

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)

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Scientific summary

The REFORM RCT

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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.

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