixation/fastening?		
Appropriate heel counter?		
Suitable sole?		
Correct size?		

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