Patient Education to Prevent Falls Among Older Hospital Inpatients

A Randomized Controlled Trial

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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


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

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Randomized trials of single interventions to prevent falls in hospitals have not identified a statistically significant reduction in falls outcomes. Multifactorial interventions have also been investigated with mixed results. A recent Cochrane review of these trials 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. 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. 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-
effective (~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. 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. 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. Participants 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. Video materials were subjected to extensive testing and consumer feedback, and the overall program underwent incremental cost-effectiveness analysis and economic modeling to ensure feasibility of the delivery approach. 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

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.” 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. 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.

Numerous participant demographic measures were taken at the baseline assessment, including the Short Portable Mental Status Questionnaire (SPMSQ) 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) when 455 available Mini-Mental State Examination scores were regressed against SPMSQ scores from this baseline demographic data set. The Geriatric Depression Scale and the EQ-5D (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
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.

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

Abbreviations: EQ-5D (formerly EuroQol) quality of life instrument; IQR, interquartile range; SPMSQ, Short Portable Mental Status Questionnaire (SPMSQ) (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 Faller is those who experienced 1 or more falls.
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). 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. 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, 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 

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**Figure 1. Study flowchart.**

- 5162 Admissions to study wards
- 1626 Referred to study
- 1206 Randomized
- 381, Control group
  - Baseline assessment
  - 17 Partially incomplete
  - No intervention
  - 381, Discharge and collation of falls data
  - 1 Withdrawal (data available retained in analysis)
  - 381, Analyzed
- 424, Materials only group
  - Baseline assessment
  - 19 Partially incomplete
  - 409, Materials provided
  - 15, Not provided
  - (9 sudden discharge, 6 medically unwell)
  - 424, Discharge and collation of falls data
  - 401, Complete program group
  - Baseline assessment
  - 9 Partially incomplete
  - 388, Complete program provided
  - 25 (20-36), Median (IQR) number of 1-to-1 sessions per participant
  - 13, Not provided (10 sudden discharge, 3 medically unwell)
  - 401, Discharge and collation of falls data
  - 401, Analyzed
- 3536 Not referred
- 87 Exclusions
  - 61, Medically unwell until discharge, transfer, or death
  - 104, Emotionally distressed
  - 061, Medically unwell until discharge, transfer, or death
  - 026, Emotionally distressed
  - 174 Patients approached but did not provide consent
  - 134, Not interested in study
  - 32 Patients did not think they would benefit
  - 8 Patients felt their hearing was too poor
  - 133 Researchers unable to contact family
  - 29 Family members approached but did not provide consent
  - 16 Family members felt patient had insufficient English communication skills to benefit
  - 10 Family members approached but were not interested

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1.5.7 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 (ACTRN1260800015347) 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: dis-
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).

Table 3. Between-Group Comparisons on Fall-Related Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Materials Only vs Control as Reference</th>
<th>Complete Program vs Control as Reference</th>
<th>Complete Program vs Materials Only as Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ratio (95% CI)</td>
<td>P Value</td>
<td>Ratio (95% CI)</td>
</tr>
<tr>
<td>Falls per 1000 patient-days</td>
<td>0.91 (0.61-1.36)</td>
<td>.65</td>
<td>0.83 (0.54-1.27)</td>
</tr>
<tr>
<td>Fallers^b</td>
<td>0.84 (0.55-1.27)</td>
<td>.40</td>
<td>0.74 (0.48-1.15)</td>
</tr>
<tr>
<td>Injurious falls per 1000 patient-days</td>
<td>1.21 (0.67-2.17)</td>
<td>.53</td>
<td>1.22 (0.69-2.20)</td>
</tr>
</tbody>
</table>

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.

Figure 2. Nelson-Aalen cumulative hazard curves for rates of falls and rates of injurious 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%) ($H^2 = -0.05$), and 17 had their group correctly identified by their treating physiotherapist (31%) ($H^2 = -0.06$). 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. 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.

![Figure 3. Interaction plots between group allocation and cognitive function (intact/impaired) on falls outcomes.](https://jamanetwork.com/)

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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.12,13

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.14,15 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.

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