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Pilot cluster randomised controlled trial of flooring to reduce injuries from falls in wards for older people

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Abstract

Background: falls disproportionately affect older people, who are at increased risk of falls and injury. This pilot study investigates shock-absorbing flooring for fall-related injuries in wards for frail older people.
Methods: we conducted a non-blinded cluster randomised trial in eight hospitals in England between April 2010 and August 2011. Each site allocated one bay as the 'study area', which was randomised via computer to intervention (8.3-mm thick Tarkett Omnisports EXCEL) or control (2-mm standard *in situ* flooring). Sites had an intervention period of 1 year. Anybody admitted to the study area was eligible. The primary outcome was the fall-related injury rate. Secondary outcomes were injury severity, fall rate and adverse events.
Results: during the intervention period, 226 participants were recruited to each group (219 and 223 were analysed in the intervention and control group, respectively). Of 35 falls (31 fallers) in the intervention group, 22.9% were injurious, compared with 42.4% of 33 falls (22 fallers) in the control group [injury incident rate ratio (IRR) = 0.58, 95% CI = 0.18–1.91]. There were no moderate or major injuries in the intervention group and six in the control group. The fall IRR was 1.07 (95% CI = 0.64–1.81). Staff at intervention sites raised concerns about pushing equipment, documenting one pulled back.
Conclusions: future research should assess shock-absorbing flooring with better 'push/pull' properties and explore increased faller risk. We estimate a future trial will need 33,480–52,840 person bed-days per arm.
Trial registration: ClinicalTrials.gov (ID: NCT00817869); UKCRN (ID: 5735).

Keywords: *floors and floorcoverings, aged, 80 and over, randomised controlled trial, hospitals, older people*

Introduction

Inpatient falls are a major issue for hospitals [1, 2], and are associated with mortality, morbidity and financial costs [3–6]. Falls are particularly prevalent in elderly care environments [3, 7], where patients have more risk factors for both falls and injury [8–11]. With an ageing society, this is an issue of increasing concern [12].

While much work has gone into falls prevention [13, 14], a secondary field is fall-related injury prevention. Hip protectors have dubious support and compliance issues [15]. Flooring is one potential solution to reduce a range of injuries. Since research in this area is lacking [16, 17], we undertook a pragmatic pilot cluster randomised controlled trial (cRCT) to assess the feasibility, potential benefits and harms and to guide further research on the use of shock-absorbing flooring for fall-related injury prevention in elderly care wards.

A cluster design was necessary given the 'multi-bed bay' design of NHS hospitals and logistical constraints of randomising individuals to rooms (e.g. single-sex bays, observation requirements, bed availability). This was a mixed methods study, incorporating a cRCT (reported here), qualitative interviews, mechanical tests and an economic analysis (to

be disseminated elsewhere). The full-study protocol is available [18].

Methods

Trial design

This prospective parallel pilot cRCT included eight sites across England (allocated 1:1). Sample size was to enable estimation of the design effect (for a power calculation). Each site designated one bay as the 'study area'. Patients were 'clustered' at the study area level. The Southampton and South West Hampshire NHS Research Ethics Committee (A) approved the study.

Sites and participants

Hospital wards predominantly for elderly care in England were eligible for inclusion, with no other location restrictions. Included sites were to have floors with a slip resistance rating of 'R9' [19] (matching the intervention floor). All floors at baseline had low slip potential when dry [mean pendulum test value (PTV) = 67.18, SD = 9.87], and high slip potential when wet (mean PTV = 15.81, SD = 3.31). Each site chose the study area bay prior to randomisation, either based on where patients at high risk of falls were placed (e.g. for observation) or for logistical reasons (e.g. for easy access/cordoning off the ward to fit flooring). Eligible bays ranged from four to eight beds in size, and with no restriction on gender usage.

Participants were identified and recruited through the sites. All adults admitted to a bed in the study area were eligible, with no exclusion criteria. Patients provided informed consent (or consultee advice was gained) for their data being utilised. Baseline data were: age, gender, length of stay, function (Barthel index), fracture risk (FRAX), ambulatory aids, reason for admission and co-morbidities/medications associated with falls/fracture risk. Participant recruitment started between April and June 2010, and continued until the end of August 2011. Participants remained in the study until discharge from the ward (with 3-month follow-up for the economic analysis).

Interventions

Intervention sites received an 8.3-mm vinyl floor over fibreglass mat with PVC foam backing (Tarkett Omnisports EXCEL) [20]. The flooring (not suitable for wet areas) was only installed into the bedroom area. Sites planned for a 1-week installation (contracted with Tyndale Flooring Limited), with bays either being gradually 'run down' (not admitting new patients) or transferring patients elsewhere. Each site chose the floor colour from the Omnisports EXCEL range (chosen designs were solid 'mint green', 'teal', 'sky blue' and 'maple' wood effect). Sites decided how to manage the threshold between the new (thicker) floor and standard floors in adjoining areas (by transition strip or gradual 'seamless' gradient). Installations took place between August and September 2010. Control sites received no change in flooring (three sites had 2-mm vinyl ~5 years old, and one site had 2-mm thermoplastic tiles over 30 years old). All sites had concrete subfloors.

Data were collected for 2 to 5 months (median = 4 months) before the floors were laid. Then, data were collected for a further 12–13 months (median = 12 months). The intervention period began from the day patients were readmitted to the study area after the new floor was laid in intervention sites, or the median date of the floors being laid for the control sites (30 August 2010). All sites had an end date of 31 August 2011.

Outcomes

The primary outcome was the fall-related injury rate per 1,000 occupied bed days (OBD). Secondary outcomes were: injury severity; fall rate per 1,000 OBD and adverse events. Injuries were stratified as: 'None'; 'Minor' (complaint of pain, requires ice, dressing, cleaning of wound, elevating limb or medication); 'Moderate' (requires suturing, steri-strips, splinting or temporary bed-rest); 'Major' (requires surgery, casting, traction, neurological consultation for change in the level of consciousness) and 'Death'. A fall is defined as 'an unexpected event in which the participants come to rest on the ground, floor or lower level' [21]. Adverse events were those potentially related to the floor, for example, falls or injury related to the physical condition of the flooring, or any problems or damage associated with the flooring itself. All outcomes were measured using standardised forms completed when events occurred; amendments to forms were made during the baseline period to improve clarity and design, but not content. Data monitoring was conducted through-out the study.

Randomisation and masking

Sites were allocated to intervention or control groups by an independent statistician using a computer-generated random list, in blocks of four. The sequence and blocking was not revealed to the researchers until after the sites had been allocated. After sites received full governance approval, the researchers contacted the statistician to reveal the group allocation. The final three sites were randomised at the same time (in the order the approvals were gained). Sites were informed of their group allocation at the beginning of the baseline period to facilitate the flooring installation. No masking was incorporated into the study.

Statistical methods

All data were double-entered and encrypted. Analyses should be treated as preliminary and exploratory and are mainly descriptive; the inferential statistical analyses are to inform future research as opposed to significance testing. Primarily, we describe the incidence rate ratios (IRRs) for fall-related

injuries and falls (with 95% confidence intervals, and the coefficient of variation, *k*), and any adverse events, during the intervention period.

IRRs were calculated utilising a negative binomial regression (count data), accounting for clustering. Exposure time was based on length of stay (those discharged on the admission day were assigned 0.5 days). Re-admissions were linked to avoid unit of analysis errors. Participants who remained inpatients at the end of data collection had their length of stay censored (31 August 2011). Individuals with missing discharge dates ($n = 6$) were not incorporated in the analysis as no exposure time was known. None of these participants had documented falls, and all were in the intervention group. This conservative approach will have somewhat inflated fall and injury rates in the intervention arm.

To address how effective replacing the floor in the bay is at reducing falls/injury during the patients' stay on the ward, analyses incorporated all falls/injuries, inside and outside the study area, without replacing missing values (we did not track the amount of time participants spent inside and outside the study area). Participants documented with more than one injury from the same fall were coded according to the most severe injury. Injury rates per 100 falls are also described (no. of injuries/no. of falls × 100).

Further analysis of fall rates utilised an Anderson and Gill (AG) intensity model [22]. The AG model generalises the Cox proportional hazards model by accommodating recurrent events. Since this model does not allow a time span between failures of zero, 0.5 was added to time-to-events of zero ($n = 5$), and 0.2 and 0.5 to the times for one participant who fell twice on the day of discharge. All analyses used Stata 11.2 [23].

Results

Participant flow

We recruited our target of eight sites (Figure 1); however, 44 sites were assessed for eligibility. Site visits ($n = 25$) were arranged to meet key staff (e.g. research, clinical, managerial, estates and facilities and infection control staff). Site surveys ($n = 9$) were undertaken by the flooring contractors at sites with continued interest.

Of the 36 sites who did not participate, four presented multiple reasons; reasons were: seven sites did not meet the inclusion criteria (four were not elderly care wards; three had a safety floor *in situ*[1]); 26 declined (12 sites provided no reason, primarily contact was lost through lack of response from the site contact person; four were concerned over the level of disruption and times of high pressure; four had an upcoming reconfiguration of the hospital/services; three had upcoming capital work/refurbishment; three were concerned about workload capacity; one had lack of support from the estates department and one expressed concerns over doorway thresholds). Other reasons for exclusion were two sites had a wooden subfloor[2] (one of these had an upcoming reconfiguration so declined anyway) and two sites expressed their interest too late.

All the patients admitted to the study area were to be allocated a Study ID to enable tracking of recruitment rates. Adherence to this was poor at one control and one intervention site. Of the 540 and 566 IDs allocated at intervention and control sites, respectively, 142 (26.3%) and 187 (33.0%) patients were not approached. Of those approached, the primary known reason for refusal was 'not wanting the bother' (28.2% of the intervention group and 43.3% of control group refusals). Four participants withdrew from the study; one from the intervention group for reasons unrelated to the flooring and three from the control group for unknown reasons. All sites remained in the study.

Baseline characteristics

Participants were of similar age, fracture risk and functionality across groups, but there were more males, use of ambulatory aids and transfers between bays within the ward in the intervention group compared with control (Table 1). More people were admitted with instability in the control group (61%) compared with the intervention group (36%). Overall the control group had more co-morbidities associated with fall risk: diabetes, dizziness, falls/fractures/injuries, incontinence, prolonged immobility and reduced mobility/gait. Medication usage was similar across groups.

Outcomes and estimation

Injuries

Eight (of 225) participants experienced one fall-related injury in the intervention group (OBD = 4,482; IR = 1.78 injuries per 1,000 OBD). In the control group, 13 (of 223) participants experienced 14 injurious falls (OBD = 4,602.5 days; IR = 3.04 injuries per 1,000 OBD). We can estimate (with much uncertainty) that laying the shock-absorbing flooring in the patient bay alone, may reduce the rate of injuries by ∼42% of that experienced by patients without the flooring (adjusted IRR = 0.58, 95% CI = 0.18–1.91, $k = 0.445$). No moderate or major injuries occurred in the intervention group (Table 2), while six occurred in the control group. As a proportion of the number of falls, the injury rate in the control group (42.4%) was almost double that of the intervention group (22.9%).

[1]One of these sites also documented concerns about cleaning the new floor (the guidance did not match their current practices), and recruiting patients with cognitive impairment.

[2]A previous flooring company specified that the flooring would not suit wooden subfloors. Following the liquidation of this company, we enlisted a new contractor with a different floor (Tarkett) suitable on wood.

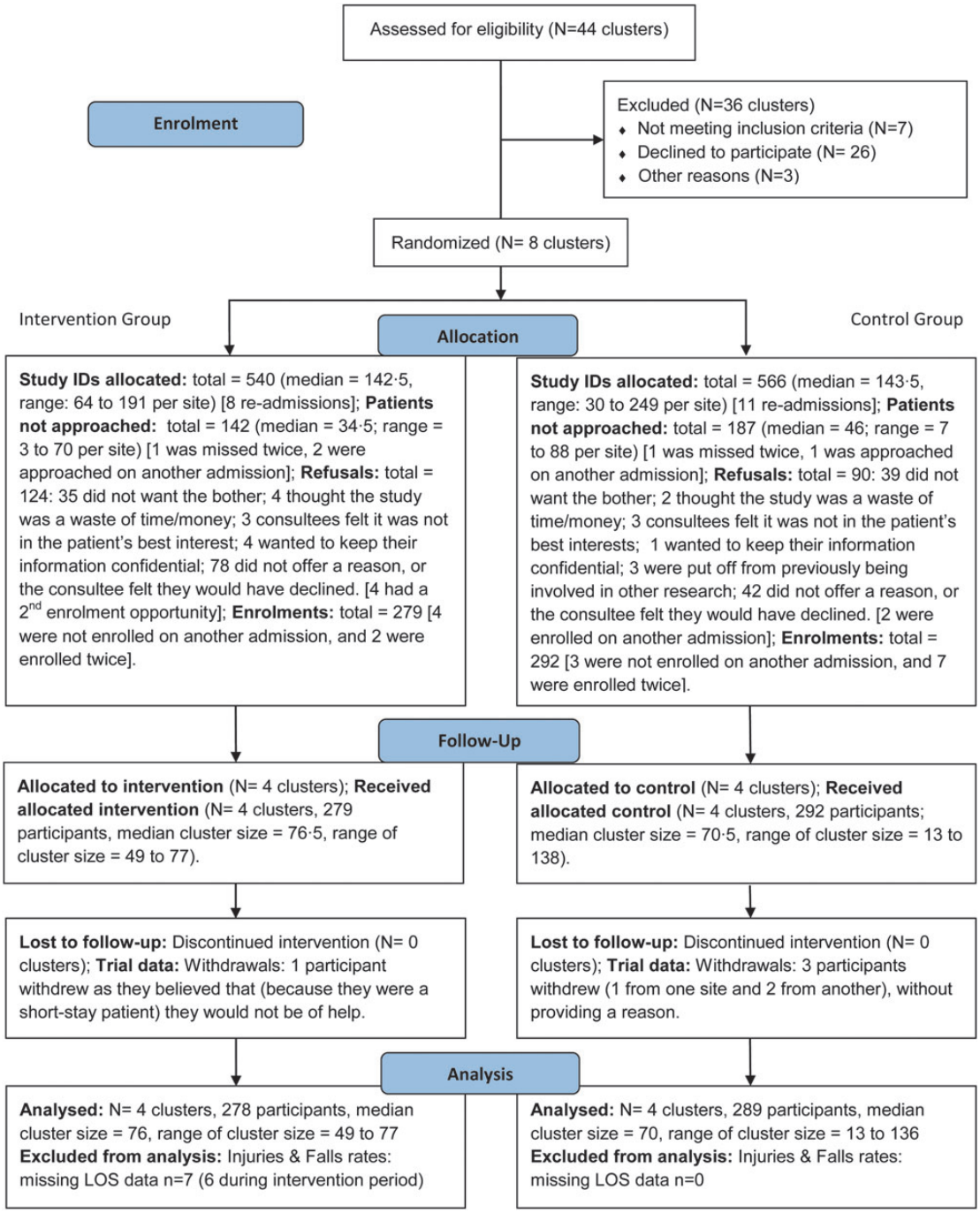

Figure 1. Recruitment and participant flow.

Falls

More people fell in the intervention group ($n = 31$ fallers; 13.8% of admissions) than in the control group ($n = 22$ fallers; 9.9% of admissions). As there were more recurrent fallers in the control group (Table 2), the incident rate for falls was only slightly higher in the intervention group ($n = 35$ falls; IR = 7.81 falls per 1,000 OBD) compared with control ($n = 33$ falls; IR = 7.17 falls per 1,000 OBD). The (uncertain) estimated effect of the intervention flooring on falls is an increase of ~7% relative to control (adjusted IRR = 1.07, 95% CI = 0.64–1.81, $k = 0.226$). Summarising the data using hazard ratios (accounting for time to each event) increases the observed difference further (adjusted HR = 1.13, 95% CI = 0.83–1.55).

Adverse events

Staff across intervention sites raised concerns about moving wheeled equipment on the intervention floor (documented through five adverse event forms relating to

Table 1. Baseline characteristics of participants

	Pre-intervention period		Intervention period	
	Intervention	Control	Intervention	Control
Participants, Total *n*	53	69	225	223
Age at admission, mean (SD)	84.02 (7.80)	80.01 (11.26)	81.10 (10.96)	80.58 (12.95)[a]
Gender, *n* (%)				
Female	49 (92.5)	69 (100)	153 (68.0)	202 (90.6)
Male	4 (7.5)	0 (0)	72 (32.0)	19 (8.5)
Length of stay				
Missing	1 (1.8)	0 (0)	6 (2.7)	0 (0)
Median (range)	14 (3–76)	17 (1–86)	14 (1–91)	16 (0.5–118)
No. of transfers between bays within ward	4 (7.5)	12 (17.4)	30 (13.3)	18 (8.1)
Barthel index score				
Missing	4 (7.5)	3 (4.3)	11 (4.9)	9 (4.0)
Mean (SD)	60.20 (28.94)	69.92 (27.25)	60.37 (30.00)	60.00 (29.06)
FRAX® fracture risk:				
Not known	5 (9.4)	15 (21.7)	45 (20.0)	16 (7.2)
Low	5 (9.4)	13 (18.8)	56 (24.9)	53 (23.8)
Medium	30 (56.6)	38 (55.1)	92 (40.9)	120 (53.8)
High	13 (24.5)	3 (4.3)	32 (14.2)	34 (15.2)
No. using ambulatory aids	37 (69.8)	49 (71.0)	171 (76.0)	152 (68.2)
No. diagnosed with osteoporosis	10 (18.9)	12 (17.4)	31 (13.8)	37 (16.6)
Reason for admission[b]				
Incontinence	4 (7.5)	1 (1.4)	17 (7.6)	18 (8.1)
Immobility	32 (60.4)	10 (14.5)	81 (36.0)	71 (31.8)
Instability	18 (34.0)	42 (60.9)	80 (35.6)	136 (61.0)
Intellectual/psychological condition	6 (11.3)	14 (20.3)	41 (18.2)	59 (26.5)
Respite	6 (11.3)	4 (5.8)	17 (7.6)	7 (3.1)
Respiratory problems	9 (17.0)	10 (14.5)	47 (20.9)	56 (25.1)
Pain	2 (3.8)	6 (8.7)	11 (4.9)	32 (14.3)
Other physiological disruption	9 (17.0)	19 (27.5)	61 (27.1)	77 (34.5)
Co-morbidities				
Cardiac arrhythmias	25 (47.2)	11 (15.9)	75 (33.3)	86 (38.6)
Coeliac disease	0 (0)	0 (0)	3 (1.3)	4 (1.8)
Delirium	7 (13.2)	2 (2.9)	33 (14.7)	26 (11.7)
Dementia	7 (13.2)	12 (17.4)	39 (17.3)	41 (18.4)
Diabetes	13 (24.5)	14 (20.3)	29 (12.9)	49 (22.0)
Dizziness	9 (17.0)	19 (27.5)	32 (14.2)	51 (22.9)
Falls/fractures/minor injuries	31 (58.5)	41 (59.4)	126 (56.0)	163 (73.1)
Hyperparathyroidism	1 (1.9)	2 (2.9)	10 (4.4)	4 (1.8)
Incontinence of bowel or bladder	13 (24.5)	19 (27.5)	72 (32.0)	122 (54.7)
Inflammatory bowel disease	3 (5.7)	2 (2.9)	19 (8.4)	14 (6.3)
Orthostatic hypotension	1 (1.9)	9 (13.0)	7 (3.1)	22 (9.9)
Parkinson's disease	1 (1.9)	4 (5.8)	7 (3.1)	13 (5.8)
Prolonged immobility	10 (18.9)	3 (4.3)	35 (15.6)	54 (24.2)
Reduced mobility/gait	37 (69.8)	41 (59.4)	149 (66.2)	167 (74.9)
Respiratory disease	6 (11.3)	17 (24.6)	75 (33.3)	62 (27.8)
Stroke	6 (11.3)	12 (17.4)	34 (15.1)	32 (14.3)
Thyrotoxicosis	0 (0)	0 (0)	5 (2.2)	1 (0.4)
Transient ischemic attacks	4 (7.5)	10 (14.5)	17 (7.6)	21 (9.4)
Medications				
Anti-diabetic drugs	9 (17.0)	13 (18.8)	27 (12.0)	41 (18.4)
Anticonvulsants/hypnotics/tranquilisers	8 (15.1)	8 (11.6)	30 (13.3)	40 (17.9)
Diuretics	31 (58.5)	30 (43.5)	122 (54.2)	122 (54.7)
Digoxin, etc.	26 (49.1)	30 (43.5)	117 (52.0)	128 (57.4)
Other psychotropic/psychoactive drugs	8 (15.1)	9 (13.0)	30 (13.3)	20 (9.0)
Polypharmacy	20 (37.7)	46 (66.7)	146 (64.9)	147 (65.9)

Data are *n* (%), unless stated.

[a]One missing data point.

[b]Taken from patient notes. Instability includes falls, dizziness, unsteadiness on feet and unstable condition.

four people from one site, and one form from another site, plus comments received at staff interviews across intervention sites). One form reported an actual event, a pulled lower back while moving a patient on a trolley (March 2011), which did not require medical attention. An ergonomics appraisal of the 'push-pull' risk factors, with

Table 2. Falls and injuries during the intervention period

	Intervention			Control		
	Inside study area	Outside study area	Total	Inside study area	Outside study area	Total
Falls with no injury	21	6	27	13	6	19
Minor	6	2	8	7	1	8
Moderate	0	0	0	3	1	4[a]
Major	0	0	0	1	1	2[b]
Death	0	0	0	0	0	0
Total falls	27	8	35	24	9	33
Proportion of falls with injury	22.22%	25.00%	22.86%	45.83%	33.33%	42.42%
Occupied bed-days (OBD)	n/a	n/a	4,482	n/a	n/a	4,602.5
All falls: rate per 1,000 OBDs	n/a	n/a	7·81	n/a	n/a	7·17
Injurious falls: rate per 1,000 OBDs	n/a	n/a	1.78	n/a	n/a	3.04
Single fallers	21	6	27	12	5	17
Multiple fallers	3	1	4	5[c]	3[c]	5
Total fallers	24	7	31	17	8	22
No. of participants	n/a	n/a	225	n/a	n/a	223
Proportion of participants falling	n/a	n/a	13.78%	n/a	n/a	9.87%

[a]Three lacerations requiring steri-strips, and one abrasion requiring bed-rest; three of these falls also incurred minor injuries (all injurious falls coded according to the most severe classification).
[b]One fractured left femoral head requiring surgery, and one possible fractured inferior and superior pubic rami (unclear if fracture was new or old); both falls also incurred a moderate injury.
[c]The three participants who fell outside the study area also fell inside the study area.

recommendations was undertaken [24]. One site reported a 20–30-cm split seam in the intervention floor (May 2011), attributed to the welding at installation, which was subsequently repaired. No adverse events related to flooring were reported from control sites.

Power calculations for future research

Based on the injury rates and coefficient of variance (k) estimated here, and current guidance [25], we can estimate (with 80% power) that a major study would require 33,480–52,840 OBD per arm to detect a 42% relative reduction in injury rates. Assuming k remains stable if we were to increase the cluster size and follow-up duration (likely to over-estimate the sample size), a study could be designed with two bays per cluster and 2-year follow-up, with 8–12 clusters per arm (~1,800–2,700 participants per arm). The number of clusters could be reduced by covering whole wards, given a novel flooring product which meets hospital standards (for fitting, cleaning and usage) and emerging guidelines on push/pull forces [24, 26]. These estimations are based on a Poisson distribution; future analyses will likely require a negative binomial distribution (due to over-dispersion), which may require larger samples. The AG model may provide a more powerful analysis as it utilises all available data.

Discussion

We have demonstrated the feasibility of applying a rigorous experimental design to a logistically complex environmental intervention. As a pilot study, the results are prone to random error and large uncertainty, and are to inform future research as opposed to provide definitive conclusions. This pilot study indicated that a shock-absorbing floor may reduce injuries; however, there is a risk of increased fallers and impact on manual handling.

This study was not blinded, increasing risk of bias, i.e. high risk fallers may have been moved into the study areas to a greater degree at intervention sites (changes in practice of internal transfers were discouraged). Risk of performance bias may also stem from staff feeling re-assured about patients' safety and relaxing observation. The potential effects of lack of blinding may be transferable to what would happen outside of a study context.

Our mechanical testing indicates that any increase in falls is unlikely to be related to slipperiness, and no falls occurred on the thresholds between the thicker intervention floors and adjoining areas. It is debatable whether the feeling of a softer floor underfoot increases the risk of falls [27–29]. Future research should take a twin track approach with a randomised trial approach to the intervention, and a systems approach [30] to assess the implications of thicker floors on the wider human activity [care] system with which the floor inter-relates.

Key points

- This is the first cluster randomised controlled trial on shock-absorbing flooring in hospital wards.
- Shock-absorbing flooring may be a viable option for fall-related injury prevention in older adults.
- The 'side effects' of a flooring intervention are observable in the staff, and are associated with manual handling.
- Further research is required to assess to the risk of increasing fall rates with a shock-absorbing floor.

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Author's roles

A.D. contributed to the study conception, design, data collection, analysis, and interpretation; drafting, revising and final approval of the article. D.W. contributed to the study design, data collection, analysis and interpretation; revising, and final approval of the article. J.U. contributed to study design, data collection, analysis and interpretation; revising, and final approval of the article. D.S. contributed to data collection, and interpretation; revising, and final approval of the article. R.O. contributed to the analysis and interpretation of the data; revising, and final approval of the article. B.H. contributed to the study design, analysis and interpretation; revising, and final approval of the article. TD contributed to the study design, and interpretation of data; revising, and final approval of the article. M.S. contributed to the study conception, design, interpretation; revising, and final approval of the article.

Conflicts of interest

This study was conducted independently of the flooring manufacturers and installers (materials and installation were paid for by the study grant).

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