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## Effects of an Intervention to Increase Bed Alarm Use to Prevent Falls in Hospitalized Patients:

### A Cluster Randomized Trial

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### Abstract

**Background**—Bed alarm systems intended to prevent hospital falls have not been formally evaluated.

**Objective**—To investigate whether an intervention aimed at increasing bed alarm use decreases hospital falls and related events.

**Design**—Pair-matched, cluster randomized trial over 18 months. Nursing units were allocated by computer-generated randomization on the basis of baseline fall rates. Patients and outcome

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assessors were blinded to unit assignment; outcome assessors may have become unblinded. (ClinicalTrials.gov registration number: NCT00183053)

**Setting**—16 nursing units in an urban community hospital.

**Patients**—27 672 inpatients in general medical, surgical, and specialty units.

**Intervention**—Education, training, and technical support to promote use of a standard bed alarm system (intervention units); bed alarms available but not formally promoted or supported (control units).

**Measurements**—Pre–post difference in change in falls per 1000 patient-days (primary end point); number of patients who fell, fall-related injuries, and number of patients restrained (secondary end points).

**Results**—Prevalence of alarm use was 64.41 days per 1000 patient-days on intervention units and 1.79 days per 1000 patient-days on control units ( $P = 0.004$ ). There was no difference in change in fall rates per 1000 patient-days (risk ratio, 1.09 [95% CI, 0.85 to 1.53]; difference, 0.41 [CI, –1.05 to 2.47], which corresponds to a greater difference in falls in control vs. intervention units) or in the number of patients who fell, injurious fall rates, or the number of patients physically restrained on intervention units compared with control units.

**Limitation**—The study was conducted at a single site and was slightly underpowered compared with the initial design.

**Conclusion**—An intervention designed to increase bed alarm use in an urban hospital increased alarm use but had no statistically or clinically significant effect on fall-related events or physical restraint use.

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Falls in hospitalized persons are widespread and serious threats to patient safety (1, 2). Accidental falls are among the most common incidents reported in hospitals (3), complicating approximately 2% of hospital stays (3–5). About 25% of falls in hospitalized patients result in injury, and 2% result in fractures (4). Substantial costs are associated with falls, including costs of patient care associated with increased length of stay and liability (6). Beginning 1 October 2008, the Centers for Medicare & Medicaid Services eliminated payment to hospitals for costs incurred in treating injuries resulting from falls during hospitalization, further compounding the fall-related costs to hospitals (7–9).

Most falls in hospitalized patients occur in patient rooms and are related to ambulating from a bed, chair, or toilet without adequate assistance (10, 11). Bed alarm systems (for example, bed or chair alarms) could therefore reduce falls by alerting personnel when at-risk patients attempt to leave a bed or chair without assistance. Another potential benefit is that bed alarm systems may reduce the need for physical restraints—a Centers for Medicare & Medicaid Services quality-of-care indicator (12). Although 1 uncontrolled study found that restraint use decreased by 37% after the introduction of alarms (13), the relationship among bed alarm monitoring, falls, and physical restraint use has not been well-studied (5, 14).

To address the utility of bed alarm systems as an approach to falls prevention in hospitals, we conducted a cluster randomized trial aimed at increasing use of bed alarms by nurses to estimate their effectiveness.

## Methods

### Design Overview, Setting, and Participants

The study was conducted at Methodist Healthcare-University Hospital, an urban, academically affiliated community hospital in Memphis, Tennessee, on 16 medical–surgical nursing units with 349 beds. Fall rates were recorded during an initial 8-month baseline period (9 September 2005 to 30 April 2006), then the nursing units were randomly assigned in pairs on the basis of those baseline rates during an intervention period (1 May 2006 to 30 October 2007). All patients became eligible for study participation at the time of admission to 1 of the 16 study units, and eligibility ended with discharge from 1 of the 16 study units. Patients were blinded to unit assignment. The Methodist Healthcare institutional review board reviewed and approved the research protocol and granted a waiver of informed consent.

### Randomization

To ensure the comparability of intervention and control nursing units, the interventionist assigned the nursing units a number between 1 and 16 in decreasing order of fall rates. “Neighbors” in this rank order were matched into 8 pairs. The first in the pair was randomly assigned to the intervention or control group so that the other unit received the opposite assignment. Units were allocated by using a random-number sequence in SAS software, version 9.2 (SAS Institute, Cary, North Carolina), generated by a statistical consultant who was blinded to the identity of the units.

### Alarm System

Discussions among study personnel and hospital leadership led to selection of the Bed-Ex occupancy monitoring system (Bed-Ex, Omaha, Nebraska) as the study device because it is widely used, typical of its class, and already in use at Methodist Healthcare’s skilled-nursing facility. Neither Methodist Healthcare nor any of the investigators has any financial relationship with the alarm manufacturer.

The alarm system operates using 1 to 2 weight-sensitive sensor pads applied to the bed, chair, or commode. When contact is broken with the alarm sensor pad, an alarm sounds within the patient’s room and as a call at the central nurses’ station.

When used for patients in bed, or “bed mode,” the pad is positioned anywhere between the buttocks and shoulder blades. Higher placement (that is, shoulder blades) allows the caregiver an increased response time to reach a patient attempting to exit the bed, and the sensing interval can be increased from 4 to 8 seconds on the bed pressure pad to reduce false alarms. When used in “chair mode,” an immediate alarm sounds as soon as a patient starts to lift his or her body off of the sensing pads. Because the pads are lightweight and flexible, they can be wrapped around 1 edge of a toilet seat, which provides monitoring for unassisted rising from the commode while maintaining patient privacy.

### Usual Care

Usual care comprised various fall prevention interventions selected on the basis of clinical judgment and patient-specific risk factors. At Methodist Healthcare-University Hospital, staff assess all patients at admission and daily thereafter for fall risk by using a scale, scored from 0 to 125, adapted with some elements of the Morse Fall Scale (15). On the basis of the risk level, documentation screens in the electronic medical record provide a list of general safety measures (for example, placing a call light in reach and assuring adequate lighting) and a list of fall prevention interventions for high-risk patients (for example, decreasing intervals between patient observations and safety rounds and establishing a toileting

schedule). The study interventionist also did rounds for approximately 15 minutes once or twice per week on control units, promoting the hospital's fall prevention protocol but without emphasizing the use of bed or chair alarms. Bed alarms were available to patients on usual care units. If requested, bed alarms were ordered from and obtained through the department of central supply, in keeping with usual practice at Methodist Healthcare-University Hospital.

## Intervention

Because no data identify patients who benefit from bed alarms, the intervention was designed to support clinical judgment rather than mandate alarm use among patients with a specific set of risk factors. The study interventionist and the principal investigator conducted extensive educational sessions on the use of the alarm system at each intervention unit. In addition, the study interventionist did rounds every weekday for approximately 15 minutes on intervention units to encourage the use of these systems by delivering them and setting them up on patients selected for their use, address technical issues related to use of the alarms, and provide training on device use. The intervention team was continuously available by pager to address false alarms or other equipment malfunction.

## Outcomes and Follow-up

The primary outcome was falls, defined as a sudden, unintentional change in position coming to rest on the ground or other lower level (16). When a fall or suspected fall occurred, the staff member noting the event would page the fall evaluation service (418-FALL), and the event was assessed using a standardized data collection tool (17). Fall evaluators were nurse managers, nurse supervisors, or study personnel providing 24-hours-per-day, 7-days-per-week coverage. Evaluators were initially blinded to nursing unit group assignment, but some may have become unblinded during the study. Falls were also ascertained from hospital occurrence reports, although these reports alone have been shown to be unreliable sources on the incidence of falls in hospitals (18, 19) and to underestimate falls and injurious falls in the study hospital by approximately 30% (17).

Secondary outcomes were patients who fell while in a nursing unit; falls with injury, classified as minor (persistent pain or pain requiring ice, dressing, cleaning of a wound, limb elevation, or pain medication), moderate (injuries requiring suturing or splinting), major (injuries needing surgery, casting, traction, or neurologic consultation for change in level of consciousness), or fatal; and physical restraint use. Fatalities were reviewed to determine association with the fall.

We used the hospital's electronic medical record as the primary data source on restraint use. Any form of physical restraint use is documented in the physicians' orders and the medical record documentation. Side rails were not classified as physical restraints.

As an intermediate measure of the effect of the intervention, we also assessed use of bed alarms by using several sources: audits of orders for alarms from the central supply department, nursing documentation in the medical records, and direct observation on both intervention and control units by the study interventionist. Each day that an alarm was used was defined as an "alarm day."

## Statistical Analysis

We used a pair-matched, cluster randomized design with the nursing unit as the unit of analysis. The potential effect of clustering on power was estimated using the coefficient of variation for pair-matched designs ( $k_m$ ) (20). For the original power analysis, we considered  $k_m$  values between 0 and 0.2. On the basis of a mean of 550 patient-days per month in each

of the 16 nursing units (clusters) and a rate of 3.9 falls per 1000 patient-days during the baseline period, we estimated that an 18-month (mean cluster size, 9900 patient-days) study would, with a 2-tailed  $\alpha$  of 0.05, detect a relative difference of 33% with a power of 0.96 ( $k_m = 0$ ) and 0.54 ( $k_m = 0.2$ ). On the basis of a higher-than-anticipated fall rate (5.2 per 1000 patient-days;  $k_m = 0.145$ ) during the baseline period, we estimated the ability to detect a 33% relative difference with a power of 0.72 and a 37% relative difference with a power of 0.80. The study team considered this adequate.

To examine the distribution of falls and covariates between intervention and control units during the baseline period, we aggregated the monthly data within unit and used a Wilcoxon test. To compare alarm use in the intervention and control units, we used a negative binomial regression model (to account for overdispersion) with a random intercept (to account for overdispersion and heterogeneity) and patient-days from the midnight census, as the offset.

The relative effect of the intervention is expressed as a risk ratio (RR), defined as (fall event rate in the intervention units during the study period/fall event rate in the intervention units during the baseline period)/(fall event rate in the control units during the study period/fall event rate in the control units during the baseline period). An RR less than 1.0 favors the intervention units. The absolute effect of the intervention was expressed as the population-averaged difference in differences (DID), which we defined as (fall event rate in the intervention units during the study period – fall event rate in the intervention units during the baseline period) – (fall event rate in the control units during the study period – fall event rate in the control units during the baseline period). A DID less than 0 favors the intervention units.

Units were analyzed as repeated measures. All models had the following terms: group assignment (that is, intervention or control), period (that is, baseline or study), and group assignment by period interaction; this is called the “base model.” Population-averaged rates were computed by analytically integrating out the unit-level random effects. Unit-level random effects from the same pair were correlated. We used a likelihood-based approach to most easily accommodate the missing data under a missing at random assumption.

In adjusted analyses, we controlled for staffing variables (registered nurse, licensed practical nurse, and nursing assistant hours per patient-day); demographic variables (proportion of patient-days for age, sex, race, and insurance status); and, because psychotropic drug use has been associated with falls in hospitalized patients (21) and their use as “chemical restraints” might be reduced by using bed alarms, psychotropic drug use (use days per 1000 patient-days of antipsychotics, antidepressants [including tricyclic antidepressants, selective serotonin reuptake inhibitors, monoamine uptake inhibitors, nefazodone, venlafaxine, and trazodone], and sedative–hypnotics [including benzodiazepines and related agents and sedating antihistamines]). Although other classes of medications have been associated with falls (21), we assumed that their use would remain constant over time and did not use these as covariates.

Staffing (hours per patient-day) was calculated for registered nurses, licensed practical nurses, and nursing assistants by using hospital staffing data. Demographic variables and psychotropic drug use were ascertained using billing data. All covariates were aggregated at the unit-month level.

The effect of covariates was tested by adding them into the base model. For these models, the population-averaged, adjusted rates were computed as previously described with the covariates set to their mean values. Because of the complex form of the population-averaged rates and the RR and DID, we computed SEs and CIs by using a nonparametric bootstrap

analysis (22) for which the pairs of nursing units were sampled with replacement. Minimal serial correlation over time (months) occurred within the unit, so the random intercept seemed to adequately account for the correlation over time within units. Because of a reorganization of hospital services, 2 units randomly assigned to the intervention group unexpectedly closed during the third month of the 18-month study; because the unit closures were not based on fall rates, incomplete data were assumed to be missing at random (23). Study personnel were blinded to group assignment (intervention or control) of nursing units during the analyses, and statistical analyses were conducted using SAS software, version 9.2.

### Role of the Funding Source

The National Institutes of Health and National Institute on Aging provided funding for the study. The funding source had no role in the study's design, conduct, or reporting.

## Results

### Characteristics of Intervention and Control Nursing Units

Figure 1 shows the study flow diagram of the nursing units. The control nursing units had a mean bed size of 24.6 (SD, 4.9) and comprised neurology, oncology, transplant, and 5 general medical–surgical services. The intervention nursing units had a mean bed size of 21.5 (SD, 3.5) and comprised stroke, transplant, orthopedic, step-down, surgical oncology, and 3 general medical–surgical services. At baseline, the 8 intervention and 8 control nursing units were similar in staffing, demographic characteristics, fall risk, and psychotropic drug use (Table 1 and the Appendix Table, available at [www.annals.org](http://www.annals.org)).

### Bed Alarm Use in Intervention and Control Nursing Units

The 8 intervention units contributed 59 011 patient-days to the study; alarms were used in 736 patients over 3801 patient-days (64.41 alarm-days per 1000 patient-days). By unit, alarm use ranged from 42.0 to 88.7 alarm-days per 1000 patient-days. The 8 control units contributed 83 604 patient-days to the study; alarms were used in 36 patients over 150 patient-days (1.79 alarm-days per 1000 patient-days). By unit, alarm use ranged from 0 alarm-days per 1000 patient-days to 4.8 alarm-days per 1000 patient-days. Alarm use was greater on intervention than control units ( $P=0.004$ ).

By month, the prevalence of alarm use on intervention units during the study period varied from 17.8 (month 1) to 141.0 (month 3) alarm-days per 1000 patient-days, whereas that on control units ranged from 0.0 (months 1, 3, and 18) to 4.5 (month 16) alarm-days per 1000 patient-days (Figure 2).

### Fall Events and Patients Restrained in Intervention and Control Nursing Units

During the 8-month baseline period, the 8 intervention nursing units contributed 30 113 patient-days during which 182 falls occurred (adjusted rate, 5.76 falls per 1000 patient-days). The 8 control nursing units contributed 35 377 patient-days during which 192 falls occurred (adjusted rate, 5.11 falls per 1000 patient-days). During the baseline period, the fall rates on intervention and control units were statistically similar ( $P=0.45$ ).

Over the 18-month study period in the intervention nursing units, 282 persons who fell contributed 315 falls over 59 011 patient-days (adjusted rate, 5.62 falls per 1000 patient-days). Of these, 77 (24.4%) resulted in injury (59 minor, 7 moderate, 1 major, and 10 not characterized). In the control nursing units, 359 patients contributed 408 falls over 83 604 patient-days (adjusted rate, 4.56 falls per 1000 patient-days). Of these, 111 (27.2%) resulted in injury (94 minor, 6 moderate, 5 major, 1 death, and 5 not characterized).

There were no significant pre–post differences in change in fall rates (RR, 1.09 [CI, 0.85 to 1.53]; DID, 0.41 [CI, –1.05 to 2.47]), number of patients who fell (RR, 1.15 [CI, 0.92 to 1.49]; DID, 0.59 [CI, –0.50 to 1.84]), injurious fall rates (RR, 1.42 [CI, 0.77 to 3.34]; DID, 0.56 [CI, –0.32 to 1.67]), or number of patients physically restrained (RR, 0.83 [CI, 0.56 to 1.18]; DID, –0.69 [CI, –3.77 to 1.03]) on intervention units compared with control units (Table 2).

Because the fall rate in intervention units during the final month of the intervention was high, we conducted a sensitivity analysis excluding this month, and our findings were similar (data not shown). In addition, among models controlling for staffing and patient demographic characteristics alone or in combination, only 1 had a CI excluding no effect (Table 3).

### Adverse Events

We did not observe or receive reports of harm to patients due to alarm monitoring.

### Discussion

This cluster randomized trial of an intervention to increase bed alarm use in hospital nursing units showed that increased use had no statistically significant effect on the number or rate of falls, injurious falls, or patients restrained on intervention compared with control units. On the basis of the 95% CIs around our estimate in fall rate differences, our findings were statistically compatible with a decrease in falls by as much as 1 per 1000 patient-days and an increase in falls by as much as 2.47 per 1000 patient-days in the intervention units, so large, clinically significant benefits (or harms) are not probable.

To identify previous studies of alarms as a strategy for fall prevention, we searched PubMed and CINAHL databases from 1975 through April 2012 using the terms *hospitals*, *accidental falls prevention*, and *clinical alarms*. We identified 4 fall prevention studies in hospitals (13, 24–26) where alarm systems were the primary intervention. Each of these studies reported that falls were reduced by 20% to 60%; however, these results should be considered with caution because only the study by Tideiksaar and colleagues (24) included a concurrent control group. In addition, 2 recently published cluster randomized studies included alarms as a part of multifactorial interventions to prevent falls in hospitals. One trial was effective (27), but the other did not reduce falls (28).

Our study was able to overcome many methodological weaknesses and informs the design of future interventions aimed at reducing falls in hospitals. Using a fall evaluator system in addition to hospital occurrence reports enhanced the accuracy and reduced potential for reporting bias. The study also used information from various data sources to develop unit-level covariates, including patient demographic characteristics, insurance, psychotropic medication use, and staffing. Finally, the long duration of the intervention permitted the novelty of the intervention to diminish, as evidenced by alarm use reaching an equilibrium state after approximately 6 months.

Our study has limitations. It was conducted at a single site; however, this assured fidelity of the intervention and facilitated standardizing our approach to end point and covariate ascertainment. The fall rates that we observed are typical of acute care hospitals in the United States (27, 29–32), and we found excellent separation of alarm use between intervention and control nursing units, suggesting that there was little evidence of contamination.

Furthermore, because of higher fall rates in the baseline period, our trial was ultimately underpowered to detect our primary end point, falls per 1000 patient-days, and was not designed to detect a difference in injurious falls. Therefore, our findings should be interpreted with caution. However, the lower 95% CIs exclude large benefits in fall rates with the intervention.

Another limitation is the inability to conduct our study in a blinded manner and to completely balance the exposure of the intervention and control nursing units to the study team. Although these might increase the risk for a Hawthorne effect, we do not believe that this played an important role in biasing our findings. Fall rates remained similar between baseline and study periods in both intervention and control units; furthermore, we found no difference in end points that would be less susceptible to reporting bias (for example, injurious falls and restraint use).

Although we were able to control for several demographic covariates, we could not completely control for fall risk at the unit level because it was captured in the electronic medical record beginning in the last month of the baseline period. However, as Table 1 and the Appendix Table show, the unit-level fall risk in both intervention and control units was similar in both baseline and study periods.

Several plausible explanations are available for why the intervention did not reduce falls or related events despite a large increase in patient-days with bed alarms in place. Despite the support of the intervention team, false alarms are a common problem of bed alarm systems in the practice setting. In a field study of nursing home patients, Capezuti and colleagues (14) found a high degree of both false-positive as well as false-negative events in a traditional alarm system like that used in this study. More advanced alarm systems, including infrared beam sensors, do exist and may produce more encouraging results (14).

False alarms may also contribute to “alarm fatigue” (33), in which staff no longer responds when an alarm appropriately sounds. Also, instruments to predict falls among hospitalized patients have limited specificity (34, 35), and the “wrong patients” may have been chosen for bed alarm monitoring. Finally, alarm signals may occur after patients had already fallen because they fell immediately on exiting the bed or chair. Although each of these factors was observed in the course of the intervention, we did not systematically quantify reasons for alarm failure.

In summary, although our intervention to increase bed alarm use increased use in intervention nursing units, there was little evidence of an effect on fall-related events or an effect on physical restraint use in intervention compared with control nursing units. Although the study was not designed to rigorously track alarm-related expenses, the costs of the study alarm system are substantial: The monitoring box, connection cables, and replacement cords cost approximately \$350, and each disposable sensor pad costs \$23. There are also facility expenses related to inventory control and maintenance. Thus, although bed alarms may yet prove useful as a part of a well-defined fall prevention program, hospitals should temper expectations that their use will provide a simple and cost-effective solution to the problem of falls.

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**Context**

Bed alarms alert health care personnel when a patient rises from a chair or bed and are intended to prevent falls.

**Contribution**

A multifactorial intervention designed to encourage use of bed alarms greatly increased their use on nursing wards but had no apparent effect on falls or use of physical restraints.

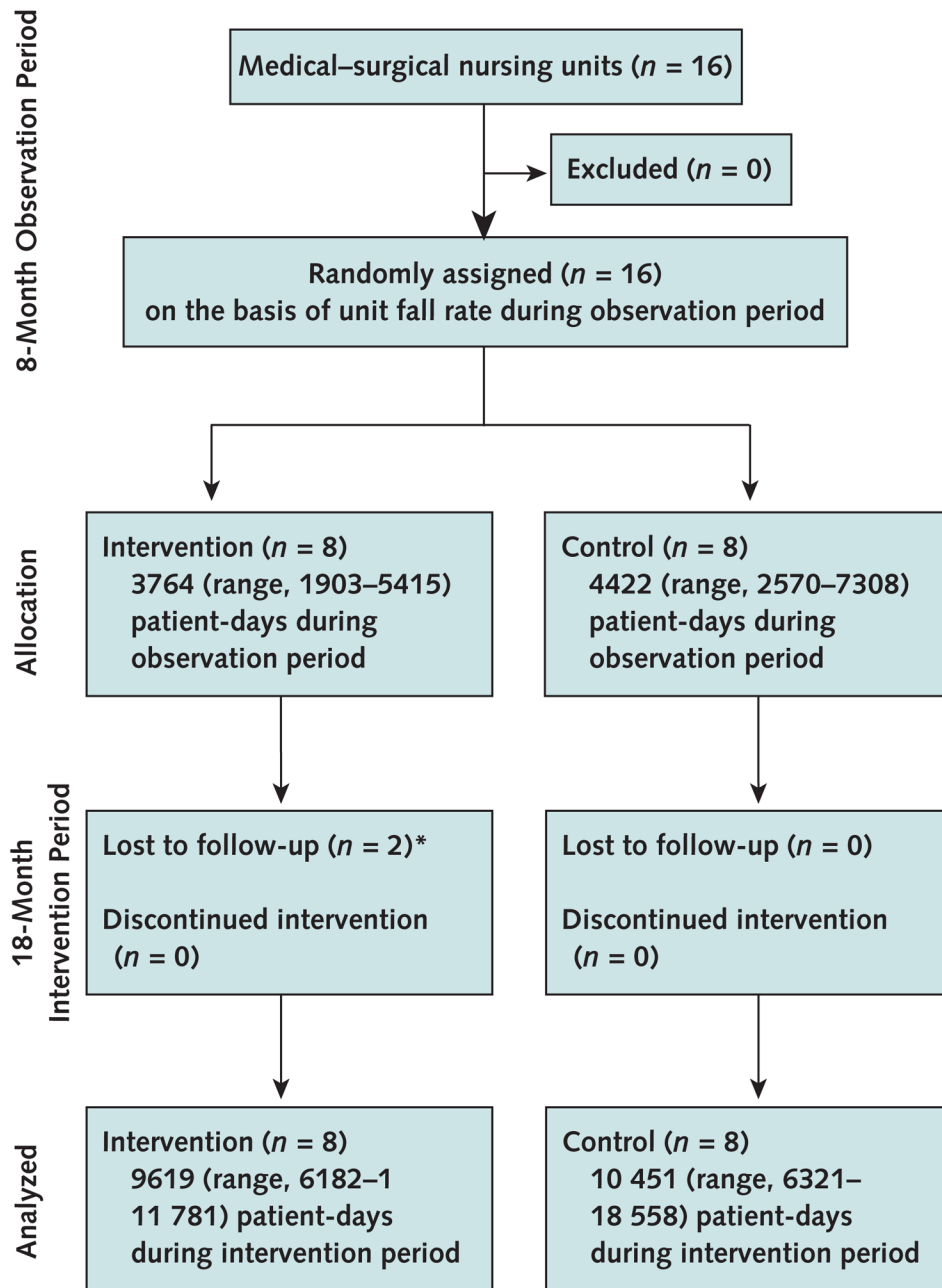
**Caution**

The study was conducted at a single hospital.

**Implication**

Bed alarms may be a useful component of a well-defined hospital fall prevention program but are unlikely to be simple and effective fall prevention solutions.

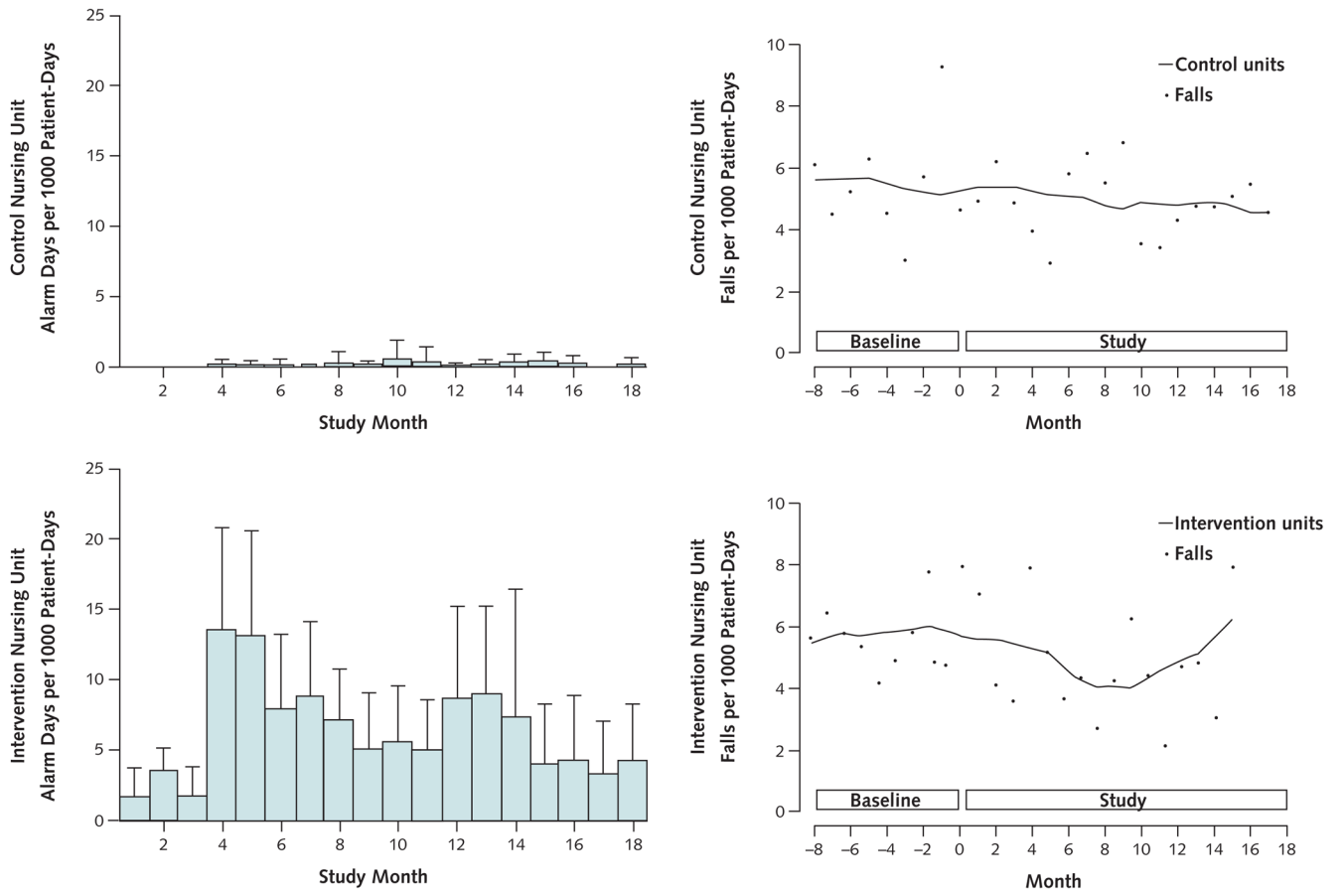
—The Editors



**Figure 1. Study flow diagram**

Mean and range of patient-days in individual nursing units over the 8-mo observation period (allocation) and 18-mo intervention period (analysis) are reported.

\* Two units unexpectedly closed during the study and provided data for only 3 mo.



**Figure 2. Alarm days and falls per 1000 patient-days on control and intervention nursing units**  
Error bars represent SDs.

**Table 1**

Characteristics of Intervention and Control Nursing Units During Baseline and Study Periods\*

Variable	Control Units		Intervention Units	
	Baseline Period	Study Period	Baseline Period	Study Period
<b>Unit-level characteristics</b>				
Units, <i>n</i>	8	8	8	8*
Patient-days	35 377	83 604	30 113	59 011
Mean fall risk score (SD) <sup>†</sup>	61.4 (25.5)	61.1 (19.8)	62.8 (24.7)	63.2 (20.2)
<b>Median proportion of patient-days (IQR), by patient-level characteristic</b>				
Age ≥75 y	0.17 (0.10–0.20)	0.25 (0.14–0.30)	0.20 (0.18–0.26)	0.30 (0.26–0.32)
Female sex	0.53 (0.49–0.57)	0.53 (0.51–0.55)	0.59 (0.55–0.61)	0.58 (0.55–0.59)
White race	0.31 (0.27–0.40)	0.32 (0.26–0.44)	0.31 (0.20–0.37)	0.32 (0.21–0.37)
Psychotropic drug use	0.25 (0.19–0.30)	0.22 (0.18–0.24)	0.26 (0.25–0.29)	0.26 (0.21–0.27)
Primary insurance				
Medicare	0.61 (0.49–0.67)	0.57 (0.50–0.67)	0.64 (0.61–0.66)	0.59 (0.57–0.65)
Medicaid	0.13 (0.10–0.17)	0.12 (0.10–0.14)	0.11 (0.10–0.12)	0.12 (0.10–0.13)
Other insurance	0.28 (0.22–0.33)	0.30 (0.21–0.39)	0.24 (0.22–0.29)	0.30 (0.23–0.33)
<b>Median proportion of hours per patient-day (IQR), by staffing</b>				
Registered nurse	5.2 (4.1–6.1)	4.3 (3.9–4.8)	4.3 (4.0–4.6)	3.8 (3.6–4.2)
Licensed practical nurse	1.5 (1.0–2.4)	1.2 (1.03–1.7)	2.4 (2.2–2.8)	1.9 (1.4–2.0)
Nursing assistant	2.8 (2.7–3.1)	2.2 (2.0–2.3)	3.0 (2.8–3.2)	2.3 (2.0–2.5)

IQR = interquartile range.

\* Two units unexpectedly closed during the study period and provided data only for 3 mo.

<sup>†</sup> Derived from the Morse Fall Scale (15) and scored from 0 to 125. This element was included in the electronic medical record only in the last month of the baseline period but in all 18 mo of the intervention period.

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**Table 2**  
**Outcomes per 1000 Patient-Days During the Baseline and Study Periods on Intervention and Control Nursing Units\***

End Point, per 1000 Patient-Days	Adjusted Fall Rates During Baseline Period (95% CI) <sup>†</sup>	Adjusted Fall Rates During Study Period (95% CI) <sup>‡</sup>	Ratio (95% CI)	RR (95% CI)	Difference (95% CI)	DID (95% CI) <sup>§</sup>
Falls	C: 5.11 (4.07 to 6.75) I: 5.76 (4.31 to 7.86)	C: 4.56 (3.80 to 5.81) I: 5.62 (4.98 to 7.76)	C: 0.89 (0.75 to 1.03) I: 0.98 (0.77 to 1.39)	1.09 (0.85 to 1.53)	C: -0.55 (-1.48 to 0.14) I: -0.14 (-1.77 to 2.02)	0.41 (-1.05 to 2.47)
Patients who fell	C: 4.57 (3.83 to 5.92) I: 5.00 (3.76 to 6.75)	C: 4.01 (3.50 to 5.00) I: 5.04 (4.47 to 6.52)	C: 0.88 (0.74 to 1.01) I: 1.01 (0.82 to 1.31)	1.15 (0.92 to 1.49)	C: -0.56 (-1.44 to 0.05) I: 0.03 (-1.18 to 1.30)	0.59 (-0.50 to 1.84)
Injurious falls	C: 1.87 (1.44 to 2.35) I: 1.30 (0.89 to 1.84)	C: 1.32 (0.97 to 1.62) I: 1.30 (1.05 to 1.56)	C: 0.70 (0.46 to 0.94) I: 1.00 (0.61 to 1.60)	1.42 (0.77 to 3.34)	C: -0.55 (-1.24 to 0.09) I: 0.00 (-0.72 to 0.57)	0.56 (-0.32 to 1.67)
Patients restrained	C: 3.86 (2.83 to 5.34) I: 5.20 (3.76 to 8.59)	C: 5.65 (3.82 to 8.24) I: 6.29 (5.21 to 9.03)	C: 1.46 (1.16 to 1.78) I: 1.21 (0.85 to 1.55)	0.83 (0.56 to 1.18)	C: 1.79 (0.57 to 3.34) I: 1.09 (-1.23 to 2.47)	-0.69 (-3.77 to 1.03)

C = control unit; DID = difference in differences; I = intervention unit; RR = risk ratio.

\* Adjusted rates are from a marginal model that accounts for the cluster randomized design; estimates are from a model adjusted for group assignment, period, and group assignment × period interaction ("base model"). For falls, an RR < 1.0 and a DID < 0 favor the intervention units.

<sup>†</sup> 65 490 patient-days.

<sup>‡</sup> 142 615 patient-days.

<sup>§</sup> Difference in change in intervention compared with control units (intervention units – control units).

**Table 3**

Relative and Absolute Effects of Alarm Intervention for the Primary and 3 Secondary End Points, Adjusted for Unit-Level Covariates

End Point	Covariate (95% CI)		
	Staffing*	Demographic Characteristics <sup>†</sup>	All <sup>‡</sup>
Falls	R: 1.18 (0.88 to 1.75) A: 0.79 (-0.77 to 3.11)	R: 1.08 (0.83 to 1.50) A: 0.33 (-0.77 to 3.11)	R: 1.17 (0.87 to 1.68) A: 0.69 (-0.88 to 3.01)
Patients who fell	R: 1.21 (0.98 to 1.64) A: 0.82 (-0.29 to 2.16)	R: 1.14 (0.95 to 1.45) A: 0.52 (-0.29 to 2.16)	R: 1.22 (1.01 to 1.55) <sup>§</sup> A: 0.81 (-0.12 to 1.89)
Injurious falls	R: 1.60 (0.84 to 3.70) A: 0.71 (-0.23 to 1.84)	R: 1.45 (0.81 to 3.65) A: 0.56 (-0.23 to 1.84)	R: 1.59 (0.81 to 3.57) A: 0.73 (-0.19 to 2.49)
Patients restrained	R: 0.83 (0.51 to 1.26) A: -0.70 (-3.99 to 1.06)	R: 0.84 (0.54 to 1.21) A: -0.79 (-3.99 to 1.06)	R: 0.82 (0.45 to 1.19) A: -0.81 (-5.34 to 0.87)

A = absolute, expressed as difference in differences; R = relative, expressed as risk ratio.

\* Adjusted for base covariates (group assignment, time period, and group assignment × time period interaction) plus staffing covariates (registered nurse, licensed practical nurse, and nursing assistant hours per patient-day).

<sup>†</sup> Adjusted for base, demographic (age, sex, race, and insurance status), and psychotropic drug use covariates.

<sup>‡</sup> Adjusted for base, staffing, demographic, and psychotropic drug use covariates.

<sup>§</sup>  $P < 0.05$ .



**Appendix Table**

Admission Characteristics of Patients on Intervention and Control Nursing Units During Baseline and Study Periods

Variable	Control Units		Intervention Units	
	Baseline Period	Study Period	Baseline Period	Study Period
<b>Patients, <i>n</i></b>	7327	16 911	5272	10 761
<b>Demographic characteristics</b>				
Mean age (SD), <i>y</i>	59.3 (16.6)	59.1 (16.8)	60.1 (17.6)	59.6 (17.3)
Female sex, %	53.7	53.8	55.7	54.7
White race, %	32.5	32.9	28.6	30.5
<b>Psychotropic drug use, %</b>	30.3	28.0	29.5	27.5
<b>Primary insurance, %</b>				
Medicare	54.7	53.9	58.3	57.2
Medicaid	13.7	13.2	12.3	11.9
Other insurance	25.7	25.0	23.4	23.3