ELPS

This is an abridged version; the full version is on bmj.com

Effect on hip fractures of increased use of hip protectors in nursing homes: cluster randomised controlled trial

Gabriele Meyer, Andrea Warnke, R Bender, I Mühlhauser

Unit of Health Sciences and Education, University of Hamburg, Martin-Luther-King-Platz 6, D-20146 Hamburg, Germany
Gabriele Meyer *research fellow*
Andrea Warnke *research assistant*
I Mühlhauser *professor*

Department of Epidemiology and Medical Statistics, School of Public Health, University of Bielefeld, PO Box 10 01 31, D-33501 Bielefeld, Germany
R Bender *statistician*

Correspondence to: Mühlhauser Ingrid_Muehlhauser@uni-hamburg.de

BMJ 2003;326:76–8

Abstract

Objective To assess the effects of an intervention programme designed to increase use of hip protectors in elderly people in nursing homes.
Design Cluster randomised controlled trial with 18 months of follow up.
Setting Nursing homes in Hamburg (25 clusters in intervention group; 24 in control group).
Participants Residents with a high risk of falling (459 in intervention group; 483 in control group).
Intervention Single education session for nursing staff, who then educated residents; provision of three hip protectors per resident in intervention group. Usual care optimised by brief information to nursing staff about hip protectors and provision of two hip protectors per cluster for demonstration purposes.
Main outcome measure Incidence of hip fractures.
Results Mean follow up was 15 months for the intervention group and 14 months for the control group. In total 167 residents in the intervention group and 207 in the control group died or moved away. There were 21 hip fractures in 21 (4.6%) residents in the intervention group and 42 hip fractures in 39 (8.1%) residents in the control group (relative risk 0.57, absolute risk difference −3.5%, 95% confidence interval −7.3% to 0.3%, P=0.072). After adjustment for the cluster randomisation the proportions of fallers who used a hip protector were 68% and 15% respectively (mean difference 53%, 38% to 67%, P=0.0001). There were 39 other fractures in the intervention group and 38 in the control group.
Conclusion The introduction of a structured education programme and the provision of free hip protectors in nursing homes increases the use of protectors and may reduce the number of hip fractures.

Introduction

Hip fractures are a major cause of disability and functional impairment among elderly people.[1] Trials of hip protectors in nursing homes have reported a reduction of 50% in the incidence of hip fracture.[2] In general, however, the acceptance of hip protectors is poor.[3] We developed a two part intervention, consisting of structured theory based education and provision of free equipment, directed at nursing staff and residents to encourage the use of hip protectors. We evaluated whether there were fewer hip fractures among elderly people in nursing homes that received the intervention programme compared with those in nursing homes with optimised usual care.

Participants and methods

Nursing homes and residents

All 86 nursing homes in Hamburg with at least 70 residents were invited and 42 agreed to participate. The 42 homes made up 49 clusters, since we defined a cluster as a nursing home by itself or an independently working ward of a large nursing home (see figure). In each cluster a study coordinator was nominated. The nursing staff selected 15 to 30 residents according to predefined inclusion criteria: ⩾70 years old, not bedridden, and living in the nursing home for more than three months.

Randomisation

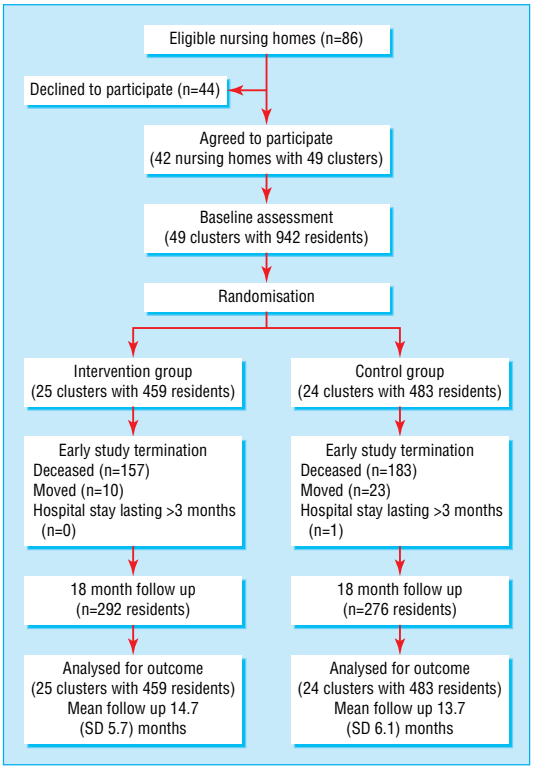
We used computer generated randomisation lists for concealed allocation of clusters by external central telephone.

Intervention

In homes allocated to usual care (control group) the nominated study coordinator received brief information (10 minutes) about and demonstration of the hip protector, and two hip protectors were provided for demonstration purposes.

The intervention (intervention group) consisted of structured education of staff, who then taught residents, and provision of free hip protectors. We provided three hip protectors per resident (Safehip (Tytex, Denmark), the only evaluated hip protector available at the start of the study[3]).

The education session lasted for 60-90 minutes, took place in small groups (average 12 members of staff from each cluster), and was delivered by two inves-



Flow of nursing home clusters and participants through trial

Table 1 Fracture data

	Intervention group (n=459)*	Control group (n=483)†	Relative risk	Absolute risk difference‡ (95% CI§)	P value§ (adjusted χ^2 test)
No of hip fractures	21	42	—	—	—
No (%) of residents with hip fractures	21 (4.6)	39 (8.1)	0.57	–3.5% (–7.3% to 0.3%)	0.072
No of other fractures	39	38	—	—	—
No (%) of residents with other fractures	35 (7.6)	32 (6.6)	1.15	1.0% (–4.0% to 6.0%)	0.695

*Mean follow up 15 months.
†Mean follow up 14 months.
‡Intervention minus control.
§Calculated according to methods of Donner and Klar,[4] which take cluster randomisation into account.

tigators. It covered information about the risk of hip fracture and related morbidity; strategies to prevent falls and fractures; effectiveness of hip protectors; relevant aspects known to interfere with the use of protector, such as aesthetics, comfort, fit, and handling; and strategies for successful implementation.

At least one nurse from each intervention cluster was then responsible for delivering the same education programme to residents individually or in small groups.

Study outcomes

Nursing staff used a specially developed documentation sheet on falls to collect outcome variables. We checked data every two months during personal visits. At the end of the study, one investigator and the nominated study coordinator from each cluster reviewed all records to verify the completeness of data.

Our primary outcome variable was hip fracture. Secondary outcome measure was use of hip protectors expressed as the proportion of falls with documented use of the protector and the proportion of fallers with documented use of the protector during at least one fall. Reasons for non-adherence were registered. We also recorded frequency of falls; other fractures related to falls; hospital admissions and consultations with a physician related to falls irrespective of the reason for falls.

Statistical methods

We analysed the main outcome "hip fracture" and the variable "other fractures" with χ^2 test adjusted for cluster randomisation.[4] For all other follow up data we used the cluster as the unit of analysis.

Results

The figure shows the flow of study clusters and participants through the trial. Baseline characteristics of clusters and residents were similar between the study groups including: age, sex, level of disability, and history of fractures and falls. Data on fractures are summarised in table 1. The relative risk of hip fractures was 0.57 and the difference in absolute risk was −3.5%, 95% confidence interval −7.3% to 0.3%, P=0.072; number needed to treat=29 (number needed to treat to benefit 14 to ∞, number needed to treat to be harmed 350). Frequency of other fractures (table 1) and falls (table 2) were not significantly different between groups. After we adjusted for cluster randomisation hip protectors were used on average by 15% of people who fell in the control group compared with 68% in the intervention group (40/274 *v* 158/237, P=0.0001) (table 2). There were more hospital admissions related to falls in the control

Table 2 Falls, use of hip protectors, and medical attention related to falls during study period. Values are means (SD) unless stated otherwise

Variables	Intervention group (25 clusters, 459 residents)	Control group (24 clusters, 483 residents)	Mean difference between groups* (95% CI)†	P value† (Wilcoxon rank sum test)
Fallers and falls‡				
Residents with ⩾1 fall	237	274		
Proportion of fallers	0.50 (0.20)	0.56 (0.16)	–0.06 (–0.16 to 0.05)	0.32
No of falls	946	1409		
Falls per resident	1.99 (1.53)	2.79 (2.07)	–0.80 (–1.85 to 0.24)	0.14
Falls per resident per month	0.17 (0.13)	0.22 (0.15)	–0.05 (–0.13 to 0.03)	0.23
Use of hip protectors				
Residents who used hip protector	158/459 (34%)	40/483 (8%)		
Proportion of residents who used hip protector	0.35 (0.21)	0.08 (0.12)	0.27 (0.17 to 0.36)	<0.0001
Fallers who used hip protector	158/237 (67%)	40/274 (15%)		
Proportion of fallers who used hip protector	0.68 (0.26)	0.15 (0.25)	0.53 (0.38 to 0.67)	<0.0001
Falls in which hip protector was used	552/946 (58%)	160/1409 (11%)		
Proportion of falls in which hip protector was used	0.54 (0.25)	0.08 (0.15)	0.46 (0.34 to 0.59)	<0.0001
Medical attention related to falls				
Residents with ⩾1 hospital admission	96	135		
No of admissions	121	211		
Admissions per resident	0.26 (0.16)	0.46 (0.33)	–0.20 (–0.35 to –0.05)	0.015
Admissions per faller	0.58 (0.37)	0.81 (0.54)	–0.23 (–0.50 to 0.04)	0.12
Residents with ⩾1 consultation with physician	93	119		
No of consultations	117	234		
Consultations per resident	0.25 (0.16)	0.47 (0.55)	–0.22 (–0.45 to 0.01)	0.27
Consultations per faller	0.51 (0.25)	0.81 (0.96)	–0.30 (–0.70 to 0.10)	0.61

*Intervention minus control.
†Confidence intervals and P values calculated on basis of data summarised at cluster level.
‡Fall data of one control cluster with 15 residents not available.

What is already known on this topic

Nursing home residents are at particularly high risk of fracturing a hip

Hip protectors can effectively prevent hip fractures

Adherence to the use of hip protectors is poor

What this study adds

The use of hip protectors in nursing homes can be substantially increased by a single session education targeted at nursing staff and residents and provision of free hip protectors

Increasing the use of hip protectors resulted in a relative reduction of hip fractures of about 40%

group than in the intervention group (P=0.015), whereas the difference in consultations was not significant (P=0.27) (table 2).

Discussion

We have shown that the use of hip protectors can be substantially increased among residents in nursing homes, resulting in a relative reduction of hip fractures of more than 40% at borderline significance. The intervention comprised structured education of nursing staff, encouragement of residents to use the protector, and provision of hip protectors free of charge.

It is difficult to compare adherence to use of hip protectors across different studies.[3 5–10] There is no generally accepted definition of adherence, and methods of assessment differ. Preselection of participants is a further source of variation. For example, Kannus et al included only residents who agreed to wear the protector.[7] They reported that in 74% of falls the hip protector had been worn. In our study the programme was offered to all eligible residents in those homes allocated to the intervention group. This approach resulted in the use of protectors during 54% of falls compared with 8% in the control group (proportions adjusted for cluster randomisation). Lauritzen et al found a compliance rate of 24% associated with a 56% reduction in hip fractures.[3] This finding was explained by a preferential use of the protector by residents at the highest risk and with the highest possible benefit.

The apparent benefit of a lower rate of hospital admissions related to falls in the intervention group should not be overinterpreted, as there was a trend of fewer falls in the intervention group that remains open to various explanations.

The present study has several strengths. To avoid violation of randomisation and selection bias we did not exclude data from participants who declined to use the hip protector. In contrast with former studies[3 5 8 9] we used properly concealed allocation. Cluster randomisation was essential because the intervention programme relied on changes to nursing techniques. We also recruited a large number of clusters and performed statistical analyses taking cluster randomisation into account.

In conclusion, we have shown that a structured education programme and provision of free hip protectors can increase use, and protect residents from hip fracture. Long term implementation of the intervention requires the provision of hip protectors on prescription for elderly people at high risk of hip fracture.

We thank the study coordinators, nursing staff, and participating residents of 49 nursing home clusters in Hamburg; Hubert Overmann, University Düsseldorf, for the external allocation of clusters; and Anke Delakowitz and Brigitte Gerloff for assistance in data collection and administration.

Contributors: See bmj.com

Funding: Public Health Research Network Northern Germany (project TP III-1). Rölke Pharma (Hamburg, Germany) provided the hip protectors for this study and has given a grant to the University of Hamburg.

Competing interests: AW was formerly an employee and is at present a consultant of Rölke Pharma, the German distributor of Safehip. AW and GM have received travel grants from Rölke Pharma.

1 Keene GS, Parker MJ, Pryor GA. Mortality and morbidity after hip fractures. *BMJ* 1993;307:1248-50.
2 Parker MJ, Gillespie LD, Gillespie WJ. Hip protectors for preventing hip fractures in the elderly. *Cochrane Database Syst Rev* 2002;4:CD001255.
3 Lauritzen JB, Petersen MM, Lund B. Effect of external hip protectors on hip fractures. *Lancet* 1993;341:11-3.
4 Donner A, Klar N. Methods for comparing event rates in intervention studies when the unit of allocation is a cluster. *Am J Epidemiol* 1994;140:279-89.
5 Ekman A, Mallmin H, Michaelsson K, Ljunghall S. External hip protectors to prevent osteoporotic hip fractures. *Lancet* 1997;350:563-4.
6 Cameron ID, Venman J, Kurrle SE, Lockwood K, Birks C, Cumming RG, et al. Hip protectors in aged-care facilities: a randomized trial of use by individual higher-risk residents. *Age Ageing* 2001;30:477-81.
7 Kannus P, Parkkari J, Niemi S, Pasanen M, Palvanen M, Järvinen M, et al. Prevention of hip fracture in elderly people with use of a hip protector. *N Engl J Med* 2000;343:1506-13.
8 Chan DK, Hillier G, Coore M, Cooke R, Monk R, Mills J, et al. Effectiveness and acceptability of a newly designed hip protector: a pilot study. *Arch Gerontol Geriatr* 2000;30:25-34.
9 Villar MTA, Hill P, Inskip H, Thompson P, Cooper C. Will elderly rest home residents wear hip protectors? *Age Ageing* 1998;27:195-8.
10 Parkkari J, Heikkilä J, Kannus P. Acceptability and compliance with wearing energy-shunting hip protectors: a 6-month prospective follow-up in a Finnish nursing home. *Age Ageing* 1998;27:225-9.

(Accepted 17 October 2002)

One hundred years ago

Lord Balfour and vaccination

THE antivaccination party has never had much success in Scotland, and this week it has met with a very decided rebuff from Lord Balfour, Secretary of State for Scotland. The Antivaccination League had asked for an interview with him in the hopes of obtaining some support in its effort to obtain for Scotland the "benefits" of the English Act granting exemption from prosecution to "the conscientious objector." Their request was granted, but they gained nothing whatever by it. In reply to the deputation which represented the League, Lord Balfour said that the benefits of vaccination seemed to him to be proved up to the hilt, and that whatever damage, if any, it might cause in individual cases was far outweighed by its general public utility. Such risks as might be alleged to exist were a constantly diminishing quantity, owing to the improvements that were introduced into the processes of vaccination. The proved evils were so infinitesimal as compared with the great protection afforded by it, that he considered the State was not only entitled, but morally bound, to do everything in its power to ensure efficient performance of vaccination.

(*BMJ* 1903;i:923)