Prevention of falls in the elderly trial (PROFET): a randomised controlled trial

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Summary

Background Falls in elderly people are a common presenting complaint to accident and emergency departments. Current practice commonly focuses on the injury, with little systematic assessment of the underlying cause, functional consequences, and possibilities for future prevention. We undertook a randomised controlled study to assess the benefit of a structured inderdisciplinary assessment of people who have fallen in terms of further falls.

Methods Eligible patients were aged 65 years and older, lived in the community, and presented to an accident and emergency department with a fall. Patients assigned to the intervention group (n=184) underwent a detailed medical and occupational-therapy assessment with referral to relevant services if indicated; those assigned to the control group (n=213) received usual care only. The analyses were by intention to treat. Follow-up data were collected every 4 months for 1 year.

Findings At 12-month follow-up, 77% of both groups remained in the study. The total reported number of falls during this period was 183 in the intervention group compared with 510 in the control group (p=0·0002). The risk of falling was significantly reduced in the intervention group (odds ratio 0·39 [95% CI 0·23–0·66]) as was the risk of recurrent falls (0·33 [0·16–0·68]). In addition, the odds of admission to hospital were lower in the intervention group (0·61 [0·35–1·05]) whereas the decline in Barthel score with time was greater in the control group (p<0·00001).

Interpretation The study shows that an interdisciplinary approach to this high-risk population can significantly decrease the risk of further falls and limit functional impairment.

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Introduction

There is a need for strategies to prevent falls in older people.[1,2] The cost of falling is high both to the individual in terms of physical[3,4] and psychological trauma,[5] loss of independence,[6,7] or even death,[8,9] and to health and allied services[8,10,11] in terms of resources and bed occupancy.

There is still no agreed approach to the management of elderly people who fall, and previous studies have produced conflicting results.[12–20] Direct comparison between studies is hampered by differences in methods, lack of clarity in definition, and differences in study populations and intervention strategies.

8% of people aged 70 years and above seek care in accident and emergency departments each year for fall-related injuries,[7] and of these, 30–40% are admitted to hospital.[21] About 50% of elderly patients discharged from accident and emergency departments show an increase in dependency,[6,22] in many cases related to trauma; yet the emergency department records make little reference to functional ability and support services are underused.[6] Although accident and emergency departments are a prime location for identification of functional problems and referral of patients, previous studies have shown important underdiagnosis of remediable problems in older people.[23]

We did a randomised controlled study to ascertain whether a structured bidisciplinary assessment of elderly people, who live in the community and attend an accident and emergency department with a primary diagnosis of a fall, could alter outcome and decrease the rate of further falls during the 12-month follow-up period. Secondary endpoints were death, major injury, moves to institutional care, functional status, and use of health care.

Patients and methods

Participants

We recruited patients between December, 1995, and the end of June, 1996. All patients aged 65 years and above, who lived in the local community and attended the accident and emergency department with a primary diagnosis of a fall were potentially eligible. Formal ethics committee approval was obtained for the study. We excluded patients with cognitive impairment defined as a score on the abbreviated mental test (AMT)[24] of less than 7 and with no regular carer because of difficulties with informed consent and accurate recall of events. Patients, who did not live locally or spoke little or no English, were excluded for practical reasons. A fall was defined as: inadvertently coming to rest on the ground or other lower level with or without loss of consciousness and other than as a consequence of sudden onset of paralysis, epileptic seizure, excess alcohol intake, or overwhelming external force.

Potential participants were identified by a computerised registration system in which all patients attending the accident and emergency department are listed in chronological order. The records of all patients fulfilling the selection criteria were reviewed regularly by a physician (JC) to ensure systematic identification.

We wrote to the patients who were discharged home after their fall, enclosing an information sheet about the study. We then contacted them by telephone 2–3 days later to answer questions about the study. Verbal consent was obtained and baseline data were collected within 7 days of the fall.

For patients with no telephone, we sent a similar letter and included a stamped addressed envelope with the offer of a home visit for collection of baseline data.

Patients admitted to hospital as a result of their fall were identified but not recruited until discharge from hospital so that clinical inpatient management of these patients was not influenced.

Methods

Baseline information, collected before randomisation by the physician (JC), consisted of a detailed history of the fall, any previous falls, concurrent disorders, drug history, functional ability before the fall, cognitive assessment, and sociodemographic details.

Randomisation was by a random-numbers table, and the list was held independently of the investigators. Participants were randomly assigned to the intervention group, which underwent detailed medical and occupational-therapy assessment and referral to relevant services if indicated, or to the control group, which underwent no such assessment. Each participant was given a "falls diary" with 12 monthly sheets to assist with the recall of further falls.

Medical assessment

The examination, undertaken in the day hospital, was a comprehensive general examination, but in addition focused on a more detailed assessment of visual acuity, balance, cognition, affect, and prescribing practice. Postural hypotension was defined as a symptomatic decrease in systolic blood pressure of 20 mm Hg or more, as the patient rose from lying to standing.[25] Visual acuity was assessed with a Snellen chart, and the patient was defined as having impaired vision if the acuity was 6/12 or worse in either eye, being partially sighted if corrected vision in both eyes was 6/24 or worse, or being blind if acuity was 6/60 or worse in both eyes. Poor binocular vision was defined as a disparity in acuity between eyes of two lines or more on the Snellen chart. We tested balance by asking the patient to stand on one leg;[4] impaired balance was defined as an inability to stand on one leg for more than 10 s. We used the Folstein mini mental state examination[26] to assess cognition (a score of $\leqslant$26 was taken as evidence of cognitive impairment) and the modified geriatric depression scale[27] to assess affect (a score of $\geqslant$6 indicated possible underlying depression). Carotid sinus studies were undertaken if the cause of the fall was unclear or clinical suspicion was high.

On completion of the assessment and in conjunction with the baseline data, a primary cause for the index fall was assigned, and identified risk factors were modified if possible. If further investigation, assessment, or follow-up was thought to be necessary a referral was made to the relevant service and the examination findings and the recommended course of action were detailed. If multidisciplinary input was thought to be appropriate, a referral was made to the day hospital. Drug modification was achieved by direct contact with the general practitioner.

There was no further medical input from the physician after the assessment.

Occupational-therapy assessment

A single home visit was undertaken by an occupational therapist after the medical assessment. Function was assessed with the Barthel index[28] and supplemented for descriptive purposes only by a modified version of the functional independence and functional assessment measures.[29] Environmental hazards were identified and documented with a checklist designed by the Health and Safety Executive, UK. The falls handicap inventory[30] was used as an indirect marker of the psychological consequences of the fall. 18 questions on health, function, and emotion produce a maximum score of 72.

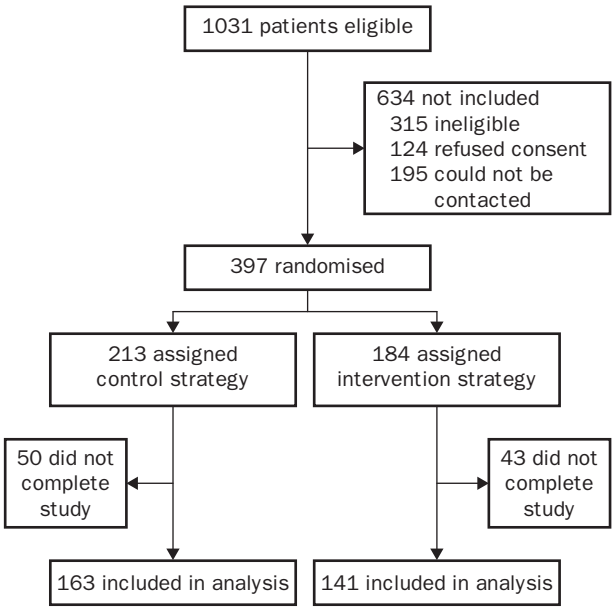

Figure 1: **Trial profile**

On completion of the assessment, advice and education was given about safety within the home, and modifications such as removal of loose rugs were made with the patient's consent. Minor equipment was supplied directly by the occupational therapist, and patients who required hand rails, other technical aids, adaptions, or additional support were referred to social or hospital services in the usual way.

Follow-up

Follow-up was done by postal questionnaire, which was sent to all participants every 4 months for 1 year after the fall. Information about subsequent falls, fall-related injury, and details of doctor and hospital visits or admissions and degree of function were requested.

Statistical analysis

Based on an average of two falls per year with an SD of 1·5 and a 25% rate of attrition, a sample size of 352 would have 90% power to detect a 30% reduction in the rate of falls from 2·0 to 1·4 in the intervention group with a probability of $p<0·05$.

At 12-month follow-up, patients were classified according to whether they had died, moved to institutional care, were otherwise lost to follow-up, or remained in the study. This status at follow-up was compared in the two study groups by means of a χ^2 test. Participants who remained in the study at 12 months were included in subsequent analyses.

We compared the two groups in terms of number of falls and serious injuries (fracture or joint dislocation) by Mann-Whitney tests, and reported ability to go out alone by χ^2 test. Differences between groups were compared after adjustment for baseline differences in Barthel index and AMT scores, by multiple logistic regression. For the analyses of risk of falling and risk of

	Number (% of total)	Mean (SD) age (years)	Female	Admitted
All patients	1031	78·2 (7·6)	694 (67%)	317 (31%)
Randomised	397 (39%)	78·2 (7·5)	269 (68%)	147 (37%)
Not randomised				
Institutional care	117 (11%)	82·3 (7·1)	85 (73%)	46 (39%)
Dementia	60 (6%)	84·2 (6·2)	48 (80%)	36 (60%)
Refused consent	124 (12%)	76·9 (7·4)	94 (76%)	12 (10%)
No contact	195 (19%)	76·9 (7·2)	122 (63%)	29 (15%)
Other	138 (13%)	75·3 (7·0)	76 (55%)	47 (34%)

Table 1: **Baseline comparison of all eligible patients**

recurrent falling, the number of falls in the previous year was also included as a covariate. Similarly, for the analysis of reported ability to go out at 12 months, reported ability to go out at baseline was included as an additional covariate.

Barthel scores during follow-up in the two study groups were compared by repeated-measures ANCOVA with baseline Barthel scores as the covariate.

Results

Demography

1031 consecutive patients aged 65 years or older attended the accident and emergency department with a primary diagnosis of a fall during the recruitment period (figure 1). This total represents 20% of all attendees and 14% of emergency admissions for this age-group. The ultimately randomised number of patients was 397 (39%). The commonest reason for not proceeding to randomisation was inabilty to contact patients after the attendance at the accident and emergency department. Table 1 summarises the reasons for exclusion of the remaining patients and shows the distributions of age, sex, and hospital admission in the different categories for comparison.

The discrepancy in numbers between intervention and control groups is attributable to chance and consistent with the use of random-number tables. Barthel index and AMT scores were slightly higher in the intervention group than in the control group (table 2).

Medical assessment

152 (83%) medical assessments were undertaken, and most were completed within 3 weeks of the index fall. Of the 32 patients who did not attend for assessment, eight had died, five had moved into institutional care, and 19 gave no reason but were willing to complete the follow-up questionnaire.

Examination revealed many different disorders. 26 (17%) patients had evidence of one or more cardiovascular or circulatory disorders which was likely to have contributed to their fall, such as symptomatic postural hypotension, compromising cardiac arrhythmias, carotid sinus syndrome, and documented pacemaker failure.

Characteristic	Control group (n=213)	Intervention group (n=184)
Demography		
Mean (SD) age (years)	78·9 (7·6)	77·3 (7·4)
Female	143 (67%)	125 (68%)
Outcome		
Admitted (%) (day)	79 (37)	70 (38)
Median (range) length of stay (days)	17 (1–117)	16 (1–221)
Fall history		
Fall in previous year	141 (66%)	118 (64%)
Recurent falls	64 (30%)	49 (27%)
Fell within home	128 (60%)	101 (55%)
Reported cause of fall		
Slip/trip	104 (49%)	89 (48%)
Dizzy spell	40 (19%)	32 (17%)
Loss of consciousness	49 (23%)	45 (25%)
Palpitations	7 (3%)	3 (2%)
Unclear	38 (18%)	36 (20%)
After fall		
Major injury	79 (37%)	70 (38%)
Able to go out alone	168 (79%)	146 (80%)
Mean (SD) psychological results		
Barthel index	18·7 (2·1)	19 (1·6)
AMT score	8·4 (1·5)	8·6 (1·5)
Lives alone	129 (61%)	114 (62%)

*Three or more falls in last year.

Table 2: **Baseline comparison of patients according to treatment group**

	Control group (n=213)	Intervention group (n=184)	p
Study status			
In study	163 (77%)	141 (77%)	0·81
Moved to institutional care	18 (8%)	18 (10%)	
Dead	27 (13%)	19 (10%)	
Lost to follow up	5 (2%)	6 (3%)	
Falls			
Cumulative number of falls	510	183	0·0002
Patients reporting falls	111 (52%)	59 (32%)	
Patients reporting three or more falls	55 (26%)	21 (11%)	
Patients reporting serious injury from falls	16 (8%)	8 (4%)	0·26
Able to go out alone	106 (65%)	108 (77%)	0·04
Mean (SD) Barthel score	17·3 (3·7)	18·6 (2·5)	
Resource utilisation			
GP visits	668	487	0·33
Hospital visits	524	438	0·55
Hospital admission	97	69	0·78

GP=general practitioner.

Table 3: **Results of 1-year follow-up**

89 (59%) patients had visual impairment, 94 (62%) had poor stereoscopic vision, and 53 (35%) had cataract formation in one or both eyes.

42 (28%) patients had decreased leg power whereas 30 (20%) had peripheral neuropathy. 109 (72%) patients were unable to stand on one leg with eyes open for more than 10 s. 51 (34%) patients had cognitive impairment and 28 (18%) scored more than 5 on the geriatric depression scale.

Occupational-therapy assessment

One occupational-therapy home assessment was undertaken in each of the 140 patients of the intervention group. 12 patients who had undergone a medical assessment declined the home assessment.

The mean Barthel score after the fall was 18 (SD 2·5); only 59 (42%) patients attained a score of 20.

The most common environmental hazards at the time of the fall were uneven outdoor surfaces, change in surface level, ramps or steps, inappropriate floor covering, and unsuitable footwear.

The median falls handicap score was 19, and only ten (7%) patients denied any handicap after the index fall.

Outcome of assessments

After completion of the assessments, a primary attributable cause was assigned in 110 (72%) of the patients. 11 falls were the result of ice on the pavement, 44 were due to external environmental hazards, 29 to internal environmental hazards, 26 to cardiovascular or circulatory disorders, and two to drugs. The cause in the remainng falls was unclear or a result of several factors.

The bidisciplinary assessment resulted in 67 referrals to hospital outpatient departments and 38 referrals to the day hospital. Follow-up by the general practitioner was recommended in 33 patients, (16 for drug modification), and a visit to an optician was suggested in 27 cases. In only 24 (16%) of the assessments no further action was required.

Follow-up

At 12-month follow-up, 163 (77%) of 213 in the control group and 141 (77%) of 184 in the intervention group remained in the study (table 3). The control and intervention groups did not differ significantly in the

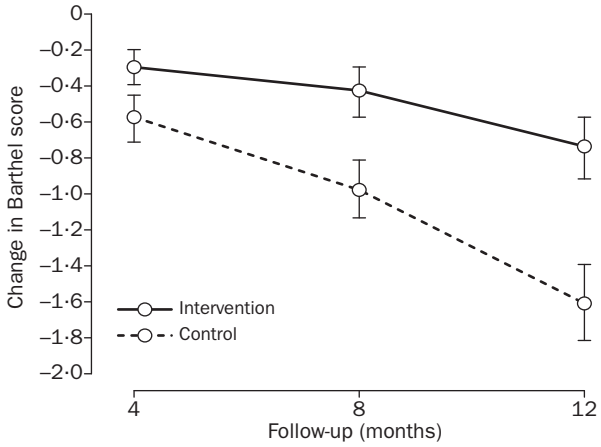

Figure 2: **Change from baseline in Barthel score during follow-up**
Data are mean and SE.

proportions followed up or not followed up for various reasons (p=0·81).

There were significantly fewer falls in the intervention group than in the control group. The median number of falls over the follow-up period was zero (IQR 0–3) in the intervention group and one (0–3) in the control group. The proportion of patients who were able to go out alone at 12 months was higher in the intervention group than in the control group, but the difference in the proportion of serious injuries was not significant.

Logistic regression analysis showed that the risk of falling in the 12-month follow-up period was lower in the intervention group than in the control group after adjustment for differences in Barthel and AMT scores at baseline and number of falls in the 12 months before the index fall (odds ratio 0·39 [95% CI 0·23–0·6]). Similarly, there was a significantly lower risk of recurrent falling in the intervention group than in the control group after adjustment for the same baseline variables (0·33 [0·16–0·68]). The odds of at least one hospital admission (as recorded from hospital admission data) were lower in the intervention group than in the control group after adjustment for baseline Barthel and AMT scores (0·61 [0·35–1·05]). The proportions who were able to go out alone at 12 months did not differ significantly after adjustment for Barthel and AMT scores and ability to go out alone at baseline (p=0·27).

Figure 2 shows the mean change in Barthel scores compared with baseline for the two groups during follow-up. The repeated-measures ANCOVA showed a significant difference between the groups (p=0·017) and a significant change in scores over time (p<0·0001).

Discussion

This controlled study has shown the efficacy of a structured interdisciplinary approach to the management and prevention of falls in older people in a routine service setting. The numbers of subsequent falls and people with recurrent falls were significantly and substantially reduced. The multifactorial approach is consistent with the prospective identification of risk factors used previously in institutional and community settings.[12,13] We applied our strategy in a more routine, and economical context. A cost-benefit analysis is being undertaken separately. The primary attributable cause was frequently related to an environmental hazard, but many patients had multiple risk factors; these findings highlight the dynamic interaction betwen intrinsic and extrinsic risk and the relevance of an interdisciplinary assessment. The revised definition of a fall reflects the need to include people who present with an episode of loss of consciousness, because previous work has emphasised both an important degree of amnesia for the initial event and remediable disorders in this group.[10]

Furthermore, patients who attend accident and emergency departments are an accessible high-risk group of individuals who are receptive to intervention. 65% of our patients had fallen in the previous year compared with the commonly quoted figure of 33%.[31] The adoption of clear interdepartmental (accident and emergency and geriatric medicine) fall-prevention strategies is strongly supported by the findings of this study, which uses a good practice model associated with little additional service cost and confirms previously reported underdiagnosis of remediable disorders in elderly patients who present to accident and emergency departments.[10,23]

The age criteria we used for inclusion of patients reflect the UK's Our Healthier Nation and the WHO Global Health for All targets to reduce mortality and morbidity rates for accidents in people aged 65 and older.[1,2] Patients who were excluded because of refusal or in whom there was no contact were younger than those who took part, and substantially fewer were admitted to hospital. This finding suggests that they may represent a healthier group of individuals. By contrast, those who were excluded because of dementia or who lived in institutional care were older than the participating group and more likely to be admitted to hospital. The latter group is more vulnerable and might benefit from intervention.

The 50% reduction in fracture rate seen in our trial is encouraging, although larger studies are needed to investigate this finding and the impact on mortality. Calcium and supplementation with colecalciferol, and hip protectors lowered the risk of hip fractures in nursing-home residents.[32,33] and steps to preserve bone mineral density and use of hip protectors to high-risk groups could be useful adjuncts to any programme that prevents falls and injury. We conclude from our findings that there is now a strong case to incorporate falls and injury prevention strategies of proven efficacy into routine clinical service.

Contributors
Jacqueline Close was the lead investigator and wrote the paper. Margaret Ellis undertook the occupational-therapy assessments. Richard Hooper was responsible for statistical analysis. Cameron Swift was the project supervisor. All investigators were involved in the study design.

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