

SHORT REPORT

Randomised controlled trial of hip protectors for the prevention of second hip fractures

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Abstract

Objective: to assess whether the use of Safehip hip protectors would prevent second hip fractures among men and women living in the community.

Design: pragmatic randomised controlled trial.

Setting: people living in the community.

Participants: men and women aged 70 years and over who had sustained one hip fracture and who were living in the community.

Results: 366 men and women who were either living outside residential care or were about to be discharged back home were randomised to receive three pairs of hip protectors or to act as controls. Approximately 34% of participants allocated to receive hip protectors wore them every day. After a median follow up of 14 months 8 participants had a second hip fracture with 6 in the intervention and 2 in the control group (Odds Ratio for second hip fracture = 3.10, 95% confidence interval 0.62–15.58). Hip protectors had no effect on risk of other fractures or on falls.

Conclusion: this trial does not suggest a benefit of the studied hip protector among people living outside residential accommodation.

Keywords: *hip fracture, hip protectors, community*

Introduction

Approximately 10% of hip fractures are second fractures [1], and people who sustain one hip fracture are 5–9 times more likely to fracture their second hip compared with age matched controls [2]. Hip protectors may potentially prevent second hip fractures. Some previous studies have indicated a reduction in hip fractures of up to 75% using hip protectors [3–5]. However, these were mainly conducted among residents within nursing homes and the largest trials were cluster randomised with potentially fatal methodological flaws. For example, the latest and largest study did not use intention to treat analysis [5]. Further, none of the cluster trials used appropriate statistical analysis. We, therefore, undertook a pragmatic randomised trial to assess whether hip

protectors prevented second hip fractures among community dwelling older people.

Methods

We recruited men and women from either orthopaedic wards, where they were recovering from their first hip fracture, or volunteers from the general population who had had a hip fracture at any time in the past. Volunteers were recruited from either articles in national newspapers (e.g. Sunday Telegraph, Telegraph, Daily Mirror) or through local television news programmes. People who had had one hip fracture and were aged 70 years and over who wished to take part in the study, were eligible. People were ineligible if they were bed or

chair-bound, had bilateral hip replacements and had a clothing size of 18 and above (as at this time this hip protector was not available in a larger size). The study population could be described as a relatively 'healthy' population since all were community dwelling or about to be discharged back to the community.

Intervention group participants were issued with three pairs of hip protectors (Safehip, http://www.tytex.com/our_products/hip_protection/) and general advice (in the form of a leaflet) on how to reduce fracture risk, whilst people in the control group received only the leaflet. Randomisation was stratified by age, gender and recruitment status (i.e. volunteer recruited by publicity or participant recruited from hospital wards) using random selection of block lengths of 4, 6, and 8. Individual randomisation was undertaken by telephone using the University of York's telephone randomisation service (randomisation schedules were produced by computer).

The main outcome was a second hip fracture. Participants were followed up at 6 monthly intervals for self-reported fractures. At the end of the study all the participants' general practitioners (GPs) were contacted for data on any new fracture occurrence and to confirm all self-reported fractures. Fractures not confirmed by the GP were not included in the analysis.

Secondary outcomes were: non-hip fractures; compliance; falls; and fear of falling (measured on a 6 point Likert scale ranging from not at all worried (0) to very worried (5)). All outcomes were self-reported by post.

At the time of planning the study a quasi-experiment suggested that hip fractures could be reduced by 75%, therefore, we chose a sample size to detect this difference. For a hip fracture incidence of 1.2% and 0.6% for women and men 70 years and over, which is increased by a factor of 5 and 9 for women and men respectively after a first hip fracture [2], giving an annual incidence of 6% and assuming a median 18 month follow-up, we would expect a hip fracture rate of 9% among untreated controls and 2% in the hip protector group. We would need about 330 participants and allowing for some loss to follow-up we planned to recruit 385 participants.

Results

Between June 1998 and December 2000 we recruited 366 participants of which 46 were men. The characteristics of the participants are shown in Table 1. Seventy-seven participants were lost to follow-up (Figure 1). During a median follow-up of 14 months (min=6, max=41) 43 fractures occurred in 39 participants; 8 hip fractures (6 in the protector group and 2 in the control), and 32 non-vertebral fractures (18 in the protector group and 14 in the control group). The odds ratio of sustaining a hip fracture for participants allocated to the hip protector group was 3.10 (95% CI 0.62–15.58). After adjusting for age and volunteer status, using logistic regression, the

Table 1. Baseline and follow-up characteristics of randomised groups

Baseline characteristics	Hip protector group <i>n</i> =182	Control <i>n</i> =184	
Mean age	80.84 (SD 5.95) (Range 70–97)	80.21 (SD 5.70) (Range 70–96)	
Volunteer status	100 (55%)	101 (55%)	
History of fracture previous to hip fracture	74 (41%)	79 (44%)	
Men	23 (13%)	23 (13%)	
Self-reported weight (kg)	58.89 (SD 13.65) (Range 31.82–95.45)	58.72 (SD 12.99) (Range 35.00–98.64)	
Maternal history of hip fracture	10 (5%)	15 (8%)	
Smoker	23 (13%)	19 (10%)	
Fallers	95 (21%)	90 (26%)	
Accommodation			
Live with partner or spouse	48 (26%)	69 (38%)	
Live alone	87 (48%)	68 (37%)	
Live with relatives or in sheltered accommodation	25 (14%)	23 (12%)	
Missing	22 (12%)	24 (14%)	
Outcomes	<i>n</i>	<i>n</i>	Odds ratio 95% CI
Hip fractures	6	2	3.10 (0.62–15.58)
Pelvic	3	0	
Other non hip (including pelvic)	18	14	1.09 (0.51–2.33)
	Mean	Mean	Mean difference 95% CI
Number of falls	0.55 (SD 0.85) (Range 0–4)	0.80 (SD 1.39) (Range 0–10)	0.25 –0.05–0.56
Fear of falling (6 weeks)	1.73 (SD 1.83) (Range 0–5)	1.75 (SD 1.91) (Range 0–5)	0.02 –0.39–0.43
Fear of falling (final follow-up)	2.59 (SD 1.54) (Range 0–5)	2.78 (SD 1.64) (Range 0–5)	0.19 –0.21–0.59

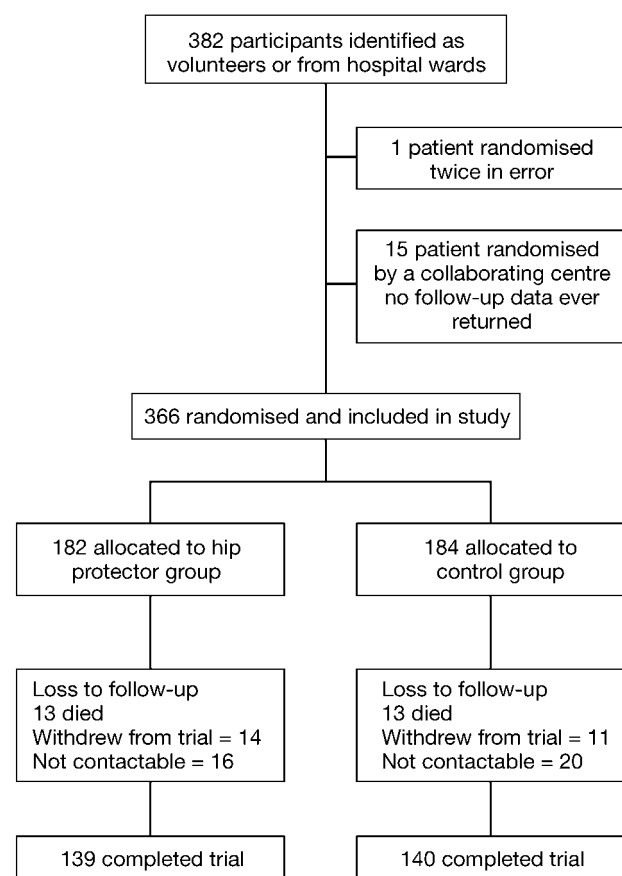


Figure 1. Flow chart of participants in the randomised trial.

odds ratios were similar (3.49, 95% CI 0.68–17.97). Of the 117 participants in the treatment group who provided final data 60% reported that they still wore hip protectors at least occasionally. However, only 5 participants wore them night and day with a further 35 wearing them only in the daytime, which left the final compliance rate at 34% ($n=40$). Participants who only wore the protectors occasionally were classed as non-compliant. The compliance rate among the volunteer participants was higher at 39% as opposed to 23% for participants recruited from hospital wards. Only one of the participants reported that she was wearing her protectors when the fracture occurred: she reported that she had fallen backwards rather than to the side.

Discussion

We did not find that the studied hip protectors reduced the incidence of second hip fractures. However, there were few hip fractures in our study and consequently this reduces the power. Only 2.3% of the participants had a second hip fracture rather than the 9% anticipated. The relatively 'healthy' sample of hip fracture patients in our study may account for this.

Compliance with hip protectors was low. While we did not collect qualitative data on reasons for non-compliance

the results clearly indicate that for whatever reason this population did not comply with this design of protectors and this low compliance must be placed within the context that the participants had already had a hip fracture. The higher rate of compliance within the volunteer group was unsurprising, since volunteers tend to be a more motivated group. However, compliance with this brand of protector in this group of elderly people was still low. Hip protectors are not inexpensive and to date the evidence is not sufficiently strong to justify this cost outside a residential care setting. The lack of compliance and low event rate does mean that this study will tend towards the null hypothesis. However, this is an important finding as hip protectors cannot be effective if they are not worn. The hip protectors used employ a design that diverts force from the hip of which the Safehip brand is only one. It is likely these results are generalisable to other similar products. Larger randomised trials among high-risk individuals living in a community setting as well as institutional settings are urgently required.

Key points

- The current evidence to support the use of hip protectors comes from residential care settings.
- This report describes the results of a secondary prevention trial in a community-based sample.
- Compliance was poor.
- No evidence for their efficacy in this sample.
- More work is required to test them in larger trials in both residential and community settings.

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