

# Pilot Cluster Randomised Controlled Trial of Flooring to Reduce Injuries from Falls in Elderly Care Units: Study Protocol

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**Key Words:** Accidental Falls; Floors and Floorcoverings; Frail Elderly.

**Word Count:** 7909

## ABSTRACT

Falls are an issue disproportionately affecting older people who are at increased risk of both falls and injury. This protocol describes a pilot study investigating shock-absorbing flooring for fall-related injuries in wards for older people. **Objectives:** To inform future research by: evaluating fall-related injuries on the intervention and existing flooring; assessing the sustainability of the flooring in ward environments; estimating the cost-effectiveness of the floor; and assessing how the floor affects patients and other users. **Design:** This study utilises mixed methods: a pilot cluster randomised controlled trial; observation via mechanical testing; and interviews. Eight participating wards (clusters) are randomised using a computer generated list. No blinding is incorporated into the study. Each site has a baseline period of approximately six months. Then, four sites receive the intervention floor, whilst four continue using standard floors. Sites are then followed up for approximately one year. **Participants:** Any person admitted to a bed in the 'study area' of a participating ward can be entered into the trial. Orientated patients, visitors, and any hospital staff who use the floor in a study area are eligible for inclusion in an interview. **Intervention:** An 8.3mm thick vinyl floor covering with PVC foam backing (Tarkett Omnisports EXCEL). **Outcomes:** The primary outcome is fall-related injuries. Severity of injuries, falls, cost-effectiveness, user views, and mechanical performance (shock absorbency and slip resistance) are also being assessed. **Trial registration:** ClinicalTrials.gov: NCT00817869; UKCRN ID: 5735. **Funding:** The Dunhill Medical Trust funds the trial. The National Osteoporosis Society supports a PhD studentship.

## **BACKGROUND**

Despite the large quantity of work carried out on falls prevention,[1] falling in hospital remains a significant problem,[2] and one of international concern.[3] This issue is set to become increasingly prominent given that older people are most at risk of falling and this population is growing.[4] There is an age-related increased risk of sustaining an injury from a fall,[4, 5] and older people additionally have an increased risk of falling due to a number of age-related risk factors.[6] Approximately 30% of patient falls result in an injury,[2, 7] creating a substantial financial burden on healthcare resources in terms of costs of continued and additional care and litigation.[8-10] As efforts continue to research the effectiveness of falls prevention strategies,[11] an additional area of research focuses on strategies that prevent injuries from falls, since the occurrence of some falls is inevitable.

A systematic review has assessed the use of hip protectors with older people living in the community or in institutional care as one potential method for reducing hip fractures from falls.[12] The review reveals that compliance with this intervention is poor due to discomfort and practicality, and the effectiveness of hip protectors looks doubtful in light of the current evidence. The environment requires no compliance on the part of the patient, thus we want to study the environment as an intervention for reducing injuries from falls.

Modifying the hospital environment to promote patient safety is currently high on the agenda,[13] and it is generally acknowledged that putting careful thought into the design and planning of hospital environments could be highly beneficial in terms of reducing long-term running costs and improving patient outcomes.[14] Falls most often result in a person landing on the ground, therefore flooring as an intervention for injury prevention is a logical step to research. Given the weight of

importance applied to flooring requirements in children's play areas (e.g. British Standard BS EN 1177) it is surprising that such little attention has been paid to the shock-absorbing qualities of flooring in healthcare settings.

A number of studies in the UK, Canada, and the USA, have assessed the various shock-absorbing properties of flooring types using mechanical testing techniques to simulate falls.[15-20] However, laboratory-based falls simulators provide only a simple approximation of how a person may fall from a stationary position,[16] and they do not account for how easy the flooring is to walk on and use in a real-world setting. Although testing rigs can evaluate the dampening effect on impact forces of various floor types, injuries are also dependent on the fall dynamics and bone strength of the faller,[21] which are aspects that only field studies can truly capture; the degree to which laboratory test results reflect the effectiveness of "real world" application is still questionable.[22]

Some field studies have been conducted on broadly categorised flooring types (such as carpet vs. vinyl),[22-23] but the findings are largely inconclusive due to weak study designs and lack of specificity in describing the types of floors assessed. There is a justifiable need for a prospective study that will provide important and relevant evidence to the international research and health community. One unpublished single-centre controlled before-and-after study has been conducted in Northumberland, UK of 2mm non-slip vinyl with 4mm thick 'Altro Everlay B' underlay as compared to carpet.[24] Although this study is small in size, and the control areas are not directly comparable to the intervention area, it has addressed some of the methodological issues posed by previous research, through conducting a prospective intervention study in a clinical setting. More rigorous research methodology is necessary for studies of this nature if valid conclusions are to be drawn. In terms of a "gold standard" methodology, a cluster randomised controlled trial would be the most rigorous approach to take in this field; since this has never been done, we are undertaking

a pilot study. A ‘cluster’ randomised trial is required because it is not feasible to administer ‘the floor’ as an intervention at the individual patient-level in a hospital environment with multi-bedded bays; but ‘the floor’ can be administered to a group (or cluster) of people.

In this study we want to gauge the effectiveness of using shock-absorbing flooring against existing regular flooring in reducing injuries from falls, to ascertain the required information for a power calculation. Tarkett Omnisport EXCEL has undergone materials testing to demonstrate its qualities as shock-absorbent, with comparable slip properties to that of regular vinyl floors found in hospitals. The flooring is composed of 20 – 25% recycled materials, and is recyclable. The flooring also meets the technical requirements for NHS floors from an infection control perspective.

## **OBJECTIVES**

The overall aims of the proposed research are to inform a power calculation for future research, and assess the appropriateness of the flooring in terms of sustainability, cost-effectiveness, and user views. This will be achieved by meeting the following specific objectives:

- 1) To evaluate the difference in the fall-related injury rate (per patient bed-days) between the intervention flooring and existing flooring.
- 2) To periodically assess the sustainability of the flooring types, recording surface irregularities, slip-resistant and shock-absorbent properties.
- 3) To estimate the cost-effectiveness of the intervention flooring.
- 4) To assess the views of staff, patients, and visitors who use the flooring.

## **STUDY DESIGN**

The first objective will be addressed using a cluster randomised controlled trial design. The second objective will be addressed utilising standardised observation techniques with repeated measures.

The third objective will be addressed through an economic evaluation of data obtained from the first two objectives. The fourth objective will be addressed through qualitative interviews with patients, visitors, and staff.

## **METHODOLOGY**

The approach to meeting each objective is detailed below. Please refer to Figure 1 for a flowchart of the data collection process.

### **Objective 1: To evaluate the difference in the fall-related injury rate (per patient bed-days) between the intervention flooring and existing flooring**

This objective seeks to explore differences in injury rates through a pilot study, in order to inform future research.

#### Study Design

This pilot study includes 8 wards across England. Each ward has a designated bay for the study (the 'study area'). Data is collected from all study areas for approximately 6 months before the new flooring intervention takes place (this may vary due to staggered start dates and timing of flooring implementation), then the new flooring is installed in four of the study areas and data will be collected for a further 12 months (approximately) from all eight sites.

Wards are allocated to be in the intervention or control groups based on a computer-generated random list in blocks of four. At the time of publishing this protocol the randomisation process has been completed. An independent statistician generated the sequence ensuring allocation concealment. The block randomisation was not revealed to the researchers until after the sites had been allocated. Once sites had received full governance approval to participate in the trial, the study researchers contacted the statistician to reveal the group allocation. The final three sites to receive

governance approval were randomised at the same time (in the order in which the approvals were gained) so not to break the allocation concealment. Sites were informed of their group allocation at the beginning of the six-month baseline period in order to allow the intervention sites time to organise and plan the flooring installation.

## Institutions

Wards considered as being predominantly for elderly care use (elderly general rehabilitation and elderly mental health) were eligible for inclusion. Originally we planned to recruit four of each type of elderly care ward, however this restriction was lifted to facilitate recruitment. These wards are representative of two groups at high risk of falling due in part to low cognitive function and disability, respectively.[3] The study set out to recruit eight sites across England, with no restrictions placed on location. Wards were screened for humidity levels in the sub-floor, to assess the need for special membranes required when laying the floor on bases with high humidity. Included sites were to have floors with a slip resistance rating of no more than 'R9'. This was to ensure that the overlay materials across sites are comparable, and to ensure that we do not replace a floor covering with one of lower slip resistance (the intervention floor has a rating of R9).

Each site designated a bay as the 'study area' for use during the study. Eligible bays ranged from 4 to 8 beds in size. No restriction was placed on gender usage of the bays. Hospital sites had the choice of which bay to use for the study; decisions could be based on where patients at high risk of falls are placed (e.g. for observation purposes), or for logistical reasons (e.g. to enable easy access/cordoning off the ward for new flooring to be fitted, should the site be allocated to the intervention group).

## Participants

Participants are identified and recruited through above-mentioned institutions. Patient-specific data is only collected from those patients who have consented (or, when appropriate, for whom consultee advice has been gained) for their data being utilised for the trial. Participant recruitment began in a staggered start between April and June 2010. Recruitment will continue until the end of August 2011.

## *Inclusion criteria*

All adults admitted to a bed in the 'study area' at a participating site.

## *Exclusion criteria*

Flooring, as an environmental intervention, will have implications for all people residing in the area; we are therefore ensuring the inclusion criteria are broad and as a result will not be excluding individuals on any ground.

## Sample size

This is a pilot study and there is no previous research on this specific flooring intervention and its effect on injuries from falls. The data that is collected from this study will be utilised to inform a power calculation to underpin further research. Laboratory tests of the flooring product predict that the energy absorbed from impact will be sufficient to avoid hip fracture in the majority of fallers; the effect of the flooring on other injury types is unknown however, and the validity of the assumptions on which laboratory tests are based, have not been pragmatically assessed in this context. Only a marginal number of falls result in fracture (for example Hitcho et al., quote 1% [25] and the 2005/2006 audit data we gathered to inform this protocol have rates ranging from 0%-2.63%, averaging at 1.3%); therefore it is likely that a study will have to be very large in order to be

sufficiently powered to find a significant effect on hip fracture reduction alone. Hence, we are collecting data on other types of injury (all of which will be stratified by severity), which will enable a more generic view of the overall impact of the flooring intervention.

This study will provide information to assist estimating an effect size for injury reduction to enter into a future power calculation. Additionally, some inflation to allow for clustering (the 'design effect') would need to be included in these estimates.[26] This pilot study will enable the calculation of the intraclass correlation coefficient (used to calculate the design effect) to better inform a power calculation for a large-scale cluster randomised controlled trial.

A cluster randomised controlled trial has not been attempted for this intervention before or indeed in the field of hospital design more broadly;[27] therefore embarking on a full-scale trial before conducting a pilot would be inappropriate. This pilot study will assess the impact of the intervention on a small number of wards and estimate the cost-effectiveness of utilising the new flooring. No effect size is known for the intervention (in terms of injury reduction) and no formal power calculation has informed the pilot study, rather we feel that four wards per arm is a modest and feasible number to begin our investigation. This number of clusters is appropriate as it will enable us to gauge the intervention effect as well as gauge the intraclass correlation coefficient which will inform future clustered trials.[28] Conducting a pilot cluster randomised controlled trial will additionally help inform a larger study by enabling us to explore the issues unique to clustered trials; such as standardising procedures across sites and dealing with irregularities in environmental designs. Additionally the inclusion of a number of sites will improve the generalisability of the findings, increase the amount of data that can be used to inform future research, and enable an assessment of the validity of assumptions made in laboratory-based testing.

## Participant recruitment

Patients who are to be admitted or transferred to the study area within the timescale of the pilot study (April 2010 – August 2011) will be informed about the study through a participant information sheet. All patients will be assessed for capacity to consent by a clinical member of staff, who will also offer support to the patient to help them understand the information and make a decision as to whether to participate or not (in accordance with the Mental Capacity Act 2005 Code of Practice). Where patients do not have the capacity to consent, a consultee will be appointed. In the first instance a personal consultee should be sought (e.g. family or friend), and if not available then a nominated consultee shall be appointed (e.g. a paid care worker). The consultee will be provided with a Consultee Information Sheet, which explains what it means to act as a consultee as well as what it would involve for the patient to take part in the study.

The patients or consultees will be able to contact the research team prior to participating in the trial should they have any questions. Where required study information will be translated for foreign language speaking patients and consultees. Personnel at the participating sites will identify these individuals and inform the Co-ordinating Centre (University of Portsmouth). Personal data will not be collected about patients, until they have been recruited on to the trial.

On admission, a designated staff member will go through the study information and respond to any questions that the patient or consultee may have. Each patient admitted or transferred to the study area will be assigned a unique identification number (ID) using a table which will be maintained at the site. The study site will notify the researchers at the University of Portsmouth when a new patient is admitted (sending them the ID number, date, and reason for internal transfer if made). Internal transfers will be monitored to ensure that staff are not allocating high risk patients to the new flooring because they think it may help them (since this may be a source of bias in the results,

which may show a higher number of falls on the new floors which is due to a change in patient risk as opposed to a change flooring).

Every patient admitted or transferred to the study area should be approached for consent for participation in the study (or a consultee sought for advice). Patients should be given at least 24 hours, if they need it, to decide if they want to take part. Patients may consent (or refuse) within 24 hours if they do not need longer to decide. If patients are transferred out of the study area before they have had the opportunity to decide, then researchers at the Co-ordinating Centre should be informed, so that this can be monitored.

If patients do not want to take part in the study, then ward personnel will complete a “refusal form” in which they will document the ID number and reason for refusal if given (this will be sent to the Co-ordinating Centre). Patients who consent to the research will complete a consent form, a copy of which will be kept with their medical notes, and copy of which will be sent to the Co-ordinating Centre, and one will be given to the patient to keep. Where a consultee is appointed, they will complete a Consultee Form, with a copy sent to the Co-ordinating Centre, a copy kept with the patient notes, and copy given to the consultee to keep. All patients will be asked to consent to having their date of birth, sex, and ethnicity recorded for the purposes of the research (even if they do not want to take part in the study). Some patients therefore, may consent to having these brief demographic details recorded but not for their personal health-related data be recorded for the study. We wish to record date of birth, sex, and ethnicity of all patients in order that we can assess the similarities between those who take part in the study and those who do not.

To clarify, patient-identifiable data will only be collected for the purposes of the research with the consent of the patient, or on the advice of a consultee. Once collected, data will be made

anonymous with a unique number on the research database, and with the decryption key held by the Co-ordinating Centre.

### Intervention

The intervention floor in this study is an 8.3mm thick vinyl floor covering over fibreglass mat with PVC foam backing (Tarkett Omnisports EXCEL). Following the baseline period, the flooring was installed into the study area (a four- to eight-bedded bay) of the four intervention sites. The flooring is not suitable for areas usually wet (e.g. bathrooms) and so is only installed into the bedroom area. Sites planned for their study area to be empty for a one-week installation, with bays either being gradually 'run down' by not admitting new patients into the bay, or by transferring patients to vacant beds elsewhere in the ward or hospital. The installation of the new floors was planned directly between the hospital estates and facilities departments and the prime contractors installing the floor. Each site had the choice of floor colour/design from the Omnisports EXCEL range, and also decided how they wished to manage the threshold between the new (thicker) floor and the standard floors in any adjoining areas (e.g. by choosing a transition strip or a gradual 'seamless' incline). The intervention floors were provided to hospitals as theirs to keep; installations took place between August and September 2010. All installations were carried out by the same prime contractor (Tyndale Flooring Limited). Control sites received no change to their existing flooring.

### Data Collection

The primary outcome measurement is the fall-related injury rate per patient bed days. In addition, site audits, patient baseline characteristics, falls per patient bed days, proportion of recurrent fallers, length of stay, fall-related healthcare interventions for the injuries sustained, and admission of fallers to other wards or institutions will be explored. This will enable us to compare characteristics of fallers in intervention and control sites.

Upon discharge or transfer to an external ward a Discharge Form should be completed and sent to the Co-ordinating Centre to notify them of the patient's location. Three months after this time, researchers at the Co-ordinating Centre will seek to follow-up with the General Practitioner (GP), and patient or consultee, to collect data for the cost-effectiveness analysis.

If a participant is transferred to another room within the same ward but outside of the study area, the researchers at the Co-ordinating Centre should be informed. Any falls that occur from participants who have been internally transferred should still be documented. This is because all participant falls that occur both within and outside of the study area will be monitored. It is possible that if the participant remains on the ward, they may return to the study area and fall over.

#### *Standardisation procedures*

Prior to the onset of data collection, staff at each site will be trained in the study protocol. Standardised forms will be implemented across the sites to record baseline characteristics, falls, and injuries, for the purposes of the study. The study investigators will conduct spot-checks through-out the study period to ensure that data are being logged appropriately. Data monitoring will be conducted through-out the study period and any anomalies or inconsistencies will be followed up by research personnel in order to maintain data recording at a high standard.

#### *Site audits*

Site audits will be undertaken at the beginning of the baseline period, and again at the beginning of the intervention period, in order to better characterise the wards included in the study. These audits will include the collation of data on environment, staffing levels, and policies and practices. Many of the aspects included in the audit will have the potential to change over the study period, so the

Co-ordinating Centre intends to liaise closely with staff at the study sites to ensure we are informed of any changes to ward policy or procedures.

There are a number of tools already available for environmental auditing of healthcare facilities, although in the field of environments for older people (particularly dementia and Alzheimer's care), the majority of these are geared towards nursing home environments and American-style Special Care Units. These tools include protocols for rating environmental aspects such as lighting, flooring, handrails, privacy and access. Barnes provides a comprehensive critique of some of the tools developed for assessing care environments for older people,[29] including: the Multiphasic Environmental Assessment Procedure (MEAP)[30]; the Professional Environmental Assessment Protocol (PEAP)[31]; the Therapeutic Environmental Screening Scale (TESS)[32]; and the Environment-Behaviour (E-B) Model.[33] The TESS has undergone some development,[34] and is now marketed as TESS-NH to include the Special Care Unit Environmental Quality Scale (SCUEQS).[35] The Sheffield Care Environment Assessment Matrix (SCEAM)[36] has been developed for UK care environments for older people however this too focuses on residential care as opposed to acute care settings.

There has been some development of hospital environmental assessment tools in the UK to include AEDET evolution (Achieving Excellence in Design Evaluation Toolkit) with the addition of ASPECT (A Staff and Patient Environment Calibration Tool),[37] however these are likely to be unsuitable for the present study as they have been designed for use during general hospital renovations and new builds and scoring involves consensus ratings obtained through workshops with stakeholders. Additionally they take a more generic focus with little to no emphasis on older people and falls specific considerations.

Due to the lack of tools currently available for acute care settings for older people, we plan to develop our environmental audit based on tools and techniques already available, with added items to include falls- and injury-specific environmental factors that are highlighted as issues in much of the falls prevention guidance.[38] The audit tool will be in the form of a checklist. We will also collate information on staffing levels and ward routines. Our audit will include at least the following features:

- Map of ward layout.
- Description of rooms (private; twin beds; 3+ beds; total rooms; patient capacity);
- Unit autonomy (nursing station positioning; dedicated nursing station/nursing station serves other units/no nursing station; line and sight of staff observing patients; positioning of curtains and screens);
- Exit control and doors (disguised doors; no. of exits; alarm monitored; locks; magnets to keep doors open; direction of door opening);
- Maintenance (areas in need of repair);
- Cleanliness (cleaning routines and policies; cleaning products utilised);
- Floor surface (evenness/steps; flooring pattern; current flooring material; sub-floor material; anti-slip flooring usage);
- Furniture (provision of chairs; stability; sharp corners; provision of ultra low beds; furniture with protruding legs e.g. intravenous drip stands/over bed tables; bed rail provision and policies);
- Storage (accessibility and positioning of supplies);
- Lighting levels (intensity; glare; evenness; sensor lighting; provision of windows and window views);
- Technologies (movement detectors; provision of hip protectors; television status and usage policy);

- Other safety aspects (handrail provision; trip hazards including clutter and cables; bedside call bells; provision of hooks/hangers for sticks; provision of wristbands/ symbols for high falls risk patients; use of restraints policy);
- Staffing (levels and turn-over, to include healthcare professionals and cleaning and maintenance staff) - to be obtained via the personnel department/ward manager.

### *Baseline characteristics*

Participant baseline data will be collected by the research personnel to characterise the intervention and control groups. Baseline characteristics will include:

- Age
- Sex
- Patient's usual place of residence
- Use of ambulatory aids
- Functional ability (Barthel Index)
- Reason for admission
- Medication.
- Diagnosis/conditions/co-morbidities
- Fall history
- FRAX<sup>®</sup> assessment (risk of fracture tool).

The World Health Organisation Fracture Risk Assessment tool (FRAX<sup>®</sup>) has been chosen as it is the most recently developed tool to assess patients risk of fracture.[39] Previously, clinicians relied on patients bone mineral density (BMD) to assess risk of fracture but the use of BMD alone yielded a low detection of fracture risk.

Developed in 2008, the FRAX<sup>®</sup> tool uses algorithms to assess a patient's 10 year probability of major fracture risk through an analysis of the patient's clinical factors which may increase their fracture risk. As FRAX<sup>®</sup> is relatively new and still requires some validation with different groups of people it is recommended that it is used in addition to clinical judgement when determining if a patient needs to receive treatment.[40] However, in a research setting FRAX<sup>®</sup> may provide an ideal means of classifying participants' levels of fracture risk for analysis purposes.

#### *Fall-related Injury rate per patient bed days (primary outcome)*

All events of patient falls and injuries will be recorded on a standardised form. This will include: time; exact fall location; positioning of faller; nearby objects; footwear of faller; bed positioning (high/low); use of bed rails; lighting status; diagnosis; and injuries received. The injuries will be stratified by injury severity: (*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 level of consciousness; *Death*) and type (to include location and type of injury, etc). Patient bed days will be calculated. The patient occupied bed days will allow for standardisation of the falls and injury rates across institutions.

#### *Fall rate per patient bed days*

The fall rate per patient bed days will be calculated. Therefore an assessment can be made of whether the intervention flooring has an additional effect on the number of falls occurring as well as the number of injuries sustained.

### *Proportion of recurrent fallers*

As many patients tend to fall more than once, and having fallen before is one of the main risk factors for falling,[41] the number of falls per individual will be recorded to be able to further calculate the proportion of recurrent fallers. Recording this information and being able to characterise the study population that falls will inform future research by highlighting potential issues for data analysis.[42]

### *Length of Stay*

The length of stay (LOS) will be calculated. This outcome will capture any change in LOS occurring with and without the intervention as a result of injuries prevented/sustained, and will additionally be used to inform the analysis in Objective 3.

### *Injury related healthcare interventions*

Any serious (major and moderate) injuries resulting from falls that require additional care in the three months following the fall, including such interventions as surgery, will be followed up through accessing the local institutions' patient administration systems.

### *Admission to other ward or institution*

In order to measure the impact of the injury on patient care, any change from the original ward to another ward or institution for intensive monitoring or additional care related to the injury will be followed.

### *Statistical analysis*

Given that this is a pilot study, the statistical analyses will be geared toward informing future research as opposed to significance testing. Primarily, we will describe each ward in terms of the incidence rate ratio (IRR) for fall related injuries and the IRR for falls both before and after the

intervention. This will enable the estimation of the treatment effect in order to facilitate future sample size calculations. Furthermore we will calculate the intracluster correlation coefficient ( $\rho$ ), which may inform future research by enabling an estimation of the design effect,  $1+(m-1)\rho$ , where  $m$  is the average cluster size.

Secondary outcomes will be summarised and described for each ward in each study group. Participants will also be profiled according to their risk of fracture (FRAX® score). Entering participants' data into the FRAX® tool will assess their 10 year probability of major fracture risk and present it as a percentage. The percentage is also presented on an assessment threshold graph to indicate whether the person should be considered at low, intermediate or high risk of major fracture, according to the National Osteoporosis Guidance Group (NOGG). These classifications will then be used to profile participants according to their fracture risk, which will be cross-tabulated against the actual fall-related injuries sustained.

**Objective 2: To periodically assess the sustainability of the flooring types, recording surface irregularities, slip-resistant and shock-absorbent properties.**

The sustainability of the flooring (in terms of its' performance properties over time) will be assessed. An article in *Hospital Development* stated that flooring needs to have a 10-20 year lifetime and corresponding low lifecycle costs;[43] it went on to highlight the necessity of delivering long-term value, meeting the demand of better design and rising to the challenges of healthcare environments. This is in line with the environmental strategy being implemented within the NHS.[44] We are not proposing to follow the performance of the floor for the entirety of its lifetime; instead we hope to gauge the performance of the floor over a relatively short period, in order to make an informed judgement of its long-term suitability for healthcare environments. We plan to

assess any changes occurring to the new floor material and compare this to damage sustained in the old flooring (within the same time period).

We do not predict that the new flooring will sustain an unusual amount of damage, since it has undergone materials testing demonstrating it to have good compression set characteristics (i.e. it returns to its' regular shape after compression). However, since Tarkett Omnisport EXCEL has not been assessed in a ward bedroom environment we do not want to overlook this important factor. For this objective we plan to monitor the performance of the flooring: a) to ensure it does not sustain any surface irregularities such as grooving, b) that the surface material maintains a degree of slip-resistance comparable to the control flooring, and c) that it maintains its added value (i.e. its' shock-absorbent properties). The physical assessments made under this Objective will additionally characterise and inform the comparability of the wards involved.

#### Institutions

The sustainability of the flooring will be measured in all wards included in the study. By assessing both the control and the intervention sites (as in Objective 1), we will be able to ensure that the sites are comparable on the physical properties of the floor at baseline, and then evaluate the differences between the floor types over time once the intervention flooring has been implemented.

#### Data collection

In the first month of the baseline period, and the first, sixth and twelfth months of the post-intervention stages of the study the sustainability of the flooring will be assessed (four time points altogether). This was in line with the advice of the Health and Safety Executive (HSE), who recommended that floors be assessed every 3-6 months (depending on the context) to fully take into account the wear characteristics of floor surfaces over time.[45] Each site has two locations (test

areas) mapped in the study area. The chosen test areas target a high traffic and a low traffic area. All data collection will be carried out with a standardised procedure and using standardised equipment. Procedures will be duplicated at each test area, and repeated at each set time point (as detailed above).

#### *Surface irregularities and wear*

Surface irregularities and wear of the floor will be ascertained through visual inspection of the whole study area.

#### *Slip resistance*

An assessment of the slip-resistant properties of the floor will be made using the “pendulum coefficient of friction (CoF) test” in wet and dry conditions, which is subject to the British Standard BS 7976. In most circumstances, both pendulum CoF and surface microroughness readings are required to give an accurate indicator of floor surface slipperiness. The pendulum CoF test (regarded as the “gold standard”) is designed to simulate the action of a slipping foot; the method uses a swinging arm which contacts, via a dummy heel, a set area of flooring in a controlled manner. The slip resistance of the flooring is measured by the over swing of the pendulum (slip resistance value) and is directly effected by the slipperiness of the floor. These assessments will be undertaken by a trained independent professional from the Health & Safety Laboratory. The instrument requires a competent operative both to use it and interpret the results.

#### *Shock absorbency testing*

A portable impact transducer has been designed and built for this study, much like the one used in the study by Simpson and colleagues.[22] This will assess the impact properties (that is reduction in energy absorption, measured in joules) of the flooring at the participating intervention and control sites. The portable impact transducer will enable an assessment of whether the intervention flooring

maintains its shock-absorbency for the duration of the trial, and how it compares to the control wards and floors at baseline. An identical protocol will be used to measure the impact of the flooring in the control and intervention sites' study areas, in high and low traffic areas, and at each of the four allocated time points.

#### Data analysis

The effects of the intervention on each of the above physical measures will be explored through repeated measures analyses of variance (ANOVAs), in which the different time points are considered as the levels of one factor in each analysis and the grouping variable (ward) is a second factor in each analysis.

#### **Objective 3: To estimate the cost-effectiveness of the intervention flooring.**

A cost-effectiveness analysis will be undertaken to assess how the effectiveness of the intervention flooring, in reducing fall-related injuries, is related to the net costs of the intervention flooring. The work will undertake two sets of analyses; short-term cost-effectiveness, which will look at the NHS costs and patient outcomes associated with the initial hospital admission, and life-time cost-effectiveness, which will look at all public sector costs and patient quality of life and mortality. The life-time analysis is essential as it is anticipated that any impact on fall-related injury rates will have significant consequences for post-discharge costs and outcomes. The life-time analysis will use a decision analytic modelling approach that complements the trial data with external literature sources. The life-time analysis also provides a valuable framework for prioritising research, through the estimation of the expected value of perfect information as recommended in a review of research prioritisation methods.[46]

## Data collection

A small core data set will be collected for all patients admitted to study wards, including age, gender, type of admission, healthcare resource group (HRG), date of admission, date of discharge, date and severity of fall (if applicable). For patients who fall, subsequent treatments related to the fall will also be gathered (e.g. operations). Data collected at the 3 month follow-up includes: place of residence; quality of life (EQ-5D<sup>TM</sup>);[47] hospital readmissions; GP visits; and healthcare personnel visits.

## *Costing of Flooring*

All direct costs of the flooring materials, installation of the intervention flooring and maintenance needs of the flooring over its expected life-time will be recorded within each ward as part of the study. Total costs of maintaining or repairing the flooring in the control stage of the study, over its expected life-time, will be also calculated. This will require close contact with Business Managers and Estates Managers in each Trust.

## *Costing of fall-related hospital care*

The events associated with each type of fall will be described where there is a clear association (e.g. operations), and also identified through statistical modelling of length of stay (e.g. excess length of stay associated with each type of fall). Costs associated with these events can then be estimated using NHS Reference Costs relating to each type of event (e.g. operations and length of stay).

## *Costing of fall-related post-discharge care*

Costs associated with different types of falls following discharge from hospital will be derived from the 3 month follow up data. Additional costs associated with falls are expected to produce differences in normal place of residence, readmissions and primary/community health care contacts.

### *Outcomes associated with the intervention*

Fall rates for moderate or major falls will be used as the measure of effectiveness for the short-term cost-effectiveness analysis. Lesser falls will not be included as the health effects are considered negligible. For the lifetime cost-effectiveness analysis quality adjusted life years will be estimated for patients suffering each type of fall, which requires estimates of mortality and quality of life (or, more specifically, utility). Utility estimates (derived from the EQ-5D) and mortality data will be available from the study, but will need to be supplemented with life expectancies derived from those produced by the Government Actuary's Department.

### Data analysis

Fall rates, events, costs and outcomes will be combined in a decision analytic model. The short-term analysis will produce an incremental cost per moderate or severe fall avoided, up to the point of discharge. When combined with the estimates for post-discharge costs and outcomes, the lifetime analysis will produce an incremental cost per quality adjusted life year gained.

A probabilistic sensitivity analysis will be undertaken using the estimates of uncertainty identified from the trial and literature. Uncertainty surrounding the short-term and lifetime analyses will be described by plotting simulations on the cost-effectiveness plane and summarised in cost-effectiveness acceptability curves. A value of information analysis will also be developed to identify which parameters contribute the greatest amount of uncertainty to our results, and which parameters will benefit the most from the collection of further information (i.e. are a high priority for further research).

#### **Objective 4: Qualitative assessment of user views**

As there are a number of issues that may otherwise go unnoticed or overlooked, we intend to assess the views of staff, patients in, and visitors to the wards. Thorne carried out a qualitative assessment of a number of flooring materials in geriatric wards,[48] which highlighted issues relating to: installation, maintenance, attractiveness, comfort, slipperiness, noise, marking, and sealing. Interviewees may have particularly pertinent insights into otherwise unmeasured impacts of the floors under study. For example, staff may notice changes in patients' behaviour when walking across the new floor, and may notice differences when pushing trolleys around. Staff in control wards may hold views about their standard flooring, which remain particularly pertinent due to the fact they have not experienced the new flooring; they may also experience different issues with their standard flooring than experienced by intervention sites. Additionally, patients and visitors may have opinions as to what the floor is like to walk on and whether or not they feel safe walking on it. Additionally, interviewing people from across the included sites will further enable an assessment of the cultural differences between ward environments, in attitudes and opinions towards the floors in use.

#### **Participants**

Sampling of ward staff will be purposive, targeting those who have worked at one of the study wards. All eligible staff will be invited to interview in an attempt to obtain as representative sample as possible (e.g. from across different working roles).

Sampling of patients and visitors will be restricted to those who are orientated to person, time, and place, and at either an intervention or control site during one of the final two site visits. Sampling will therefore be done on a convenience basis.

## Data collection

All potential participants will be provided with information regarding the interviews prior to taking part, and if willing, will sign an informed consent form. Interviews with staff will be arranged in advance of the scheduled site visits to coincide with these where possible. If this is not feasible then telephone interviews will be arranged as an alternative. Staff interviews will be conducted on a one-to-one basis using a semi-structured interview schedule. Interviews will be audio-taped, transcribed verbatim with the participants made anonymous through the assignment of an interviewee number. The staff interview schedule will be tailored towards the role of the staff member and the duties that they perform in the ward. The interviewer will be flexible with the interview schedule, adding more prompts and probes as staff generate new themes, and allowing staff to highlight the issues that are of highest importance to them. It is anticipated that staff interviews will last from 20-45 minutes depending on how much the participant has to say.

Information to patients and visitors will be distributed a day or two in advance of the scheduled site visit, to allow time for them to decide if they wish to contribute an opinion, as well as to have a think about what they may want to say. Interviews will be conducted within the ward setting in order that the flooring can be used to cue conversation topics. Interviews will be semi-structured and patients and visitors will be given the opportunity to discuss the aspects of the flooring that are important to them (and/or the person they are visiting). It is anticipated that these interviews will be shorter than those with staff, lasting up to 20 minutes. Patient and visitor opinions will be audio-taped and transcribed verbatim and made anonymous through the assignment of an interviewee number. Visitors will additionally be given the option of a telephone interview.

## Data analysis

The views of interviewees will be analysed through a process of thematic content analysis.[49] Transcripts will be open coded, and from these codes themes will be generated and then validated through corroboration between the research team. Transcripts will then be coded according to these themes and written up accordingly, drawing comparisons between the patients, visitors, and different staff roles, as well as between opinions on the standard flooring versus the intervention flooring.

## **ETHICAL CONSIDERATIONS**

### **Ethical approval**

Approval for this multi-centre study has been obtained from the Southampton & South West Hampshire NHS Research Ethics Committee (A), which has been flagged to deal with applications falling within the scope of the Mental Capacity Act.

### **Informed consent**

For this pilot study, patients (or their consultee) will receive an information sheet explaining the study. Should the patient be unable to consent then their consultee will be approached for advice. Our procedure will be in accordance with the Mental Capacity Act 2005 Code of Practice. It will be stressed that participation is purely voluntary and that non-participation will not affect the patients' healthcare treatment in any way. Patients (and consultees) will be informed that they are free to withdraw from the study at any time.

A separate informed consent procedure will take place for all individuals willing to be interviewed about their views on the flooring. In this instance, consent will be obtained from all those willing to take part. We will not be recruiting individuals who lack the capacity to consent for this part of the

study. Interviewees will be made aware that they can terminate the interview at any time, that both positive and negative views are equally valued, and that their opinions will be made anonymous when the study is written up.

### **Data Management and confidentiality**

All data will be kept in a locked cabinet in the research teams' office and electronically in a secure password-protected file. Patient confidentiality will be maintained by ensuring that no individual will be identifiable from the data reported in the final analysis. This will be monitored by the Steering Committee.

### **EXPECTED OUTCOMES AND DISSEMINATION**

This study will describe the changes that occur in elderly care units when shock-absorbent flooring is utilised. This study will describe any changes to fall and injury rates which may be related to the use of the new flooring in elderly care units, as well as exploring maintenance issues, cost implications, and users' opinions. By incorporating effective design technology into the healthcare setting, the standards of care environments for elderly populations at risk of falling may be improved. It is envisaged that the proposed study will set a precedent for future research. It is hoped that this pilot study will inform the size (and follow-up period) of a large-scale cluster randomised controlled trial needed to identify a significant reduction in injuries from falls, should the floor prove beneficial. The findings from the pilot study will be disseminated through reports, peer-reviewed publications and national and international conference presentations. We will follow the guidance of the CONSORT statement for reporting of cluster randomised controlled trials.[50] Institution staff, participants, and their carers, will also receive debriefing and feedback on the findings.

## **STUDY MANAGEMENT AND MONITORING**

A Steering Committee has been established with a wide range of expertise, reflecting the interdisciplinary nature of the study. This group will meet every four months to monitor the progress of the study, ensure adherence to the research protocol and to oversee the publication of any reports or publications generated from the study. Additionally, although a change in the flooring represents a very low risk to patients, there is the possibility that the change may temporarily affect the rate of hospital-acquired infections (which have been shown to increase during periods of reconstruction).[14] With this in mind, pre- and post-intervention data on all reported hospital-acquired infections will be monitored, and it will be ensured that the proper advice and safety precautions are taken during the renovation work. During the study (and as part of the third objective), any surface breakages or irregularities such as grooving will be regularly monitored by ward staff and any need for maintenance will be recorded. The study investigators and flooring companies will be informed and appropriate action will be taken to mend any fault arising. Should the flooring irregularities grow to such a proportion that the institution or Steering Committee feels that the flooring should be replaced due to health and safety hazards, the site will be removed from the study to enable the flooring to be changed. All sites will be provided with Adverse Event Forms on which they can document and relay any problems arising which may be related to the floor.

Service users are represented on the Steering Committee, as well as key figures within the NHS and academics with specialist expertise. The Steering Committee consists of the following members, including patient and public representatives:

- Nigel Caldwell (Centre of Research in Purchasing and Supply (CRiSPS), University of Bath);
- Prof. Taraneh Dean (Head of Centre for Research and Knowledge Transfer, University of Portsmouth);

- Prof. Simon Dixon (Health Economist, University of Sheffield);
- Amy Drahota (Research Fellow in healthcare environments, University of Portsmouth);
- Diane Gal (Former Steering Committee member, University of Portsmouth);
- Kate Greenwood (R&D Manager, Portsmouth Hospitals NHS Trust);
- Kevin Hallas (Pedestrian Safety Specialist, Health & Safety Laboratory)
- Frances Healey (Joint Head of Clinical Review and Response, National Patient Safety Agency);
- Bernie Higgins (Medical Statistician, University of Portsmouth);
- Nick Latimer (Senior Lecturer in Health Economics, University of Sheffield);
- Heather Mackenzie (Former Steering Committee member, Research Associate, University of Portsmouth);
- Jonathan Millman (Head of Knowledge and Information, Estates and Facilities Division, DoH);
- Prof. Julian Minns (Consultant Clinical Scientist, formerly Newcastle General Hospital);
- Prof. Martin Severs (Associate Dean [Clinical Practice], University of Portsmouth);
- Dia Soilemezi (Research Associate, University of Portsmouth);
- Steve Thorpe (Principal Scientist at the Health & Safety Laboratory; Chair of the United Kingdom Slip Resistance Group);
- Julie Udell (PhD student, University of Portsmouth);
- Derek Ward (Research Fellow, University of Portsmouth);
- Keith White (member of Engage, a service user research advisory group);
- Julie Windsor (Clinical Nurse Specialist Falls Prevention, Nursing Directorate, Portsmouth Hospitals NHS Trust);
- Patricia Young (formerly design specialist National Patient Safety Agency, now at DNV [Det Norske Veritas]).

## **ACKNOWLEDGEMENTS**

With special thanks to the Steering Committee for approving this protocol and providing feedback and advice.

## **COMPETING INTERESTS**

None to declare.

## **FUNDING**

The Dunhill Medical Trust and the National Osteoporosis Society.

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## **FIGURE LEGEND**

Figure 1: Flow diagram of study design.