TITLE

Reducing falls in rehabilitation hospital units using individualised patient and staff education:

a pragmatic stepped-wedge cluster randomised controlled trial

Authors

Anne-Marie Hill PhD, 1,2 Steven M McPhail PhD, 3,4 Nicholas Waldron MD, 5,6 Professor

Christopher Etherton-Beer PhD, ^{7,8} Katharine Ingram MBBS, ⁹ Professor Leon Flicker PhD, ^{7,8}

Professor Max Bulsara PhD,² Terry P. Haines PhD^{10,11}

1. School of Physiotherapy,

2. Institute for Health Research

The University of Notre Dame Australia

19 Mouat Street (PO Box 1225)

Fremantle, Western Australia

Australia 6959

Telephone +61 8 9433 0239

Facsimile: +61 8 9433 0210

Email: anne-marie.hill@nd.edu.au

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- 3. Institute of Health and Biomedical Innovation and School of Public Health & Social Work, Queensland University of Technology c/o PO Box 6053 Buranda, QLD Australia 4102.
- 4. Centre for Functioning and Health Research, Metro South Health, Brisbane, Australia.
- 5. Department of Rehabilitation and Aged Care, Armadale Kelmscott Memorial Hospital, Department of Health, Government of Western Australia, 189 Royal Street, East Perth, WA, Australia 6004.
- 6. Health Strategy and Networks, Strategic System, Policy & Planning, Department of Health, Government of Western Australia, Perth, Australia.
- 7. School of Medicine and Pharmacology, WA Centre for Health & Ageing, University of Western Australia, 48 Murray Street Perth WA, Australia 6004.
- 8. Royal Perth Hospital, Department of Health, Government of Western Australia, Perth, Australia.
- 9. Department of Rehabilitation and Aged Care, Sir Charles Gairdner Hospital, Department of Health, Government of Western Australia 189 Royal Street, East Perth, WA, Australia 6004.
- 10. Physiotherapy Department, Monash University, Frankston, Victoria, Australia.
- Allied Health Research Unit, Monash Health, 246 Clayton Road Clayton, Victoria,
 Australia 3168.

ABSTRACT

Background

Falls remain one of the most frequent adverse events in hospitals. This study examined the effectiveness of individualised patient falls prevention education supported by training and feedback for staff when delivered as a ward-level program.

Methods

Eight rehabilitation hospital units participated in this stepped-wedge, cluster randomised study, conducted over 50 weeks. Patients with Mini-Mental State Examination >23/30 received individualised education based on principles of health behaviour change, from a trained health professional in addition to usual care. Patients' goals, feedback regarding the ward environment and perceived barriers to engagement in falls prevention strategies were provided to staff who were trained to support uptake of strategies by patients. Primary outcome measures were falls, injurious falls, proportion of patients falling and length of stay. Data were analysed allowing for correlation of outcomes (clustering) within units. Rates of falls per 1000 patient days were compared between groups using negative binomial regression.

Findings

There were 3606 patient admissions to the eight units (n=1983 control period; n=1623 intervention period). Patients (mean age 82 years) had a median length of stay of 11 days. There were 576 (197 injurious) falls, among 384 (10.65%) patients. There were significantly fewer falls, injurious falls and fallers in the intervention group compared to the control group (falls n=196, 7.80/1000 patient days versus n=380, 13.78/1000 patient days, adjusted rate

ratio 0.60, [robust 95% CI 0.42 to 0.84], p=0.003); fall injuries (n=66, 2.63/1000 patient days versus n=131, 4.75/1000 patient days, adjusted rate ratio 0.65, [robust 95% CI 0.48 to 0.88], p=0.006); fallers (n=136 [8.38%] versus n=248 [12.51%] adjusted odds ratio 0.55, [robust 95% CI 0.38 to 0.81], p=0.003). There was no significant difference in length of stay (median [IQR] intervention n=11 [7-19] days, control n=10 [6-18] days).

Interpretation

Individualised patient education combined with training and feedback to staff to support the program in addition to usual care reduced rates of falls and injurious falls by older patients in rehabilitation hospital units.

Funding

State Health Research Advisory Council, Health Department Western Australia, Australia

Trial registration

This trial is registered with the Australian New Zealand Clinical Trials registry (ACTRN12612000877886).

BACKGROUND

Falls remain the most common adverse event reported in hospitals, comprising 20% to 30% of all incident reports. Geriatric and rehabilitation wards have higher falls rates (between 10 and 17 per 1000 patient bed days)^{2–4} than surgical or acute care wards. Approximately 30% of in-hospital falls result in physical injuries, which incur increased costs. Non-injurious falls are also associated with substantially increased costs through longer lengths of stay in hospital. Non-injurious

Meta-analyses of randomised trials that delivered multifactorial falls prevention interventions in hospitals^{9–12} demonstrate that multifactorial interventions can reduce falls, but that the optimum type and intensity of interventions is unknown. Recent trials that have investigated individual strategies of bed alarms or a policy of introducing low-low beds, have found that these were ineffective strategies. He-16

Individualised patient education has some evidence of benefit when provided as a part of multifactorial programs^{12,17} and as a single intervention.¹⁸ An individualised patient education program delivered in addition to usual care prevented falls among a subgroup of older patients with better cognitive function but was not effective for patients with cognitive impairment.¹⁸ This trial enrolled individual patients and was not implemented as a ward-level program. Ward staff were not made aware of who was participating in the trial to minimise confounding and did not receive feedback gathered by researchers who provided the education. Hence, potential benefits of a ward-level delivery of the education could not be explored in that trial. We therefore designed the present study to evaluate the effectiveness of providing this falls prevention patient education program, with the addition of staff training and feedback to support the program, on rates of falls in hospital rehabilitation units.

METHODS

Design

This cluster randomised controlled trial was conducted using a stepped wedge design (Figure 1). ^{19,20} The duration of the trial was 50 weeks between January and December 2013. The full protocol for the trial, including a description and rationale for use of the stepped wedge design has been reported previously. ²¹

Participants and setting

The participants and setting have been described in detail previously. ²¹ Briefly, eight publicly-funded geriatric rehabilitation hospital units (clusters) that admit patients for rehabilitation for conditions such as hip fracture or medical illness enrolled in the trial. The eight clusters contained n=267 beds in total. All multidisciplinary unit staff were eligible to participate in the education program when their site was randomised to crossover into the intervention condition. Patients admitted to a participating unit during an intervention condition were prospectively screened upon ward admission and, where eligibility criteria were met, were offered the individualised education. Patients were eligible to receive the individualised education if they were aged over 60 years, had a projected length of stay (LOS) of at least three days, and had basic cognitive functioning intact. This was defined as having a Mini-Mental State Examination (MMSE) score of >23/30 or an Abbreviated Mental Test Score (AMTS)>7/10^{22,23} and the treating clinical team considering that the patient had levels of cognition where they had potential to benefit from the education.

Randomisation and masking

Randomisation of the eight units was conducted eight weeks prior to the study commencement using a computer-generated, random allocation sequence, by an investigator (TPH) who was not involved in recruitment, data collection or in contact with the units. The allocation was then communicated to the chief investigator (AMH) who informed the unit managers (mid-December 2012), with hospital ward staff informed at the commencement of the trial. After a ten week control period two units commenced the intervention and this procedure continued at ten week intervals, until all eight units had crossed over into the intervention condition (Figure 1). There were no delays or alteration in the randomisation sequence or in the dates that units commenced the intervention. The research assistants who collected falls data were blinded to the methodology of the trial and audited case notes in a different location to education delivery. Hospital falls incident data were collected on the wards routinely using the hospital reporting system which operated on all units. These data were then collated by hospital administrative staff who were not aware of which units were participating in the trial or which patients received education.

Intervention

The full description of the intervention has been reported previously. ²¹ Briefly, the Safe Recovery program ^{18,24} consists of an individualised patient falls prevention education program which is framed on the principles of health behaviour change. ^{25,26} The program was provided in a pedagogically sound manner ²⁷ by physiotherapists (educators). These educators were provided by the research team, were not employed at the hospital and not permitted to deliver any intervention other than the trial intervention. The educators, along with two clinical representatives from each ward, underwent six hours of online, video conference-based training delivered by a study researcher (TPH). The patient component of the program consisted of a multimedia education package (digital video disc and a written workbook) and

individually tailored follow-up sessions from the educator. Each patient viewed the DVD at their bedside and received a workbook to review and keep. The educator then provided follow-up sessions for each patient which were tailored for the patient's individual circumstances. The educator had discretion over the number and time of sessions although the program was designed to be delivered in approximately 30 minutes across two to four sessions. The education aimed to alert patients to their personal risk of falls, raise their knowledge about falls epidemiology and falls prevention and motivate them to engage in falls prevention strategies. The educator facilitated the patient to set personal goals to reduce their risk of falls and to complete a written action plan, for example: "always use my mobility aid when walking." The staff component of the program consisted of face to face staff training in the week of the commencement of the intervention on their unit. This training provided staff with information about the program such that staff understood what education the patients would receive. The educator also provided ongoing weekly feedback to individual and groups of staff on the wards. The feedback provided staff with information about the goals that the patients had set and patients' feedback about barriers that they perceived impacted on their ability to engage in their chosen falls prevention strategies, including relevant aspects of the ward environment. For example, the educator alerted staff if during an education session the patient reported that their mobility aid was not placed within reach at the bedside. Staff could then ensure the aid was placed in a suitable location for the patient to access.

Usual care

All units used the same falls risk assessment and management tool to enable consistent delivery of a comprehensive, tailored falls prevention program. This included charted environmental, medical and mobility interventions, falls risk alert stickers and nurse led discussion with patients about falls prevention. Staff on all units also received regular training

in falls reporting and falls prevention as part of hospital training programs and the falls prevention officers at each hospital reinforced that training prior to the trial commencement.

Outcome measures

The primary outcome measures as recommended by falls research guidelines ¹³ were patient rate of falls, proportion of patients being fallers and rate of injurious falls while in the study units. Falls were defined as "an event which results in a person coming to rest inadvertently on the ground or floor or other lower level." ²⁸ In-hospital falls data were collected using two approaches; i) data extracted from the hospital incident report system and ii) auditing of patient case notes. Previous work has demonstrated that multiple approaches to falls data collection are required to gather valid data. ^{5,29} Falls were classified as injurious if they resulted in a physical injury including bruising, laceration, dislocation, fracture, loss of consciousness or if the patient reported persistent pain. ¹⁸ This is consistent with previous research investigating falls reporting in hospital settings ⁵ and also with previous large epidemiological falls research investigations conducted in hospital settings. ^{1,2} LOS by patients in a unit participanting in the trial was also a primary outcome.

Process outcomes measured included the number of education sessions delivered and the number of patients who completed a written action plan. Demographic and clinical information were collected within the hospital system for patients admitted to the units and included the number of patient admissions to the unit, patient LOS, age, diagnosis and functional ability, measured using the Functional Independence Measure (FIMTM) which includes motor and cognitive items.³⁰

Procedure

The procedure has been described in detail previously. ²¹ The educators visited the ward to provide the intervention two to three times weekly between Monday and Friday during the hours of 9am to 4pm. They also provided feedback to staff at each visit about patients' individual action plans and patient concerns about the unit environment which could be addressed by staff; for example if a call bell was being placed out of reach of a patient. All patients who received education had a sticker placed at their bedside and in their case notes to alert staff to which patients had a written falls prevention plan. Staff were encouraged verbally by the educator to support these patients to carry out their action plan by engaging with patients about the education as part of providing clinical care. This included delivering relevant tailored education messages when in the company of patients who were eligible to receive the education program and using feedback from patients who had received education to inform unit level clinical practice for all patients.

Statistical Analysis

All analyses were conducted on an intention-to-treat basis. The trial statistical analysis plan was pre-specified. Primary analyses compared the following outcomes between the intervention and the control period: i) the rate of falls (falls per 1000 patient days) using negative binomial regression, ^{13,31} ii) the proportion of patients who experienced one or more falls versus no falls using logistic regression, and iii) the rate of falls resulting in injury using negative binomial regression. Each analysis used patient level data that were clustered within "rehabilitation unit." The STATA command option "cluster" was used to identify each rehabilitation unit as the unit of clustering in these analyses. This option employs the Huber-White sandwich method of calculating robust variance estimates. This allows relaxation of the assumption of independence of observations within clusters. ^{32,33} All primary analyses were adjusted for covariates comprising the 10 week time period in which the patient was

discharged (treated as a categorical variable), age, gender, FIMTM, ³⁰ number of comorbidities and the rate of falls on the units for the same time period from the previous year at the research locations. Data from patients admitted following the start of trial were included, and the data were censored at trial conclusion (27th December 2013) for patients remaining on the units after this point. Patients present on the ward at the point where the unit transitioned from being a control unit to an intervention unit had their data censored from the day prior to the start of transition. Differences in LOS on the unit between intervention and control periods were compared using linear regression analysis with patients clustered by unit. This analysis was conducted using data only from patients who were both admitted and discharged during the unit's control period or intervention period. The LOS dependent variable was log transformed to normalise its distribution prior to linear regression analysis. Pre-specified²¹ examination of the interaction between patients' cognition and the effect of the intervention was undertaken for each of the primary analyses, with an a priori cognition subgroup analysis undertaken for any primary outcome with a significant cognition-intervention interaction effect.³⁴ This a priori cognition subgroup analysis repeated the primary analysis for a higher and a lower cognition subgroup using a MMSE cut-off of greater than 23/30.²²

The association between falls outcomes (dependent variable) and 'weeks since the start of the intervention condition on that unit' was examined using negative binomial regression analyses (for rate of falls and rate of injurious falls) or logistic regression (proportion of patients who fell) to identify whether there was a cumulative unit-level effect of the education intervention on patient falls over time. This analysis was also conducted for LOS (using linear regression) to identify whether there was a cumulative unit-level effect of the intervention on LOS. An intervention-by-unit interaction effect (I² statistic) was determined by random-effects meta-regression of unit-level analyses for both falls and length of stay, to describe the percentage of total variation across units that was due to heterogeneity rather

than chance.³⁵ All analyses were conducted using Stata13 (Stata Statistical Software: Release 13. College Station, TX: StataCorp LP).

Sample Size

An a priori sample size calculation was performed accounting for a design effect brought about by clustering of data within rehabilitation units. This calculation identified the trial would have >80% power to detect a 30% relative reduction in falls assuming an ICC of 0.002. Further details of this sample size calculation have previously been reported.²¹

Ethical approvals

The study was approved by university and local hospital ethics committees. Unit medical directors consented to units participating in the trial prior to randomisation. Given the requirement for a pragmatic approach, a waiver of obtaining individual staff and patient consent was approved by the ethics committees.

Role of the funding source

The funding body had no role in the study design, data collection, analysis, access to raw data, interpretation of the data, or in writing this report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

RESULTS

There were 3606 admissions (characteristics of patient admissions shown in Table 1) to the eight clusters during the 50 weeks of the trial; 1623 during the intervention period and 1983 during the control period (Figure 1). This included 3121 first admissions, 402 second admissions and 83 admissions from patients who were admitted three or more times.

Intervention delivery

There were 914 (56·31%) patients admitted during the intervention period who were eligible, to receive the individual patient education based on their cognitive status. None of these patients were subsequently deemed ineligible based on the clinical judgement of their treating clinical team. Of the patients meeting the cognitive eligibility criteria, 80 patients (8.75%) were not eligible to receive the education as they had a projected LOS of less than three days. The educators delivered a total of 1668 education sessions to 757 (90.77%) of the 834 remaining eligible patients (Figure 1). The 77 (9.23%) eligible patients who did not receive individual education were either transferred or discharged from hospital prior to receiving the intervention as planned. The median (inter quartile range [IQR]) number of education sessions provided for each patient was 2 (1-3) and the median (IQR) time taken to provide the education to an individual patient was 45 (35-55) minutes. Patients who had received the education intervention and were subsequently readmitted to the rehabilitation unit were reminded of the education content and assisted to adapt their action plan to suit their current admission. Patients set a total of 1643 behavioural goals to facilitate their safe recovery (median [IQR] of 2 [1-3] goals), with 704 (93%) patients completing a written action plan. Examples of frequently set goals were: ring call bell for assistance; wait for help from staff; use prescribed walking aid. The educators provided 400 hours of staff formal and informal education and feedback (approximately 2 hours per week at each of the 8 units) to enable

staff to support the education program. The most commonly identified categories of patient feedback provided to staff were: staff need to clarify required mobility levels to ensure that accurate mobility instructions were provided for patients; staff need to provide consistent levels of assistance; staff need to leave the call bell within reach at all times. There were no adverse events reported during the trial.

Falls outcomes

There were 576 falls among 384 participants during the 50 weeks of the trial of which 197 (34·20%) were injurious: 503 falls were recorded in the hospital incident reporting system and 73 additional falls were identified during auditing of case notes. There were six fractures in the control group (three hip fractures, wrist, humerus and nose) and four in the intervention group (tibial plateau, humerus, wrist, zygomatic arch). The overall rate of falls on all units for the 50 weeks of the trial was 10.9 falls per 1000 patient days. The median site falls rate for control and intervention conditions are presented in Figure 1 for each 10-week interval of the trial. There were significantly fewer falls, injurious falls and patients who were fallers during the intervention period compared to the control period (Table 2).

There were 1676 (46·48%) patients admitted during the 50 weeks of the trial (n=709 intervention; n=967 control) who were classified as having impaired cognition. There was no significant intervention-by-cognition interaction for either the fallers or injurious falls outcomes. There was a significant intervention-by-cognitive impairment interaction effect for the falls outcome (incident rate ratio 0.64, 95% CI [0.48 to 0.86], p=0.003). Falls rates for sub-groups based on cognition are presented in Table 3.

There was no significant difference in LOS on the units between patients admitted during the control period compared to intervention period (median [IQR], intervention=11 [7-19] days;

control=10 [6-18] days: [β 0·20, 95% CI (-0·45 to 0·85), p=0·49]; (intracluster correlation coefficient 0·14, 95% CI [0·003 to 0·26]). There was also no significant cumulative unit level reduction in LOS over time during the intervention period [β 0·01, 95% CI (-0·02 to 0·04), p=0·40]. However the intervention by time analysis demonstrated that there was a significant cumulative unit-level reduction in falls and injurious falls rates and the proportion of fallers over time on units during the intervention period (Table 2). There was some variability in the effect of the intervention on falls between units due to heterogeneity rather than chance (I^2 statistic=25·7%), but not for LOS (I^2 statistic=0%).

DISCUSSION

This is the first trial conducted in hospital wards to demonstrate that a single intervention program in addition to usual care can successfully prevent falls and fall-related injuries. No previous trials of falls prevention interventions, whether single or multifactorial interventions, have shown a significant reduction in injurious falls with the exception of one trial which provided a comprehensive geriatric service by a multidisciplinary team in a geriatric ward for patients who fractured their hip and compared this approach with usual care in an orthopaedic ward.¹¹ The intervention in the current trial provided individualised education to patients, training of hospital staff to support the program and provision of patient feedback to staff. Falls were reduced in the whole group including those patients who had cognitive impairment although as expected, the program had the largest effect among patients with better cognition who directly received individualised education. The reduction in falls rates among patients who had cognitive impairment indicates that pragmatic ward based delivery of the education program resulted in benefit to patients who did not directly receive the education. This is important because patients with cognitive impairment have consistently been shown to have an increased risk of falling while in hospital. 8,13 The previous trial that delivered this program was only effective in a subgroup of patients without cognitive impairment, but that trial did not use a ward level implementation approach. 18 The finding of fewer falls within units as the intervention time period increased was also consistent with our expectation that this wardlevel intervention would have a cumulative, beneficial effect over time. This may have been brought about by growing safety culture that supported the patient education program or by incremental changes made to usual care practices brought about by the patient feedback provided to staff by the educator, which identified specific problems on the ward.

This trial demonstrates how a patient education program can be incorporated into ward-level practices such that it reduces falls, including injurious falls. Previous studies have found that other single intervention strategies were ineffective 1416 and studies testing multifactorial interventions, including those that contain education components have been unable to determine what individual strategies are important to implement. ¹³ This education is individualised for each patient and allows them to understand their risk of falling and become capable and motivated to engage in suitable ward based falls prevention strategies. 18,24 While up to 85% of falls occur when patients are unobserved, ^{5,36} interventions that aim to alert staff to patient movements have not been effective. 14,15 Providing patients with education allows the patient to understand how to initiate safe behaviours within the hospital environment, particularly when unobserved, including alerting staff to their need for assistance. Further, staff were also provided with individualised patient feedback which identified safety problems from the perspective of the patient. Health behaviour change concepts support this pragmatic delivery of the education as a ward based program which enables staff to provide the physical and social opportunity required for patients and staff to engage in the desired falls prevention behaviours.²⁶

This study has strengths and limitations that warrant consideration. The use of two data sources for capturing falls information during the trial should be deemed a strength. ^{5,29} The pragmatic study design meant no patients were lost to follow up and the ward level implementation of the intervention carried foremost relevance for subsequent implementation in similar geriatric and rehabilitation hospital wards. One conceivable limitation of stepped wedge trial designs is the potential for underlying seasonal trends to inadvertently influence study outcomes. To account for this, the pre-specified analysis plan included provision for statistical adjustment to account for potential seasonal effects. However, the stable median site falls rate during the control condition and absence of any interaction effect between time

since control period commenced and patient falls outcomes indicated that any potential confounding seasonal influence on the trial outcomes was unlikely. Trial sites were not able to be blinded to the trial procedure or their allocation state due to the nature of the intervention. However there were no observed changes in admission procedures at sites between their control and intervention periods or systematic changes at the sites which prevented measurement of the outcomes. All wards in a site were randomised as a single unit so that movement of patients or staff within the site would not affect the trial.

The study was intentionally restricted to rehabilitation units which have a longer length of stay than acute units. Although the length of stay observed in the trial was shorter than the investigators had initially anticipated, this did not negatively influence the power of the study, with statistically significant and clinically meaningful effects detected for all falls outcomes. It is also noteworthy that the nurse to patient ratios in Western Australia are largely consistent with ratios used elsewhere, with Australia having formal nurse-patient ratios established across a range of health settings. The Similarly, allied health disciplines (such as physiotherapy, social work, occupational therapy, speech pathology, dietetics) were also provided at all of the participating sites; consistent with international practices on geriatric rehabilitation wards. Having an adequately staffed and skilled team providing care on these rehabilitation wards may have mediated the effect of this intervention. Each of the participating units also already delivered a structured falls prevention program as a part of usual care. This intervention may not have had the same level of effectiveness on other ward types, or hospital wards that do not already have structured falls prevention programs in place.

In conclusion individualised patient and staff education provided as part of ward clinical care reduces falls and injurious falls in wards where older patients are undergoing rehabilitation.

Hospitals should incorporate this type of education into falls prevention programs that are delivered in rehabilitation units.

Panel – Research in context

Systematic review

Findings of the Cochrane library database of systematic reviews for falls prevention in hospital and care home settings were reviewed;¹³ this included 17 RCTs. In addition, RCTs that examined interventions for falls prevention in hospitals published since the aforementioned Cochrane review were also examined.^{14,15}

Interpretation

Prior to the present study, there was some evidence that multifactorial strategies can reduce rates of falls in hospitals (Rate ratio 0.69, 95% CI 0.49 to 0.96) and risk of falling (Rate ratio 0.71, 95% CI 0.46 to 1.09) although the evidence for reducing risk of falling was inconclusive. However the previous multifactorial interventions included various combinations and intensities of intervention components; including education, risk assessment and management, environmental alterations and exercise. No particular component, or combinations of components, was able to be recommended. The RCTs published since the Cochrane review found no beneficial effect of providing bed alarms as a single intervention. Only one previous RCT found a significant reduction in injurious falls. However, that study compared the provision of a comprehensive geriatric service by a multidisciplinary team in a geriatric ward for older patients who fractured their hip with usual care in an orthopaedic ward with relatively lower staffing.

Patient education as part of a multifactorial intervention has some previous evidence of potential benefit. 12,17,18 However, to the authors' knowledge, this is the first trial using a single intervention approach consisting of an individualised patient and staff education program to demonstrate a significant reduction in falls, proportion of patients falling and

injurious falls. This intervention uses a structured, pedagogically sound program that is founded in the principles of health behaviour change and can be replicated with fidelity.

Based on findings from this trial it is recommended that individualised patient education with staff support be provided on rehabilitation wards in addition to usual care to reduce patient falls.

CONTRIBUTERS

AMH contributed to study conception, design, trial management, intervention training, undertaking statistical analyses, principal manuscript drafting and editing. SMMcP contributed to study conception, design, data management, undertaking statistical analyses, manuscript drafting, appraisal and editing. NW contributed to study conception, design, trial management, site management and data collection and management. CEB, LF and KI contributed to study conception, design, site management and provided advice on data collection and management. MB contributed to data management and undertaking statistical analyses. TPH contributed to study conception and design and intervention training. All authors contributed to manuscript appraisal, revision and editing and read and approved the final manuscript.

CONFLICTS OF INTEREST

TPH is the Director of Hospital Falls Prevention Solutions Pty Ltd. This company provides training for provision of the Safe Recovery programme. As such, TPH has a direct financial interest in the outcomes of this research. TPH has been involved in the conception of this research, the selection of the research design, the analysis approach, the design of the economic evaluation and the drafting of this manuscript. He has provided training in the Safe Recovery programme to project personnel at no cost to the project. He has no involvement in the extraction of data or the analysis of data beyond providing guidance as to appropriate methods for conducting the analysis at the stage of writing the trial protocol. He has no agreement or ability that restricts the ability of other investigators to publish the trial results. TPH has provided expert witness testimony for Minter Ellison Law Firm on the subject of prevention of falls in hospital and has received speakers' fees to talk on the subject of the

and Medical Research Council (of Australia) fellowships. TPH is supported by a National Health and Medical Research Council (of Australia) Career Development award

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REFERENCES

- 1. Healey F, Scobie S, Oliver D, Pryce A, Thomson R, Glampson B. Falls in English and Welsh hospitals: a national observational study based on retrospective analysis of 12 months of patient safety incident reports. *Qual Saf Health Care* 2008; **6**: 424–30.
- 2. Schwendimann R, Buhler H, De Geest S, Milisen K. Characteristics of hospital inpatient falls across clinical departments. *Gerontology* 2008; **6**: 342–48.
- 3. Haines T, Kuys SS, Morrison G, Clarke J, Bew P. Balance impairment not predictive of falls in geriatric rehabilitation wards. *J Gerontol A Biol Sci Med Sci* 2008; **5**: 523–28.
- 4. Teasell R, McRae M, Foley N, Bhardwaj A. The incidence and consequences of falls in stroke patients during inpatient rehabilitation: factors associated with high risk. *Arch Phys Med Rehabil* 2002; **3**: 329–33.
- 5. 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; **7**: 1347–52.
- 6. Bates DW, Pruess K, Souney P, Platt R. Serious falls in hospitalized patients: correlates and resource utilization. *Am J Med* 1995; **2**: 137–43.
- Haines TP, Hill AM, Hill KD, et al. Cost effectiveness of patient education for the prevention of falls in hospital: economic evaluation from a randomized controlled trial. BMC Med 2013; 135.
- 8. Oliver D, Healey F, Haines TP. Preventing falls and fall-related injuries in hospitals. *Clin Geriatr Med* 2010; **4**: 645–92.
- 9. Healey F, Monro A, Cockram A, Adams V, Heseltine D. Using targeted risk factor reduction to prevent falls in older in-patients: a randomized controlled trial. *Age Ageing* 2004; **4:** 390–95.

- Cumming RG, Sherrington C, Lord SR, et al. Cluster randomized trial of a targeted multifactorial intervention to prevent falls among older people in hospital. *BMJ* 2008;
 7647: 758–60.
- 11. Stenvall M, Olofsson B, Lundstrom M, et al. A multidisciplinary, multifactorial intervention program reduces postoperative falls and injuries after femoral neck fracture.

 *Osteoporos Int 2007; 2: 167–75.**
- 12. Haines TP, Bennell KL, Osborne RH, Hill KD. Effectiveness of targeted falls prevention programme in subacute hospital setting: randomized controlled trial. *BMJ* 2004; **7441**: 676.
- 13. Cameron ID, Gillespie LD, Robertson MC, et al. Interventions for preventing falls in older people in care facilities and hospitals. *Cochrane Database Syst Rev.* 2012: CD005465.
- 14. Shorr RI, Chandler AM, Mion LC, et al. Effects of an intervention to increase bed alarm use to prevent falls in hospitalized patients: a cluster randomized trial *Ann Intern Med* 2012; **10**: 692–99.
- 15. Sahota O, Drummond A, Kendrick D, et al. REFINE (REducing Falls in In-patieNt Elderly) using bed and bedside chair pressure sensors linked to radio-pagers in acute hospital care: a randomized controlled trial. *Age Ageing* 2014; **2**: 247–53.
- 16. 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; **3**: 435–41.
- 17. Ang E, Mordiffi SZ, Wong HB. Evaluating the use of a targeted multiple intervention strategy in reducing patient falls in an acute care hospital: a randomized controlled trial. *J Adv Nurs* 2011; **9**: 1984–92.

- 18. Haines TP, Hill AM, Hill KD, et al. Patient education to prevent falls among older hospital inpatients: A randomized controlled trial. *Arch Intern Med* 2011; **171**: 516–524.
- 19. Brown C, Lilford R. The stepped wedge trial design: a systematic review *BMC Med Res Methodol* 2006; **1**: 54.
- 20. Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. *Contemp Clin Trials*. 2007; **28**: 1829–1.
- 21. Hill AM, Waldron N, Etherton-Beer C, et al. A stepped-wedge cluster randomised controlled trial for evaluating rates of falls among inpatients in aged care rehabilitation units receiving tailored multimedia education in addition to usual care: a trial protocol.

 BMJ Open 2014; 1.
- 22. Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975; **3**: 189–98.
- 23. Hodkinson HM. Evaluation of a mental test score for assessment of mental impairment in the elderly. *Age Ageing* 1972; **4**: 233–38.
- 24. 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; **8**: 1458–63.
- 25. Orji R, Vassileva J, Mandryk R. Towards an effective health interventions design: an extension of the health belief model. *Online J Public Health Inform* 2012; **4**. doi: 10.5210/ojphi.v4i3.4321
- 26. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implement Sci* 2011; **6**: 42. doi:10.1186/1748-5908-6-42.
- 27. Merriam SB, Caffarella RS, Baumgartner LM. Learning in adulthood: a comprehensive guide. 3rd ed. San Francisco: Jossey-Bass; 2007.

- 28. WHO. World Health Organisation. www.who.int/violence_injury_prevention/ other injury/falls/en/index.html (Accessed 30th January 2014).
- 29. Shorr RI, Mion LC, Chandler AM, Rosenblatt LC, Lynch D, Kessler LA. Improving the capture of fall events in hospitals: combining a service for evaluating inpatient falls with an incident report system. *J Am Geriatr Soc.* 2008; **56**: 701–4.
- 30. Granger CV, Hamilton BB, Linacre JM, Heinemann AW, Wright BD. Performance profiles of the functional independence measure. *Am J Phys Med Rehabil* 1993; **2**: 84–9.
- 31. Haines TP, Hill AM. Inconsistent results in meta-analyses for the prevention of falls are found between study-level data and patient-level data. *J Clinical Epidemiol*. 2011; **64**: 1546–2.
- 32. White H. A heteroskedasticity-consistent covariance matrix estimator and a direct test for heteroskedasticity. *Econometrica* 1980; **48**: 817–838.
- 33. Williams RL. A note on robust variance estimation for cluster-correlated data. *Biometrics* 2000; **56**: 645–646.
- 34. Assmann SF, Pocock SJ, Enos LE, Kasten LE. Subgroup analysis and other (mis)uses of baseline data in clinical trials. *Lancet* 2000; **355**: 1064–69.
- 35. Higgins JP, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in metaanalyzes. *BMJ* 2003; **7414**: 557–60.
- 36. Staggs VS, Mion LC, Shorr RI. Assisted and unassisted falls: different events, different outcomes, different implications for quality of hospital care. *Jt Comm J Qual Patient Saf.* 2014; **40**: 3586–4.
- 37. Brogan G.Safety in numbers ratios around the world. *National Nurse* 2012.10–12.

Table 1. Characteristics of patient admissions during control (n=25 weeks) and intervention periods (n=25 weeks)

Characteristic	Intervention Period	Control Period (n=1983
	(n=1623 admissions)	admissions)
Age, years, mean±SD	81·4 <u>+</u> 9·3	82·1 <u>+</u> 8·3
Gender, female, n (%)	999 (61.6)	1211 (61·1)
Length of stay in rehabilitation unit,	12 (7-21)	11 (6-20)
days, median (interquartile range)		
Diagnosis on admission to		
Rehabilitation ward, n (%)		
Medical conditions*	461 (28·4)	654 (33·0)
Orthopaedic, musculoskeletal [†]	369 (22.7)	395 (19.9)
Hip fracture	168 (10.4)	182 (9·2)
Stroke	192 (11·8)	175 (8.8)
Other neurologic disease [‡]	101 (6.2)	162 (8·2)
Cardiac	141 (8.7)	198 (10.0)
Respiratory	105 (6.5)	120 (6.0)
Other surgery§	86 (5·3)	97 (4.9)
Number of comorbidities, n (%)		
none	58 (3.6)	108 (5·5)
1-5	334 (20-6)	575 (29·0)
5-9	712 (43·8)	819 (41·3)
10-14	365 (22·5)	334 (16·8)
> 14	154 (9.5)	147 (7.4)

Admission living situation, [¶]n (%)

Community	1512 (93·2)	1806 (91·1)				
Residential care facility	102 (6·3)	163 (8.2)				
Receives services if lives in	816 (50-3)	807 (40·7)				
community,***n (%)						
Admission FIM ^{TM††} mean <u>+</u> SD						
Cognitive	25·2 <u>+</u> 7·4	24·3 <u>+</u> 7·6				
Motor	49·5 <u>+</u> 17·4	51·7 <u>+</u> 17·6				
Death during admission, n (%)	16 (0.9)	25 (1·3)				

^{*} includes cancer, diabetes, infections, complications due to medical or surgical interventions, digestive system disorders, general malaise

- † upper limb and lower limb fractures (excluding hip), dislocations, joint replacements, spinal disorders
- ‡ includes Parkinsons disease, dementia
- § other than orthopedic surgery
- ¶ missing data for admission living =(9 in intervention period, 14 in control period)
- hostels and nursing homes which provide accommodation support, nursing care and personal care
- ** transport, domestic services, social support
- †† Functional Independence MeasureTM: 18 items total score range 18 to 126; motor items=range 0 to 91; cognitive items=range 0 to 35, higher score indicates better motor or cognitive function

Table 2. Falls outcomes compared between the intervention and the control period

	Intervention	Control period	Adjusted ratio	Cumulative unit level	Intracluster correlation
	period (n=1623	(n=1983	(robust 95% CI), p-	effect of intervention	coefficient (95% CI)
	admissions)	admissions)	value*	over time (Adjusted ratio	
				(robust 95% CI), p-	
				value)*	
Falls /injurious falls	196/ 66/136/4	380/131/248/6			
/fallers /fractures, n					
Falls, rate per 1000	7.80	13.78	IRR 0.60 , (0.42 to)	0.95, $(0.92 to 0.99)$, 0.02	0.02 (0.00 to 0.04)
patient days			0.84), 0.003		
Injurious falls, rate	2.63	4.75	IRR 0.65, (0.48 to	0.96, (0 92 to 0.99), 0.01	0.00 (0.00 to 0.01)
per 1000 patient			0.88), 0.006		
days					
Fallers, % group	8.38	12.51	OR 0.55, (0.38 to	0.97, $(0.93 to 1.00)$, 0.05	0.02 (0.00 to 0.04)
having one or more			0.81), 0.003		

falls

*data clustered by site, with length of stay as exposure variable, analyses adjusted for step time period in trial, age, gender, admission

FIM,TM number of comorbidities, historical monthly site-specific falls rates from previous year

CI= confidence interval, IRR=incident rate ratio, OR= odds ratio

Table 3. Falls outcomes compared between subgroups based on cognition levels

	Intervention period (n=1623	Control period (n=1983	Adjusted ratio (robust 95% CI),
	admissions)	admissions)	p-value†
Higher cognition score, n (%)*	914 (56·32)	1016 (51·24)	
Falls /injurious falls /fallers	61/23/52	137/34/92	
Falls, rate per 1000 patient days	4.87	10.68	IRR 0.53, (0.36 to 0.77), 0.001
Lower cognition score, n (%)	709 (43.68)	967 (48·76)	
Falls /injurious falls /fallers	135/43/84	243/97/156	
Falls, rate per 1000 patient days	10.70	16.46	IRR 0.65, (0.40 to 1.05), 0.08

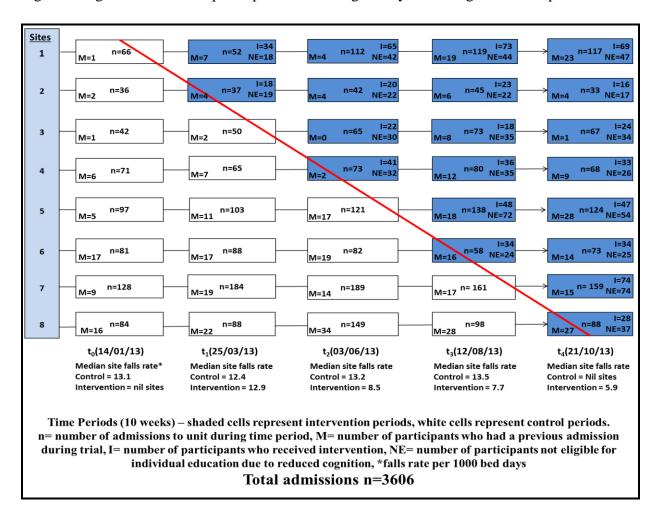
^{*}patient in higher cognition group if Mini-Mental State Examination score >23/30

†data clustered by site, with length of stay as exposure variable; analyses adjusted for step time period in trial, age, gender, admission

 $\mathsf{FIM},^\mathsf{TM}$ number of comorbidities, and historical monthly site-specific falls rates from previous year

CI = confidence interval, IRR=incident rate ratio, OR=odds ratio

Figure 1 Legend. Cluster and participant flow through study, including number of patients who received the individual education.



Trial Profile