ONLINE FIRST

Patient Education to Prevent Falls Among Older Hospital Inpatients

A Randomized Controlled Trial

Terry P. Haines, PhD; Anne-Marie Hill, MS; Keith D. Hill, PhD; Steven McPhail, BS; David Oliver, MD; Sandra Brauer, PhD; Tammy Hoffmann, PhD; Christopher Beer, MBBS

Background: Falls are a common adverse event during hospitalization of older adults, and few interventions have been shown to prevent them.

Methods: This study was a 3-group randomized trial to evaluate the efficacy of 2 forms of multimedia patient education compared with usual care for the prevention of in-hospital falls. Older hospital patients (n=1206) admitted to a mixture of acute (orthopedic, respiratory, and medical) and subacute (geriatric and neurorehabilitation) hospital wards at 2 Australian hospitals were recruited between January 2008 and April 2009. The interventions were a multimedia patient education program based on the health-belief model combined with trained health professional follow-up (complete program), multimedia patient education materials alone (materials only), and usual care (control). Falls data were collected by blinded research assistants by reviewing hospital incident reports, hand searching medical records, and conducting weekly patient interviews.

Results: Rates of falls per 1000 patient-days did not differ significantly between groups (control, 9.27; materials only, 8.61; and complete program, 7.63). However, there was a significant interaction between the intervention and presence of cognitive impairment. Falls were less frequent among cognitively intact patients in the complete program group (4.01 per 1000 patient-days) than among cognitively intact patients in the materials-only group (8.18 per 1000 patient-days) (adjusted hazard ratio, 0.51; 95% confidence interval, 0.28-0.93]) and control group (8.72 per 1000 patient-days) (adjusted hazard ratio, 0.43; 95% confidence interval, 0.24-0.78).

Conclusion: Multimedia patient education with trained health professional follow-up reduced falls among patients with intact cognitive function admitted to a range of hospital wards.

Trial Registration: anzctr.org.au Identifier: ACTRN12608000015347

Arch Intern Med. 2011;171(6):516-524.
Published online November 22, 2010.
doi:10.1001/archinternmed.2010.444

FALLS ARE A LEADING PATIENT safety incident event in general hospitals and are especially common in older patients.[1] Approximately 30% of falls result in injury,[2] the consequences of which may cause increased length of stay or risk of institutionalization for the patient,[3] and legal complaint with subsequent litigation against the health service.[4]

See also page 525

Randomized trials of single interventions to prevent falls in hospitals have not identified a statistically significant reduction in falls outcomes.[5-8] Multifactorial interventions have also been investigated with mixed results.[2,9-11] A recent Cochrane review of these trials[12] found that although multifactorial interventions appeared effective for preventing falls in hospitals, no recommendations could be made regarding effective components of these multifactorial interventions. In addition, compared with individual interventions, multifactorial falls programs may (1) be more difficult and costly to implement, (2) create confusion for individual patients, and (3) reduce the effectiveness of constituent components.[13] Hence, there is need to identify single intervention strategies that prevent falls across a mixture of hospital wards.

A promising intervention is the patient education program used as a part of the first targeted multifactorial program shown to prevent falls in a randomized trial.[2] The education program involved providing written information coupled with 1-to-1 follow-up with a research occupational therapist. Surprisingly, exploratory analyses revealed that the intervention was ef-

Author Affiliations are listed at the end of this article.

fective (~50% reduction) in people with impaired cognitive function as well as in those with intact cognitive function, although contamination by other interventions included in that trial clouds these results.[14] This finding led authors to recommend further investigation of patient education in isolation to determine if this intervention was effective in isolation and equally effective for patients who have intact vs those with impaired cognitive function. The present study addresses this recommendation by comparing 2 models of providing patient education to prevent in-hospital falls vs usual care.

METHODS

DESIGN, PARTICIPANTS, AND SETTING

A 3-group randomized controlled trial with recruiters, data collectors, and statistical analyst blind to group allocation, was undertaken.[15] Potential participants were older adults admitted to acute (orthopedic and acute-respiratory medicine) and subacute (geriatric assessment and rehabilitation) wards of the Princess Alexandra Hospital, Brisbane, Australia, and the acute (medical-surgical) and subacute (restorative–stroke rehabilitation) wards of Swan Districts Hospital, Perth, Australia. Patients were excluded if (1) they were too ill to provide informed consent, as determined by hospital staff, until discharge, death, or transfer to a nonstudy ward; or (2) if they had previously participated in the trial.

INTERVENTIONS

Two models of a patient education program were tested. The first (complete program) involved providing written and video-based materials and 1-to-1 follow-up with a health professional (physiotherapist) trained to provide this program at the patient's bedside. The content and progression of this education program was based on the health-belief model and included presentation of epidemiologic falls data (frequency and outcomes), causes of falls, self-reflection of individual risk, problem area identification, development of preventive strategies and behaviors, goal setting, and goal review.[16] Video materials were subjected to extensive testing and consumer feedback,[17] and the overall program underwent incremental cost-effectiveness analysis economic modeling to ensure feasibility of the delivery approach.[18] Video materials were viewed by patients using a portable digital video disk player with a 9-inch screen and external head phones. Bedside curtains were drawn during the 1-to-1 follow-up to minimize contamination with participants not allocated to this group. One-to-1 follow-up sessions were aimed to be completed during the first week of patient involvement in the study. The number of actual sessions provided was at the discretion of the research physiotherapists providing the follow-up.

The second model (materials only) involved providing the written and video-based materials without the trained health professional follow-up. Assistance was provided by the trained health professional to use the portable digital video disk player for viewing of the video materials.

Both interventions were provided in addition to usual ward-based care.

CONTROL

A usual-care-only control group (control) received no specific falls prevention education from the research team members. Usual ward-based care varied between and within hospitals though it primarily consisted of falls risk screening using locally developed instruments, use of risk alert items (arm bands), generic interventions (eg, nursing checklist to prompt activities such as a regular toileting program and regular visual observation of patients), and additional 1-to-1 nursing for patients with acute agitation and/or confusion at extreme risk of falls. Physical restraint was not a front-line method for managing patients with agitation and/or confusion at either of the participating sites. Multidisciplinary input (eg, medical, nursing, physiotherapy, occupational therapy) was routinely provided on all wards, although therapists such as physiotherapists and occupational therapists provided more intensive input (ie, daily 1-hour sessions) on subacute rehabilitation wards.

MEASUREMENTS

The primary outcome measure was participant falls. The definition of a fall used in this study was the World Health Organization definition: "an event which results in a person coming to rest inadvertently on the ground or floor or other lower level."[19] Prestudy training was provided to hospital staff on study wards regarding classification of falls and procedures for recording falls on incident reports using previously developed video materials.[20] Falls data were collated from 3 sources during the trial: computerized incident reports, hand searching of individual patient medical notes, and weekly patient interviews (or at patient discharge if earlier than 1 week), and falls captured through any of these approaches were included. It was considered important to use multiple sources of data collection for the primary outcome owing to identified limitations of using single sources.[21-23]

Numerous participant demographic measures were taken at the baseline assessment, including the Short Portable Mental Status Questionnaire (SPMSQ)[24] as a screen of cognitive function where scores of 7 of 10 or below indicated impairment. This cut point corresponded to 23 of 30 or below on the Mini-Mental State Examination (the cut point used in the previous subgroup analysis of the education program[14]) when 455 available Mini-Mental State Examination scores were regressed against SPMSQ scores from this baseline demographic data set. The Geriatric Depression Scale[25] and the EQ-5D[26] (formerly EuroQol) health-related quality of life instruments were also administered (**Table 1**).

Time spent by trained health professionals providing the complete program was recorded session by session. The trained health professional at the Princess Alexandra Hospital site also recorded the written behavior modification goals that were set by participants in the complete program and materials-only groups.

PROCEDURE

Recruitment

Participant flow through this study is presented in **Figure 1**. All patients admitted to subacute study wards were referred to researchers by clinical staff. Patients older than 60 years on acute wards who were expected to stay at least 3 more days were also referred. Those referred were approached for consent by researchers to participate as soon as practicable. Family members were approached for consent where treating clinicians had assessed the patient to have impaired cognitive function. Recruitment occurred between January 2008 and April 2009, with the final participant being discharged in October 2009. Participants recruited on one ward but later transferred to another ward participating in this study (eg, transferred from acute ward to rehabilitation ward) were observed until discharge to

Table 1. Participant Demographics and Baseline Assessment Outcomes[a]

Characteristic	Control	Materials Only	Complete Program
Total No.	381	424	401
Recruited on acute study wards	257 (67)	254 (60)	258 (67)
Recruited on subacute study wards	124 (33)	170 (40)	143 (33)
Transferred from acute study ward to subacute study ward during trial	15 (4)	11 (3)	11 (3)
Age, mean (SD), y	75.3 (10.1)	74.7 (11.7)	75.3 (11.0)
Male sex	178 (47)	201 (47)	185 (46)
Diagnosis group			
Stroke	29 (8)	41 (10)	28 (7)
Orthopedic	136 (36)	160 (38)	151 (38)
Pulmonary	66 (17)	47 (11)	55 (14)
Other geriatric management[b]	46 (12)	46 (11)	41 (10)
All other diagnoses combined	104 (27)	130 (31)	126 (31)
English as a first language	348 (91)	376 (89)	359 (90)
Highest educational level attained			
Primary school (up to age 11-12 y)	114 (30)	120 (28)	111 (28)
Year 10	163 (43)	189 (45)	171 (43)
Year 12	38 (10)	46 (11)	47 (12)
Tertiary	65 (17)	69 (16)	72 (18)
Premorbid living arrangements			
Community alone	136 (36)	148 (35)	140 (35)
Community with partner	168 (44)	193 (46)	185 (46)
Community with other	54 (14)	55 (13)	54 (13)
Hostel	12 (3)	19 (4)	17 (4)
Nursing home	11 (3)	9 (2)	5 (1)
Cognitive function			
SPMSQ score, mean (SD)	8.3 (2.1)	8.3 (2.1)	8.4 (2.0)
Participants with intact cognitive function (SPMSQ score ≥8)	316 (75)	280 (73)	310 (77)
Faller in previous 6 mo[c]	210 (55)	247 (58)	212 (53)
Health-related quality of life score, mean (SD)			
EQ-5D VAS	58.5 (12.8)	57.6 (12.9)	57.6 (13.7)
EQ-5D Utility (Dolan method −0.59 to 1.0), mean (SD)	0.46 (0.35)	0.39 (0.36)	0.44 (0.35)
Geriatric depression scale out of a possible 15, mean (SD)	6.9 (2.0)	7.1 (2.0)	6.7 (2.0)
EQ-5D mobility item			
No limitations	84 (22)	94 (22)	103 (26)
Some limitations	240 (63)	248 (58)	232 (58)
Severe limitations	51 (13)	80 (19)	63 (16)
EQ-5D personal care item			
No limitations	169 (44)	155 (37)	165 (44)
Some limitations	167 (44)	204 (48)	181 (45)
Severe limitations	39 (10)	63 (15)	52 (13)
EQ-5D usual activities item			
No limitations	93 (24)	92 (22)	106 (26)
Some limitations	153 (40)	165 (39)	148 (37)
Severe limitations	129 (34)	164 (39)	144 (36)
Days, median (IQR), No.			
In study (consent to discharge)	11 (5-31)	14 (6-36)	13 (5-32)
In hospital (both study wards and nonstudy wards)	19 (8-44)	23 (8-51)	20 (7-46)
Between admission to hospital and consent	4 (1-12)	4 (1-14)	4 (1-12)
In study on acute wards (only participants who were on acute study wards)	6 (3-11)	7 (4-13)	6 (3-13)
In study on subacute wards (only participants who were on subacute study wards)	28.5 (14-47)	25 (12-49)	26.5 (15-45)

Abbreviations: EQ-5D (formerly EuroQol)[26] quality of life instrument; IQR, interquartile range; SPMSQ, Short Portable Mental Status Questionnaire (SPMSQ)[24] (10 is the highest possible SPMSQ score); VAS, visual analog scale.

[a] Unless otherwise indicated, data are reported as number (percentage) of participants.

[b] Other geriatric management is its own diagnostic code and is not a summation of all other diagnostic categories.

[c] Fallers are those who experienced 1 or more falls.

the community or a ward or facility not participating in this study.

Randomization and Masking

A computer-generated, random allocation sequence (without permuted blocks) was developed by the principal investigator (T.P.H.), and the randomly allocated numbers were placed into opaque, consecutively numbered envelopes by 2 investigators (T.P.H. and S.M.). The randomization envelopes were kept in the locked research office at each site, and 1 envelope was opened for each participant in order of recruitment on completion of the baseline assessment by the trained health professionals providing the intervention at each site (A.-M.H. and S.M.), who were unaware of the participant's result from the baseline assessment. The trained health professionals then provided the materials-only intervention or the complete program to participants as soon as practicable following this random allocation sequence.

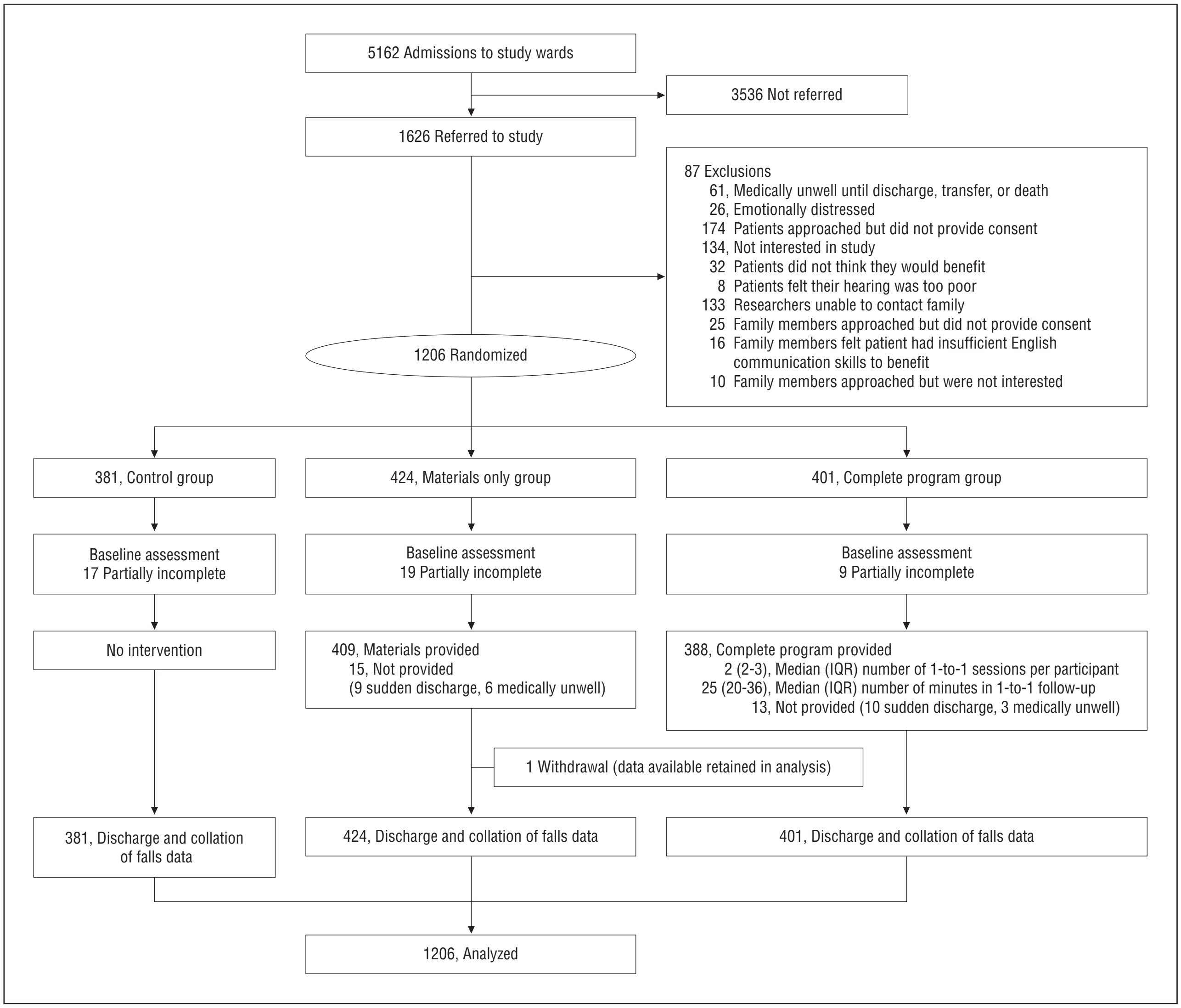

Figure 1. Study flowchart.

Research assistants who approached participants for consent also completed the baseline assessments, weekly falls reviews, and discharge assessments and were blind to group allocation. Data, with mock codes for group allocation (inserted by S.M.), were forwarded to the principal investigator (T.P.H.), who undertook the study interim analysis and final data analysis procedures. A blinding survey was also distributed to clinical staff members (nursing and allied health) caring for participants during the final month of the study recruitment period, asking the staff members which group they believed their patients had been allocated to.

Analysis

Falls outcomes were divided into 3 categories: the rate of falls, the proportion of patients who experienced 1 or more falls (fallers), and the rate of injurious falls. The rate of falls was measured in events per 1000 patient-days. *Injurious falls* were defined as falls resulting in bruising, laceration, fracture, loss of consciousness, or patient reports of persistent pain. All analyses were conducted with participants in their assigned groups and were adjusted for whether the patient was treated on a subacute ward during the study (given the imbalance between groups in this factor and the impact this factor has on length of stay and rate of falls).[2,10]

The rate of falls and rate of injurious falls per 1000 patient-days outcomes were compared across groups using Andersen-Gill Cox recurrent events survival analysis with clustering by participant and robust variance estimates.[27,28] The proportion of patients who incurred 1 or more falls was compared between groups using logistic regression. For these analyses, an initial model was constructed that included an interaction term between the group variables and the dichotomous variable of whether a patient's admission SPMSQ score was 7 of 10 or less. Where significant interaction was identified, simple effects were investigated for participants with intact cognitive function separately from those with impaired cognitive function.

The Andersen-Gill Cox recurrent events survival analysis approach models data under the assumption of proportional hazards. Nelson-Aalen plots displaying the cumulative hazard curves for each group were used to investigate this assumption. Where there was graphical evidence of this assumption being violated, negative binomial regression was used instead.

Statistical power for this study was calculated using 1000 bootstrap simulations of patient-level data previously collected from the Australian hospital setting,[2] and the results indicated that our experiment would have 80% power to detect a difference between groups in the rate of falls of 30%. This assumed a sample size of 390 patients per group, a falls rate of

Table 2. Between-Group Comparisons on Fall-Related Outcomes

Outcome	Control	Materials Only	Complete Program
Total Sample			
Falls/injurious falls/falls resulting in fracture, No.	81/25/2	96/40/2	70/32/1
Falls per 1000 patient-days	9.27	8.61	7.63
Fallers, No. (%)[a]	54 (14)	56 (13)	44 (11)
Injurious falls per 1000 patient-days	2.86	3.59	3.49
Cognitively Intact Participants			
Falls/injurious falls/falls resulting in fracture, No.	46/15/2	61/25/1	25/10/0
Falls per 1000 patient-days	8.72	8.18	4.01
Fallers, No. (%)[a]	30 (11)	32 (10)	20 (6)
Injurious falls per 1000 patient-days	2.84	3.34	1.60
Cognitively Impaired Participants			
Falls/injurious falls/falls resulting in fracture, No.	35/10/0	35/15/1	45/22/1
Falls per 1000 patient-days	10.10	9.47	15.30
Fallers, No. (%)[a]	24 (24)	24 (22)	24 (26)
Injurious falls per 1000 patient-days	2.89	4.06	7.49

[a] Fallers are those who experienced 1 or more falls.

15.7 per 1000 patient-days in the group with the higher falls rate, and a 2-tailed alpha of .05. An additional 12 patients per group were recruited (additional 3%) to account for potential dropouts, creating a per-group size of n=402 (total, n=1206).

Deviation From Published Protocol

The published protocol for this trial did not include detail on use of negative binomial regression where the proportional hazards assumption did not hold, nor did it include adjustment for whether the participant was treated on a subacute ward during the study. These modifications were made in light of the distribution of trial data collected. Examination of the interaction effect between intervention group and cognitive impairment was not included in the published protocol despite the previously stated intention of the authors to examine this interaction.[14]

TRIAL REGISTRATION AND ETHICAL APPROVAL

This trial was registered with the Australia New Zealand Clinical Trials Registry (ACTRN12608000015347) on January 11, 2008. Ethical clearance was provided by the medical research ethics committee of the University of Queensland and the human research ethics committees of the Princess Alexandra Hospital and Swan Districts Hospital.

RESULTS

Baseline and demographic characteristics of participants allocated to each group are summarized in Table 1. Participants in each group were broadly similar, although a noticeable difference was evident for the proportion of participants allocated to each group who were recruited from a subacute ward. There were no control participants provided with either of the intervention conditions, but some participants allocated to the intervention conditions did not receive their intervention for reasons presented in Figure 1.

There were 247 falls across the study sample and 97 injurious falls (**Table 2** and **Table 3**). Five falls resulted in fractures (control: pubic rami and sacrum in one case and olecranon in another; materials only: distal radius and first metacarpal in one case and distal radius and rib in another; and complete program: orbital fossa and C2 vertebra). Pairwise comparisons did not reveal significant differences between groups overall (Table 2, Table 3, and **Figure 2**). Interaction plots between group allocation and cognitive impairment for each fall outcome (**Figure 3**) and statistical investigation of these revealed significant interaction for each falls outcome ($P<.05$).

The rate of falls was significantly lower among participants with intact cognitive function and allocated to the complete program group (4.01 falls per 1000 patient-days) compared with the rate among similar participants allocated to the control and materials-only groups (8.72 falls per 1000 patient-days and 8.18 falls per 1000 patient-days, respectively), and the proportion of these patients who became fallers was lower in the complete program group than in the control group (6% vs 11%). The unadjusted number needed to treat with the complete program to prevent 1 patient becoming a faller relative to the control group was 32.9; and to prevent 1 fall, it was 15.4. The proportion of cognitively intact participants in the complete program group who fell was significantly lower than that in the control group (6% vs 11%). There was a trend toward a reduction in the rate of injurious falls among cognitively intact participants in the complete program group compared with those in the control group.

Among participants with impaired cognitive function, those allocated to the complete program incurred a significantly higher rate of injurious falls per 1000 patient-days than participants in the control group (7.49 vs 2.89). However, there were no serious injuries (fractures) incurred by any of these patients, and the proportion of participants with impaired cognitive function who fell was comparable (complete program, 26%; control, 24%).

The median (interquartile range) time spent by the trained health professional setting up the multimedia materials and in face-to-face contact with participants in the complete group was 25 (20-36) minutes, with a maxi-

Table 3. Between-Group Comparisons on Fall-Related Outcomes[a]

Outcome	Materials Only vs Control as Reference		Complete Program vs Control as Reference		Complete Program vs Materials Only as Reference	
	Ratio	*P* Value	Ratio	*P* Value	Ratio	*P* Value
Total Sample						
Falls per 1000 patient-days	0.91 (0.61-1.36)	.65	0.83 (0.54-1.27)	.39	0.91 (0.58-1.42)	.63
Fallers[b]	0.84 (0.55-1.27)	.40	0.74 (0.48-1.15)	.18	0.89 (0.58-1.38)	.62
Injurious falls per 1000 patient-days	1.21 (0.67-2.17)	.53	1.22 (0.69-2.20)	.49	0.99 (0.56-1.76)	.99
Cognitively Intact Participants						
Falls per 1000 patient-days	0.83 (0.48-1.44)	.51	0.43 (0.24-0.78)	.006	0.51 (0.28-0.93)	.03
Fallers[b]	0.80 (0.46-1.38)	.41	0.51 (0.28-0.94)	.03	0.65 (0.36-1.18)	.16
Injurious falls per 1000 patient-days	0.96 (0.44-2.08)	.92[c]	0.53 (0.23-1.22)	.13[c]	0.55 (0.23-1.27)	.16[c]
Cognitively Impaired Participants						
Falls per 1000 patient-days	0.99 (0.55-1.78)	.97[c]	1.48 (0.86-2.53)	.15[c]	1.45 (0.82-2.59)	.21[c]
Fallers[b]	0.92 (0.48-1.78)	.82	1.38 (0.70-2.75)	.35	1.49 (0.75-2.95)	.25
Injurious falls per 1000 patient-days	1.51 (0.64-3.57)	.35	2.63 (1.19-5.84)	.02	1.98 (0.92-4.25)	.08

[a] Unless otherwise indicated, data are reported as adjusted hazard ratios (robust 95% confidence intervals [CIs]) or adjusted odds ratios (95% CIs). All analyses were adjusted for whether the patient was treated on a subacute hospital ward during the study.
[b] Fallers are those who experienced 1 or more falls.
[c] Negative binomial regression incidence rate ratio (95% CI); *P* value used if proportional hazards assumption violated.

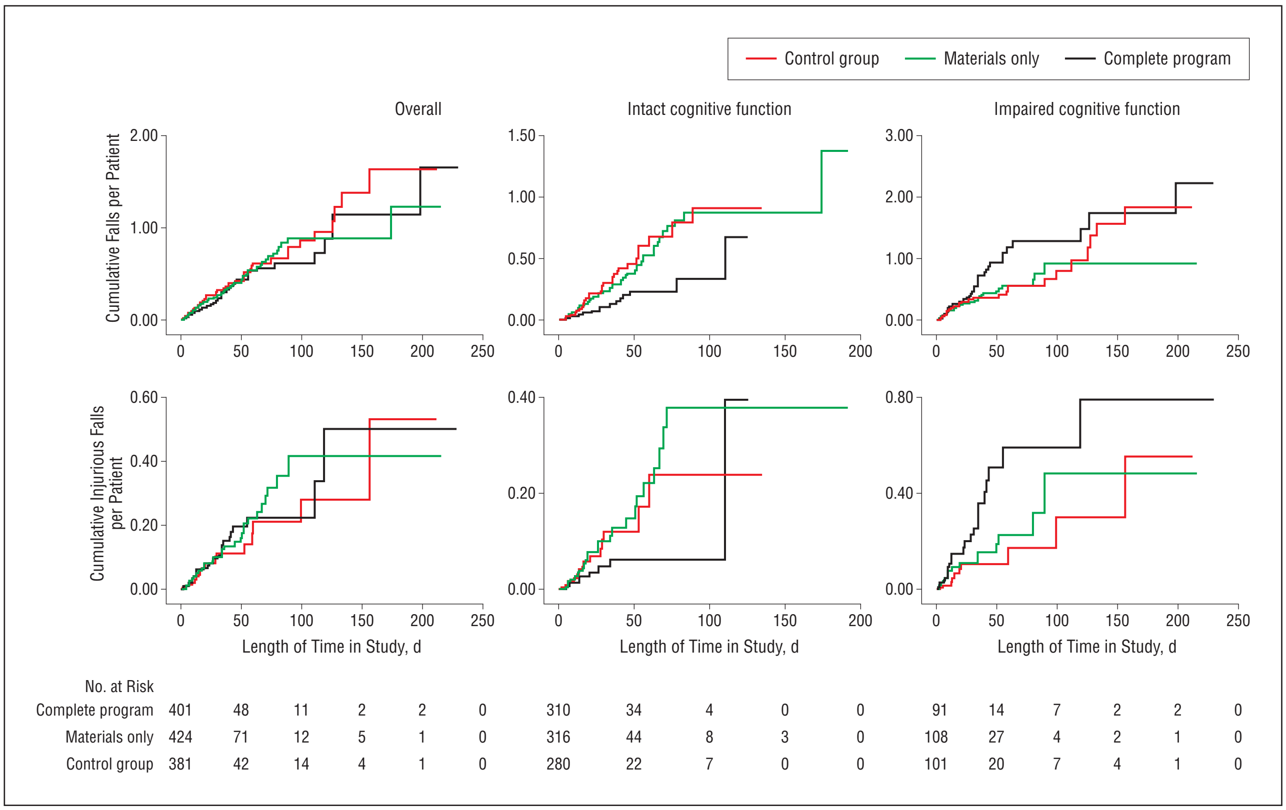

Figure 2. Nelson-Aalen cumulative hazard curves for rates of falls and rates of injurious falls outcomes.

mum of 200 minutes for 1 participant. Of the 280 patients allocated to the complete program group at the Princess Alexandra Hospital site, 273 patients recorded a total of 700 goals in relation to behavior modification in their education materials. The most common goal (142 patients) related to asking for help, followed by identifying environmental hazards (131 patients), using walking aids or other aids (97 patients), waiting for help after it has been asked for (71 patients), wearing safe footwear or clothing (38 patients), and doing more exercise to get stronger and better balance (34 patients). Of the 299 patients allocated to the materials-only intervention at the Princess Alexandra Hospital site, 31 patients recorded a total of 75 goals. The most common goals related to asking for help and waiting for help to arrive once it had been asked for (14 patients each), followed by identifying environmental hazards (9 patients) and using aids (8 patients).

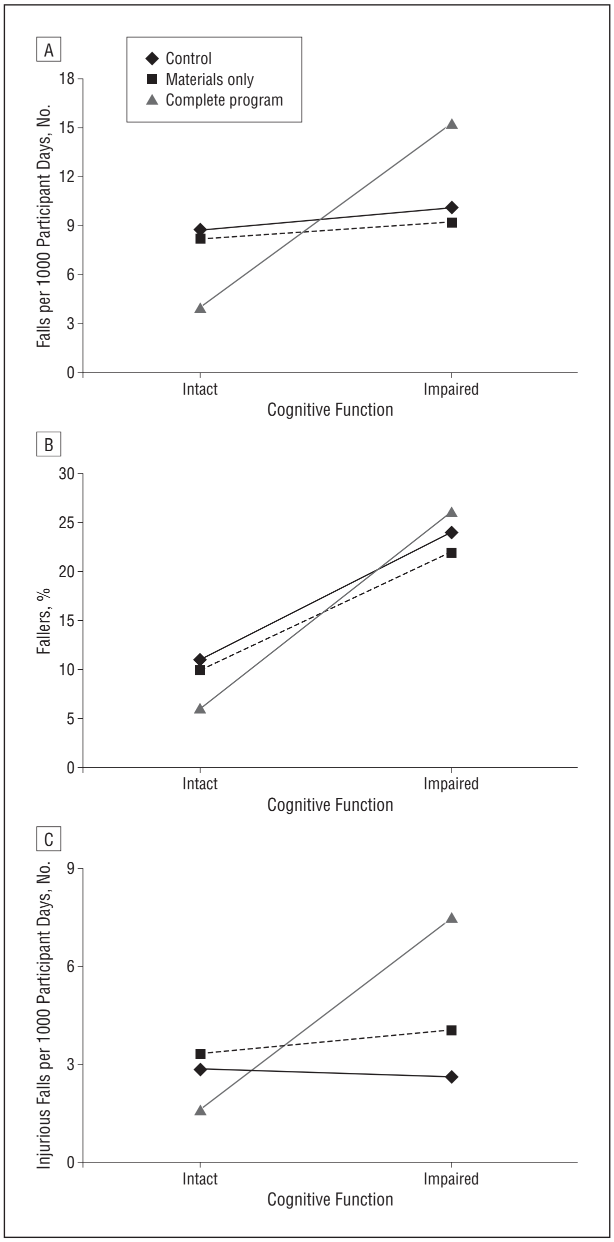

Figure 3. Interaction plots between group allocation and cognitive function (intact/impaired) on falls outcomes.

The cross-sectional hospital staff blinding survey revealed that of 54 study participants, only 16 had their group allocation correctly identified by their primary care nurse (29%) ($\kappa = -0.05$), and 17 had their group correctly identified by their treating physiotherapist (31%) ($\kappa = -0.06$). No adverse events were reported directly from interaction with the education materials.

COMMENT

The 2 models of patient education did not significantly reduce falls outcomes across the entire sample. This study was one of the few falls prevention randomized trials to specifically target cognitively impaired patients for recruitment, and this decision was made on the basis of encouraging findings from an earlier trial. An exploratory subgroup analysis revealed that the effect of the complete program (with trained health professional follow-up) was modified by whether the patient had cognitive impairment for each of the 3 falls outcomes examined. For cognitively intact patients, the complete program produced a relatively consistent and sizeable reduction (~50%) across each of the falls outcomes examined, and the difference was significant in 2 of these outcomes. The complete program also demonstrated a significant reduction in rate of falls among cognitively intact participants relative to the materials-only group. The magnitude of reduction in falls outcomes was comparable with results from previous research examining an earlier version of this intervention in the hospital setting.[14] Hence, there is now growing evidence that the complete program may be an effective strategy for preventing falls among hospital patients who are cognitively intact.

Many of the strategies pursued by patients as a result of participating in the complete program focused on (1) working more effectively with staff members caring for them; (2) identifying environmental hazards; and (3) using appropriate aids, equipment, and clothing. These proposed strategies form a plausible mechanism of action for reducing falls among these patients and highlight the importance of behavioral elements in the causes of falls in this setting. However, the complete program was not an effective strategy and may even be harmful for patients with impaired cognitive function: the rate of injurious falls was higher in this group. Cognitive impairment can limit the ability of patients to adhere to the planned safety-promoting behaviors and is a reason why an education program might not be beneficial among these patients. However, reasons why it may be harmful are less apparent. It is possible that the education process made these participants more willing to report injuries from falls, such as pain, to the blinded research assistants. In support of this notion, we found a discrepancy in the proportion of injurious falls to total falls reported by patients in the materials-only (43% of falls were injurious) and complete program (49% injurious) groups compared with those in the control group (29% injurious).

Our study was limited by its inability to conceal from study participants their group allocations, although this limitation is common for education-based interventions. It may have influenced results because participants allocated to the intervention groups may have been particularly motivated to avoid falls by virtue of knowing they had been allocated to the intervention groups. This enhanced level of motivation might not have been present had the complete program been provided outside the research context.

The simple randomization approach used in the present study generated groups that were not equal in total size or proportion recruited from subacute hospital wards. The investigators had anticipated that a simple randomization approach would be sufficient for generating groups of relatively equal size and comparable baseline demographics given the number of participants being recruited. However, the discrepancy in proportion of participants recruited from subacute hospital wards necessitated adjustment for this in the analyses to account for the effect of this imbalance.

A high proportion of patients admitted to study wards were not approached for consent to enter this study. Study recruiters were not present 7 days per week at participating sites, and periods of leave meant that not all patients admitted could be approached before they were within 3 days of anticipated discharge, particularly on acute wards.

The present study has strengths relative to previous work in this field. Most importantly, this study has evaluated the efficacy of a single intervention for the prevention of falls in hospitals. Previous studies that have demonstrated a reduction in falls in this setting have all used multifactorial interventions, and it was very difficult to determine which elements were the most important.[2,9,11]

The present study has not only investigated patient education in isolation, but it has analyzed 2 models of patient education so that the important elements within this approach can be further identified. As a result, we now know that low-cost, materials-only educational approaches are unlikely to be of benefit.

This study also used the most rigorous approach to collection of falls data (primary outcome) in a randomized trial to date. This is particularly important because falls prevention research in hospitals commonly relies on reports from third parties (hospital clinicians) who are commonly not blinded to the research hypothesis or participant group allocation and who have been shown to be inconsistent in their approach to classifying and reporting falls.[20,22] In the present study, a research assistant blinded to participant group allocation collated data not only from medical records and computerized incident reports but also from direct, weekly patient interviews. It was impossible to blind hospital staff to participant group allocation in the present study, but the surveys of hospital staff members revealed that they were largely unaware of participant group allocation.

Further research is warranted to examine the efficacy of the complete program targeted at cognitively intact patients and used within the context of a broader falls-prevention program that uses other strategies to reduce falls among cognitively impaired patients. Such an intervention may need to take the form of a complex intervention that can adapt to the specific strengths and limitations of individual wards. Even with the education intervention investigated in the present trial, the cost-effectiveness of this approach is likely to vary between acute and subacute wards owing to the higher rate of falls and slower throughput on subacute wards; thus, the cost-effectiveness of this and future interventions should also be examined.

Accepted for Publication: July 31, 2010.
Published Online: November 22, 2010. doi:10.1001/archinternmed.2010.444
Author Affiliations: Allied Health Clinical Research Unit, Physiotherapy Department, Monash University and Southern Health, Cheltenham, Victoria, Australia (Dr Haines); Physiotherapy Department (Ms Hill and Dr Brauer) and Division of Occupational Therapy (Dr Hoffmann), University of Queensland, Brisbane, Queensland, Australia; LaTrobe University, Northern Health and the National Ageing Research Institute, Melbourne, Victoria, Australia (Dr Hill); Institute of Health and Biomedical Innovation and School of Public Health, Queensland University of Technology, and Centre for Functioning and Health Research, Queensland Health, Brisbane (Mr McPhail); School of Community and Health Sciences, City University, London, England (Dr Oliver); and Western Australia Centre for Health and Ageing, Centre for Medical Research, and School of Medicine and Pharmacology, University of Western Australia, Perth, Western Australia, Australia (Dr Beer).
Correspondence: Terry P. Haines, PhD, Allied Health Clinical Research Unit, Physiotherapy Department, Monash University and Southern Health, Kingston Centre, Kingston Road, Cheltenham, Victoria 3192, Australia (terrence.haines@med.monash.edu.au).
Author Contributions: Dr Haines had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Haines, A.-M. Hill, K. D. Hill, McPhail, Oliver, Brauer, and Hoffmann. *Acquisition of data:* Haines, A.-M. Hill, McPhail, and Beer. *Analysis and interpretation of data:* Haines, A.-M. Hill, K. D. Hill, Oliver, Hoffmann, and Beer. *Drafting of the manuscript:* Haines, McPhail, and Oliver. *Critical revision of the manuscript for important intellectual content:* Haines, A.-M. Hill, K. D. Hill, McPhail, Oliver, Brauer, Hoffmann, and Beer. *Statistical analysis:* Haines and A.-M. Hill. *Obtained funding:* Haines, K. D. Hill, and Brauer. *Administrative, technical, and material support:* Haines, A.-M. Hill, K. D. Hill, McPhail, Brauer, Hoffmann, and Beer. *Study supervision:* Haines, A.-M. Hill, McPhail, Oliver, Brauer, Hoffmann, and Beer.
Financial Disclosure: None reported.
Funding/Support: This trial was supported by National Health and Medical Research Council (Australia) (NHMRC) project grant number 456097 (Drs Haines, Hill, Brauer, Oliver, and Hoffmann), an NHMRC Career Development Award (Dr Haines), and a Menzies Research Scholarship (Ms Hill).

REFERENCES

1. US Department of Veterans Affairs. National Center for Patient Safety 2004 Falls Toolkit. http://www4.va.gov/ncps/SafetyTopics/fallstoolkit/index.html. Accessed April 2009.
2. Haines TP, Bennell KL, Osborne RH, Hill KD. Effectiveness of targeted falls prevention programme in subacute hospital setting: randomised controlled trial. *BMJ*. 2004;328(7441):676-679.
3. Aditya BS, Sharma JC, Allen SC, Vassallo M. Predictors of a nursing home placement from a non-acute geriatric hospital. *Clin Rehabil*. 2003;17(1):108-113.
4. Oliver D, Killick S, Even T, Willmott M. Do falls and falls-injuries in hospital indicate negligent care—and how big is the risk? a retrospective analysis of the NHS Litigation Authority Database of clinical negligence claims, resulting from falls in hospitals in England 1995 to 2006. *Qual Saf Health Care*. 2008;17(6):431-436.
5. Haines TP, Bell RA, Varghese PN. Pragmatic, cluster randomized trial of a policy to introduce low-low beds to hospital wards for the prevention of falls and fall injuries. *J Am Geriatr Soc*. 2010;58(3):435-441.
6. Mayo NE, Gloutney L, Levy AR. A randomized trial of identification bracelets to prevent falls among patients in a rehabilitation hospital. *Arch Phys Med Rehabil*. 1994;75(12):1302-1308.
7. Tideiksaar R, Feiner CF, Maby J. Falls prevention: the efficacy of a bed alarm system in an acute-care setting. *Mt Sinai J Med*. 1993;60(6):522-527.
8. Donald IP, Pitt K, Armstrong E, Shuttleworth H. Preventing falls on an elderly care rehabilitation ward. *Clin Rehabil*. 2000;14(2):178-185.
9. Healey F, Monro A, Cockram A, Adams V, Heseltine D. Using targeted risk factor reduction to prevent falls in older in-patients: a randomised controlled trial. *Age Ageing*. 2004;33(4):390-395.
10. Cumming RG, Sherrington C, Lord SR, et al; Prevention of Older People's Injury

Falls Prevention in Hospitals Research Group. Cluster randomised trial of a targeted multifactorial intervention to prevent falls among older people in hospital. *BMJ*. 2008;336(7647):758-760.
11. Stenvall M, Olofsson B, Lundström M, et al. A multidisciplinary, multifactorial intervention program reduces postoperative falls and injuries after femoral neck fracture. *Osteoporos Int*. 2007;18(2):167-175.
12. Cameron ID, Murray GR, Gillespie LD, et al. Interventions for preventing falls in older people in nursing care facilities and hospitals. *Cochrane Database Syst Rev*. 2010;(1):CD005465. doi:10.1002/14651858.CD005465.pub2.
13. Campbell AJ, Robertson MC. Rethinking individual and community fall prevention strategies: a meta-regression comparing single and multifactorial interventions. *Age Ageing*. 2007;36(6):656-662.
14. Haines TP, Hill KD, Bennell KL, Osborne RH. Patient education to prevent falls in subacute care. *Clin Rehabil*. 2006;20(11):970-979.
15. Hill AM, Hill K, Brauer S, et al. Evaluation of the effect of patient education on rates of falls in older hospital patients: description of a randomised controlled trial. *BMC Geriatr*. 2009;9:14.
16. Janz NK, Becker MH. The Health Belief Model: a decade later. *Health Educ Q*. 1984;11(1):1-47.
17. Hill AM, McPhail S, Hoffmann T, et al. A randomized trial comparing digital video disc with written delivery of falls prevention education for older patients in hospital. *J Am Geriatr Soc*. 2009;57(8):1458-1463.
18. Haines T, Kuys SS, Morrison G, Clarke J, Bew P. Cost-effectiveness analysis of screening for risk of in-hospital falls using physiotherapist clinical judgement. *Med Care*. 2009;47(4):448-456.
19. World Health Organization. Definition of a fall. www.who.int/violence_injury_prevention/other_injury/falls/en/index.html. Accessed January 15, 2010.
20. Haines TP, Massey B, Varghese P, Fleming J, Gray L. Inconsistency in classification and reporting of in-hospital falls. *J Am Geriatr Soc*. 2009;57(3):517-523.
21. Sari AB, Sheldon TA, Cracknell A, Turnbull A. Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review. *BMJ*. 2007;334(7584):79.
22. Haines TP, Cornwell P, Fleming J, Varghese P, Gray L. Documentation of in-hospital falls on incident reports: qualitative investigation of an imperfect process. *BMC Health Serv Res*. 2008;8:254.
23. Hill AM, Hoffmann T, Hill K, et al. Measuring falls events in acute hospitals-a comparison of three reporting methods to identify missing data in the hospital reporting system. *J Am Geriatr Soc*. 2010;58(7):1347-1352.
24. Pfeiffer E. A short portable mental status questionnaire for the assessment of organic brain deficit in elderly patients. *J Am Geriatr Soc*. 1975;23(10):433-441.
25. Sheikh JI, Yesavage JA, Brooks JO III, et al. Proposed factor structure of the Geriatric Depression Scale. *Int Psychogeriatr*. 1991;3(1):23-28.
26. Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. *Ann Med*. 2001;33(5):337-343.
27. Therneau TM, Hamilton SA. rhDNase as an example of recurrent event analysis. *Stat Med*. 1997;16(18):2029-2047.
28. Robertson MC, Campbell AJ, Herbison P. Statistical analysis of efficacy in falls prevention trials. *J Gerontol A Biol Sci Med Sci*. 2005;60(4):530-534.