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A cluster randomised controlled trial to evaluate a policy of making hip protectors available to residents of nursing homes

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Abstract

Objectives: to evaluate the effectiveness of a policy of making hip protectors available to residents of nursing homes.
Design: a cluster randomised controlled trial of the policy in nursing and residential homes, with the home as the unit of randomisation.
Setting: 127 nursing and residential homes in the greater Belfast area of Northern Ireland.
Participants: 40 homes in the intervention group (representing 1,366 occupied beds) and 87 homes in the control group (representing 2,751 occupied beds).
Interventions: a policy of making hip protectors available free of charge to residents of nursing homes and supporting the implementation process by employing a nurse facilitator to encourage staff in the homes to promote their use, over a 72-week period.
Main outcome measures: the rate of hip fractures in intervention and control homes, and the level of adherence to use of hip protectors.
Results: there were 85 hip fractures in the intervention homes and 163 in the control homes. The mean fracture rate per 100 residents was 6.22 in the intervention homes and 5.92 in the control homes, giving an adjusted rate ratio for the intervention group compared to the control group of 1.05 (95% CI 0.77, 1.43, $P=0.76$). Initial acceptance of the hip protectors was 37.2% (508/1,366) with adherence falling to 19.9% (272/1,366) at 72 weeks.
Conclusions: making hip protectors available to residents of nursing and residential homes did not reduce the rate of hip fracture. This research does not support the introduction of a policy of providing hip protectors to residents of nursing homes.

Keywords: *hip protectors, hip fracture, older people, falls, randomised controlled trial, health services research, fractured neck of femur, elderly, nursing home*

Introduction

Every year increasing numbers of older people fall and break a hip. In 1990, the world-wide incidence of hip fracture was estimated at 1.26 million [1]. This figure is predicted to double to 2.6 million by 2025, and rise to 4.5 million by 2050 [2]. Efforts aimed at preventing hip fractures include targeting high-risk groups with lifestyle advice, interventions to reduce the risk of falls and, where appropriate, drug treatments for osteoporosis [3]. Attention has also focused

on hip protectors: protective pads designed to cover the greater trochanter and attenuate or disperse the force of a fall sufficiently to prevent a fracture. Promising results from tightly controlled trials in nursing homes [4–8] have resulted in hip protectors being widely recommended in the health care literature and in national guidelines [3, 9, 10]. These recommendations have prompted commissioners of health care, including our local health board (a regional health authority), to consider whether hip protectors should be provided to residents of nursing homes.

There are many factors, unrelated to the efficacy of a health care technology, that have the potential to reduce its effectiveness in an everyday health care environment. These include generic operational issues and, in the case of hip protectors, low patient acceptability and adherence [11]. This raises the question of how effective a policy of providing hip protectors to the residents of nursing homes may be in preventing hip fractures. In order to address this issue, we undertook a trial of a policy of providing hip protectors free of charge to the residents of nursing homes. The null hypothesis was that the rate of hip fracture in nursing and residential homes randomised to a policy of offering external hip protectors to their residents would be no different to the rate of hip fracture in homes randomised not to introduce this policy.

Methods

The study was a cluster randomised controlled trial with nursing and residential homes acting as the clusters. All homes registered with the Registration and Inspection Unit (RIU) of the Eastern Health and Social Services Board (EHSSB), Northern Ireland, to offer residential or nursing care to the old and infirm (O&I), and the elderly mentally infirm (EMI), were invited through their managers to take part in the study by P.D.O. Homes that agreed to participate were randomly allocated to either intervention or control groups in a 1:2 ratio by a statistician unconnected to the recruitment procedure (G.W.C.), using block (restricted) randomisation, within strata determined by the organisational characteristics of the homes (the type, size, client category and affiliation of the home; Table 1). The study was carried out between May 2000 and January 2003. The intervention period was 72 weeks.

The intervention

The intervention was the introduction of a policy of offering hip protectors to all eligible residents within the home, using an evidence-based approach to intervention. Residents of homes in the control group received usual care. The intervention was introduced in a manner that was judged to be consistent with everyday practice and with the deployment of a level of resource that would be replicable in a normal health care environment. The framework for introduction of the intervention was evidence based [12]: it took account of the available level of evidence for the efficacy of hip protectors, the importance of facilitation of the implementation process and the context into which the intervention was being introduced [13].

The intervention comprised the following elements:

- obtaining the support of managerial staff in the homes and the care organisations running groups of homes;
- ongoing support for homes (including a telephone help line) through the employment of a trained nurse facilitator who made regular daytime (09:00–17:00 hours) visits to all intervention homes throughout the trial to promote implementation and monitor progress;
- a 1-hour workshop for relevant home staff, provided by the nurse facilitator, focusing on the risks and consequences of hip fracture, the use of hip protectors to prevent hip fracture and the evidence supporting their efficacy;
- distributing the manufacturer's leaflets, posters and reminder stickers promoting the use of hip protectors;

Table 1. Home characteristics

	Number (%)	
Home characteristics	Intervention group $n = 40$	Control group $n = 87$
Type of home		
Nursing homes	22 (55)	51 (58.6)
Residential homes*	18 (45)	36 (41.4)
Size of the home		
30 or more beds	25 (62.5)	55 (63.2)
< 30 beds	15 (37.5)	32 (36.8)
Client category		
EMI only	7 (17.5)	11 (12.7)
Mixed EMI and O&I	5 (12.5)	9 (10.3)
O&I only	28 (70)	67 (77)
Affiliation of the home		
Independently owned and managed	30 (75)	61 (70.1)
Part of a larger group	10 (25)	26 (29.9)
Management		
Mean percentage of R&I care quality standards not met	(27.6)	(28.9)
Change of senior manager during the study	13 (32.5)	18 (20.7)

*Offer residential support but not nursing care; EMI = Elderly Mentally Infirm; O&I = Old and Infirm; Mixed = Mixture of EMI and O&I beds; R&I = Registration and Inspection Unit.

providing a broadcast-standard videotaped presentation on hip fracture and hip protectors, suitable for both staff and residents, to each home;
providing information sessions for residents and relatives upon request;
providing a clear protocol for the use of hip protectors to home managers;
free provision of four pairs of Safehip® [14] hip protectors for every resident agreeing to wear them—they could be replaced as required during the project.

Residents were ineligible to receive the hip protectors if they had pressure sores on the hip, were confined to bed 24 hours a day or were temporarily admitted for respite care. New eligible entrants into the home were also offered hip protectors and residents were encouraged to wear the protectors day and night, or as much as possible.

Outcome measures

The primary outcome of interest was fracture of the proximal femur (International Classification of Diseases codes S72.0, S72.1). Secondary outcome variables were pelvic fractures, other injurious falls (falls resulting in an injury requiring medical attention) and, in the intervention homes, adherence to wearing hip protectors (defined as being observed to wear the hip protectors when the nurse facilitator visited the home at 2, 4, 8, 12, 18 and 24 weeks, and every 8 weeks thereafter). Data on hip fractures in all homes were obtained and cross-referenced from three sources: information collected by the nurse facilitator during visits to the homes, information systems within local hospitals and mandatory accident reporting from homes to the RIU. Information on pelvic fractures was collected by the nurse facilitator and cross-checked against RIU records, and data on injurious falls were obtained from RIU records.

Statistical analysis

The required sample size was calculated on the basis of a reduction in the rate of hip fracture from 8.4% to 5% over 18 months (based on the results from two earlier studies [4, 15]), a ratio of control to intervention participants of 2:1, 80% power, and a significance level of 5%. The cluster design effect (calculated as 1.7) was determined using an average cluster size of 36 and an intraclass correlation coefficient of 0.02 (obtained by simulations of frequencies of fractures in homes) [16]. This gave target sample sizes of 1,217 participants in the intervention homes and 2,435 in the control homes. However, since each home (or cluster) was randomly allocated to either the intervention or control group, the appropriate unit of analysis is the home rather than the resident. Event rates per home were defined as the number of events (hip fractures, pelvic fractures and falls) occurring per occupied bed during the study period (504 days). Bed occupancy within each home was obtained on four occasions over the study period, from which the mean number of occupied beds was calculated. Mean fracture and fall rates were calculated for the intervention and control groups; to facilitate comparison, these are presented as mean fracture rates over the study period per 100 occupied beds. Crude and adjusted rate ratios were calculated (using Poisson regression including a correction for over-dispersion where appropriate), adjusting for the following home characteristics: client category (EMI or O&I, EMI or mixed EMI, and O&I), type of home (nursing or residential), size of home, whether the home was independent or part of a larger management group, number of injurious falls in the home during the study period, proportion of care quality standards met by the home (as measured by the RIU) and change of senior manager during the study period. All principal analyses were intention-to-treat analyses, using data from all 127 homes entered into the study, although subsidiary 'per protocol' analyses were also performed excluding homes that did not allow monitoring visits, or (for those in the intervention group) did not offer the hip protectors. A subgroup analysis was also undertaken, exploring an *a priori* hypothesis that the policy may be more effective in the homes providing care to EMI residents.

For the purposes of analysis, residents were identified as having adhered to using the hip protectors if they were seen by the nurse facilitator to be continuing to wear them at 24 weeks. Individual adherence data were then aggregated to the level of the home. All statistical analyses were carried out using STATA version 8.0 for Windows [17].

Ethical approval

Ethical approval was obtained from the Research Ethics Committee of the Queen's University of Belfast. Written informed consent was obtained from residents in the intervention homes. If a resident was mentally infirm, the next-of-kin was asked to consent to their relative participating in the study.

Results

One hundred and sixty-four nursing or residential homes were identified within the EHSSB area. Thirty-two homes refused to take part and five homes closed before the study began (Figure 1). One hundred and twenty-seven homes were therefore randomly allocated (within strata) achieving an approximate 1:2 ratio of intervention to control homes (Table 1). Seven homes ('low-cooperation' homes) in the intervention group and six in the control group did not cooperate fully with subsequent data collection and, in the case of the intervention group, with introducing the hip protectors (Figure 1). However, these homes did provide information on injurious falls and hip fractures. There were an average of 1,366 occupied beds in intervention homes and 2,751 in the control homes, providing an estimated 688,464 resident days of observation in the intervention group and 1,386,504 in the control group. There were 206 occupied beds in the low-cooperation homes in the intervention group and 105 in the low-cooperation homes in the control group.

Hip fractures

The results of the home level intention-to-treat analysis are presented in Table 2. Eighty-five residents in the intervention homes and 163 residents in the control homes suffered a hip fracture during the study period. Eleven (13%) of the 85 hip fractures within the intervention group occurred whilst the resident was wearing the hip protectors. The mean fracture rate per 100 residents was 6.22 (SD 4.8, range

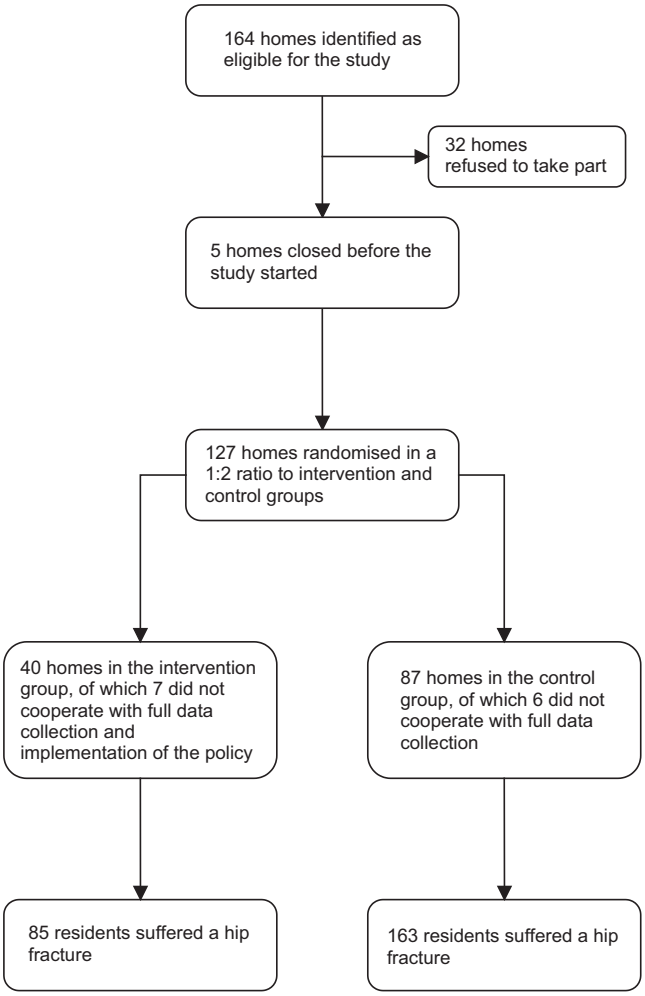

Figure 1. Flow of homes through the study.

0–22.6) in the intervention homes and 5.92 (SD 6.0, range 0–31.0) in the control homes (equivalent to rates of 4.50 and 4.29 hip fractures per 100 residents per year, respectively), giving an unadjusted rate ratio for the intervention group compared to the control group of 1.05 (95% CI 0.76, 1.45; $P=0.76$). Adjustment for home characteristics did not substantially alter the rate ratio or the confidence intervals.

When the analysis was repeated using only data from the 114 homes that followed the study protocol, a small reduction in hip fracture risk was seen in intervention compared to control homes but this did not achieve statistical significance at the 5% level (Adjusted Rate Ratio (ARR) 0.93, 95% CI 0.66, 1.31; $P=0.69$). The policy of offering hip protectors was not associated with a reduced rate of hip fractures when the Poisson regression analysis was repeated for the 32 homes designated as EMI or mixed EMI and O&I.

In the multivariable Poisson regression model (all homes), the following home characteristics were associated with an increased rate of hip fracture: EMI rather than O&I (ARR 1.98, 95% CI 1.38, 2.86; $P<0.0005$); EMI rather than mixed O&I and EMI (ARR 1.5, 95% CI 0.95, 2.38; $P=0.084$) and being part of a managed group of homes rather than an independent home (ARR 1.42, 95% CI 0.89, 2.05; $P=0.058$).

Pelvic fractures

There were 18 pelvic fractures recorded during the study: 6 in the control group, 12 in the intervention group, including 2 where the resident was reported to be wearing the hip protectors at the time of the fracture (Table 2). An increased pelvic fracture rate was seen in the intervention group in both the intention-to-treat analysis (ARR 4.03, 95% CI 1.48, 10.96; $P=0.006$) and the per-protocol analysis (ARR 4.95, 95% CI 1.80, 13.61; $P=0.002$).

Injurious falls

Seventy-three injurious falls were recorded in intervention homes and 122 in control homes (Table 2), giving an adjusted rate ratio in the intervention group of 1.16 (95% CI 0.77, 1.76; $P=0.48$) in the intention-to-treat analysis and 1.07 (95% CI 0.68, 1.70; $P=0.76$) in the per-protocol analysis. An increase in the rate of injurious falls was seen in residential homes compared with nursing homes (ARR 1.76, 95% CI 1.12, 2.78; $P=0.015$) and in homes with 30 or more beds compared with smaller homes (ARR 1.80, 95% CI 0.93, 3.46; $P=0.079$), but not in EMI homes compared with O&I or mixed homes.

Initial acceptance of the hip protectors and adherence to their use

Initial acceptance and continued adherence were measured by taking as the numerator the total number of residents

Table 2. Rates of hip fracture, pelvic fracture and injurious falls per home – intention to treat

Event	Intervention	Control	Unadjusted Rate Ratio (95% CI)	Adjusted Rate Ratio (95% CI)*
Number of hip fractures	85	163		
Mean [SD, Range] hip fracture rate per 100 occupied beds	6.22 [4.83, 0–22.64]	5.92 [6.03, 0–31.0]	1.05 (0.76, 1.45)	1.05 (0.77, 1.43)
Number of pelvic fractures	12	6		
Rate [SD, Range] per 100 occupied beds	0.88 [1.56, 0–6.19]	0.22 [1.11, 0–7.55]	4.03 (1.51, 10.74)	4.03 (1.48, 10.96)
Number of injurious falls †	73	122		
Rate [SD, Range] per 100 occupied beds	5.35 [5.45, 0–22.88]	4.43 [5.91, 0–29.17]	1.21 (0.79, 1.83)	1.16 (0.77, 1.76)

*95% CI adjusted for home characteristics, client category (EMI or O&I; EMI or mixed EMI and O&I), type of home (nursing or residential), size of home, whether the home was independent or part of a larger management group, number of injurious falls in the home during the study period, number of care quality standards met by the home (as measured by the RIU), and change of senior manager during the study period.

† Falls resulting in an injury requiring medical attention (excluding hip fractures).

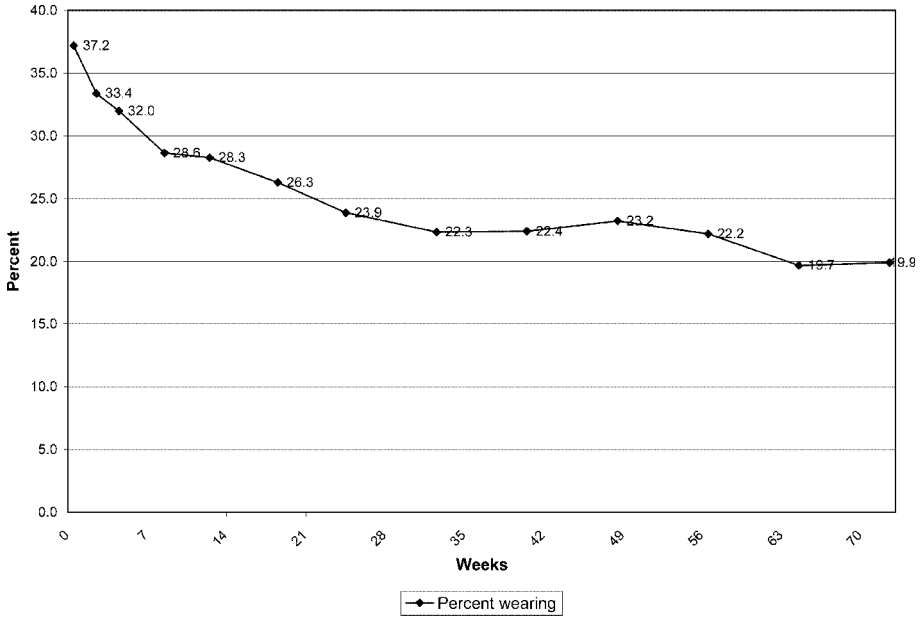

Figure 2. Residents wearing the hip protectors at each observation point as a percentage of all (n = 1,366) occupied beds.

wearing the hip protectors at any observation point and as the denominator the mean number of occupied beds in the intervention group (=1,366). This gives figures for initial acceptance of 508/1,366 (37.2%); and adherence of 326/1,366 (23.9%) at 24 weeks; 317/1,366 (23.2%) at 48 weeks; and 272/1366 (19.9%) at 72 weeks (Figure 2). In the control group, 24 (0.9%) of the estimated 2,751 residents occupying the homes at the start of the study were reported to be already wearing hip protectors.

Discussion

Earlier research supported the efficacy of hip protectors [4–8]. In the light of this evidence, the aim of this study was to assess the effectiveness of a policy of providing hip protectors free of charge to the residents of nursing and residential homes in order to reduce the incidence of hip fracture. The study was not designed to assess the efficacy of providing hip protectors on a case-by-case basis to particular individuals. As the policy was to be implemented at the level of the home it was appropriate to randomise homes rather than individuals. Because the policy failed in those homes that did not fully introduce the intervention, it was appropriate to include them in an intention-to-treat analysis. It is possible that some homes failed to introduce the intervention properly because participation in the research project was voluntary and sanctions could not be imposed. However, the project was both funded and strongly endorsed by the EHSSB, which funds the care of the majority of residents in the homes participating in the study. The study was also undertaken under the auspices of the RIU, which is the body that monitors, inspects and governs practice within these homes, and which licenses the homes to provide care to EHSSB residents. Therefore, it is likely that a similar degree of low cooperation would be present if commissioners of health care introduced such a policy.

The study has shown that the policy of making hip protectors available free of charge to residents of nursing and residential homes, and supporting the implementation of the policy using an affordable evidence-based approach, is not effective in reducing rates of hip fractures. There are a number of possible explanations for the failure of the policy. It is clear that the hip protectors did not always prevent a hip fracture in the event of a fall, as 13% of fractures in residents of intervention homes occurred while protectors were being worn. Most studies report no hip fractures whilst hip protectors are worn but two studies which did so report rates of 31% [7] and 19% [18]. Further development is needed to increase the force-attenuating properties of hip protectors.

Low levels of adherence to wearing hip protectors have undoubtedly contributed to the ineffectiveness of the policy. However, the level of adherence achieved in this study is consistent with that achieved in other trials of hip protectors, although it is difficult to make definitive comparisons as adherence has been measured in many different ways [11]. The method employed to introduce the policy into the intervention homes was designed to be both evidence-based and replicable within a normal service environment. It may be that the policy could have been implemented more effectively and greater use of hip protectors achieved had greater resources been available. However, what is arguably the most comprehensive approach to introducing hip protectors described in the literature to date achieved an initial acceptance of only 43% and adherence of ~30% at 6 months [19] (compared with figures of 37.2% and 23.9%, respectively, in our study). This intensive approach required greater resources than are likely to be available in an everyday service environment. Further research is required to identify methods of improving the acceptability of hip protectors without incurring prohibitive costs.

It is possible that the policy failed because those most at risk of hip fracture were not those most likely to wear hip

protectors. The educational session for staff focused on identifying resident characteristics known to be associated with an increased risk of hip fracture (especially female sex, cognitive impairment and a history of falls). However, these risk factors characterise the great majority of residents, and as a group they are recognised as being at high risk [20], so further targetting of individuals was not deemed to be appropriate.

Our data suggest that the policy was not only ineffective in reducing hip fracture rates, but was also associated with increased rates of pelvic fracture. However, only two of the 12 pelvic fractures occurred when the hip protector was reported to be worn, which appears to rule out a direct effect of the protectors. Another possibility is that staff or residents in the intervention homes took fewer precautions to prevent falls than those in control homes [21]. However, no increase in injurious falls was seen in the intervention group. In view of the small number of pelvic fractures sustained during the trial it is prudent to interpret this finding cautiously.

Most trials have reported a significant reduction in the rate of hip fracture when hip protectors were used [4–8, 22], but several of these studies were small [5, 6, 8] and others randomised clusters, but employed individual level analyses [4, 7, 15]. However, it appears that the main reason for a difference between our findings and those of other investigators is that our policy trial was undertaken within a very broad health care setting and employed methods that could be replicated in standard practice. It is interesting to note that our findings are in keeping with those of two recent trials of hip protectors, one cluster randomised [18] and the other randomised by individual [23].

Conclusions

We have been unable to show that a policy of making Safehip® hip protectors available to residents of nursing and residential homes is an effective method of preventing hip fractures. Until more efficacious hip protectors are available, and until more is known about how adherence to their use can be improved, health care commissioners should not provide hip protectors free of charge to this group.

Key points

- Following promising results from early trials, the efficacy and effectiveness of hip protectors have not been established. Randomised controlled trials have often been underpowered and sometimes randomised by cluster but analysed by individual. Nevertheless, hip protectors continue to be recommended in the effectiveness literature.
- This large, cluster randomised study suggests that a policy of offering hip protectors free of charge to residents of nursing and residential homes, using an evidence-based approach to the implementation of the policy, does not result in a reduction in the rate of hip fracture.
- Until more efficacious hip protectors are available, and until more is known about how adherence to their use can be improved, health care commissioners should not provide hip protectors free of charge to this population.

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Competing interest statement

Robinson Healthcare Ltd (UK suppliers of Safehip® Hip Protectors) contributed £2,000 to the costs of making the promotional video and provided other promotional materials for use in the homes. They subsequently paid £500 for the right to reproduce the video for promotional purposes. This money is held by the School of Nursing at Queen's University for use in further research by P.D.O.

Guarantor

The corresponding author (P.D.O.) had full access to all the data in the study and has final responsibility for the decision to submit for publication.

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