

STUDY PROTOCOL

Full title of project:

The SAFEST Review: The Shock-Absorbing Flooring Effectiveness SysTematic Review including older adults and staff in care settings.

Short title of the project: The SAFEST Review

This protocol has regard for the HRA guidance

Research Reference Numbers

Protocol version number and date: Version 2. Date: 01/05/2019

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History of amendments

	Details of amendments
<i>Version 1. Date: 20/12/18</i>	<p>This document has been adapted from the ‘Detailed Research Plan’ (version 2, date: 10-09-18) submitted to the HTA as part of the funding application process. The Detailed Research Plan has been adapted in the following ways to create this protocol:</p> <ul style="list-style-type: none"> • Incorporated the reference list, flow diagram, plain English summary, and additional details on public and patient involvement from the funding application form, so all information is in one document. • Minor updates to formatting/layout (e.g. table of contents, title page) and wording to enhance clarity. • Additional sections have been added to include a signature page, roles of the funder, sponsor, and committees, in line with HRA templates.
<i>Version 2. Date: 01/05/2019</i>	<p>This protocol has been updated following a discussion with our Advisory Board on 20th February 2019. These changes were decided upon prior to selection of included studies or any data collection.</p> <ul style="list-style-type: none"> • PROSPERO Registration number has been incorporated. • Further detail has been incorporated to elaborate on our plan for the Summary of Findings Tables. • We have ordered the priority of our secondary outcomes to align with our plan for the Summary of Findings Tables. • Minor changes have been made to wording to improve clarity of content. • Updated search sources to include a wider breadth of trial registration sources and removal of one conference proceedings because the conference has not been re-run since it was last searched in the scoping review. • The economic analysis section has been further clarified and elaborated upon, with some minor amendments to approach.

Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles and guidelines outlined in the UK Research Integrity Office Code of Practice for Research, the Concordat to Support Research Integrity (Universities UK, 2012), General Data Protection Regulation (2018), and the ethical issues for systematic reviews set out by Wager and Wiffen (doi.org/10.1111/j.1756-5391.2011.01122.x).

I confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature: 
.....

Name: (please print) Amy Drahota
.....

Date: 10/05/2019

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Study Funders

The Health Technology Assessment, National Institute for Health Research, have awarded a grant for £126,914 to support this research.

The Health & Safety Executive are supporting 10 days of Olanrewaju Okunribido's time in kind on this project.

Role of study sponsor and funder

The sponsor (University of Portsmouth) takes on overall responsibility for proportionate, effective arrangements being in place in order to set up, run and report on the research project. In addition, the University of Portsmouth takes overall responsibility for the design, conduct, data analysis and interpretation, manuscript writing, and dissemination of the results. Written consent is required from the funder prior to any publicity of the research (e.g. via media announcements, websites, or oral presentations), and publications will acknowledge the financial support and carry a disclaimer that this is independent research, and that the views expressed are those of the authors and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health and Social Care.

Draft copies of publications need to be sent to the funder at the same time as submission for publication or at least 28 days before the date intended for publication, whichever is earlier. The sponsor will provide a draft final report of the research within 14 days of the completion date of the project, for which the funder will arrange external peer review. The sponsor will respond to the peer review comments within four weeks of receiving them. If the sponsor has not produced a report which satisfies the funder within one year of the end of the research period, the funder may prepare and publish, or arrange for the preparation and publications of such a report.

Roles and responsibilities of the Advisory Board and Public and Patient Involvement group

The Advisory Board is comprised of all study collaborators, co-applicants, and the Senior Research Associate (Lambert Felix; LF), and is chaired by the Chief Investigator (Amy Drahota; AD). The role of the Advisory Board is to provide overall supervision for the project on behalf of the Project Sponsor and Project Funder and to ensure that the project is conducted to the rigorous standards set out in the Health Research Authority's "UK Policy Framework for Health and Social Care Research" that are applicable to systematic reviews, and "The Concordat to support Research Integrity".

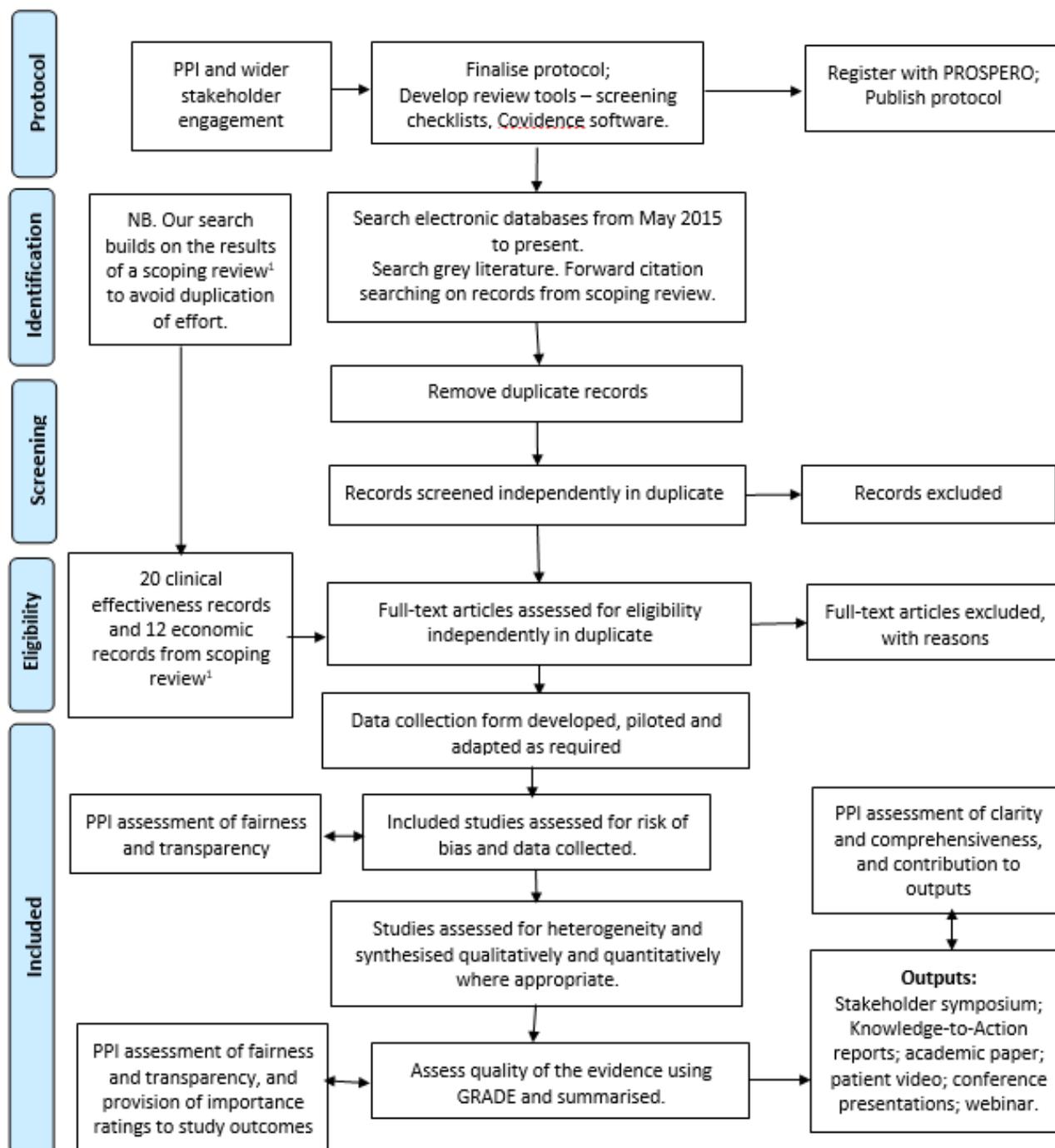
The day-to-day management of the project is the responsibility of the Chief Investigator (AD), with the assistance of the core research team (LF, KFS, BK, CL, OO, JR). The main features of the Advisory Board are as follows:

- To provide advice to the funder, sponsor, and Chief Investigator on all appropriate aspects of the project;
- To concentrate on progress of the project, adherence to the protocol, and the consideration of new information of relevance to the research question;
- To agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments;
- To provide advice to the investigators on all aspects of the project;
- To support impact and dissemination activities to facilitate the uptake of the study findings into practice.

The Public Involvement Group will be integral to assuring the transparency and fairness of judgements made throughout the review process, helping to prioritise outcomes and how the findings are set out, improving the clarity and the appropriate level of comprehensiveness of review outputs, as well as helping make the findings accessible. Public Involvement members are to expect an appropriate level of training and information to be provided to them to enable them to fulfil their roles. The Chief Investigator, with the support of the Senior Research Associate, will be responsible for the provision of training and information. The main roles of the Public Involvement Group will be:

- To advise on the clarity and comprehensiveness of the protocol and study outputs;
- To monitor and provide independent judgement on the fairness, transparency, and consistency of risk of bias and quality assessments made by the research team;
- To inform the design of the Summary of Findings Tables, with particular emphasis on ensuring the clarity of information provided, importance granted to different outcomes, and appropriate ordering of information;
- To help in the design and production of the patient experience video study output;
- To feed into and actively participate with the Advisory Board.

Study flow diagram



Adapted from: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. *PLoS Med* 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

1. Plain English Summary

Aims of the research: We aim to summarise what is known about shock-absorbing flooring in hospitals and care homes in terms of reducing injuries from falls. We want to help health organizations decide whether or not to invest in using shock-absorbing floors. We will establish if shock-absorbing flooring can: (1) reduce injuries from falls; (2) increase the chances of older people falling over; and (3) lead to injuries in staff who may find it harder to move equipment across a softer floor. We will also summarise any research on the costs and savings of shock-absorbing floors. Finally, we will look at any practical issues people have had when installing the new floors, and explore the experiences and attitudes of people who have used the floors (staff, residents/patients, and visitors).

Background to the research: Falls and fall-related injuries are a major problem in hospitals and care homes. Older people are more at risk of falling, and more at risk of injuring themselves if they do fall. Injuries from falls can lead to loss of independence and mobility, shorter lives, and lower quality lives. Shock-absorbing flooring is one potential solution to help reduce the impact of a fall. Researchers from different countries have been studying the use of shock-absorbing floors in hospitals and care homes, but nobody has brought all of these studies together to summarise their findings in a systematic way.

Design and methods used: We will carry out a thorough systematic search to identify all the studies we can find that have looked at shock-absorbing flooring use in hospitals and care homes. We will assess these studies for quality, and gather data on what they did, who they involved, and what they found. We will summarise the information we find, to make it more easily understood. Where appropriate, we will combine the data from different studies to produce an overall result. We will explore the differences between studies, to help us understand which factors might influence whether shock-absorbing flooring works, and to determine how trustworthy the findings are. We will use the findings from studies included in the review to produce recommendations that can guide end-users of the review.

Patient and public involvement: Our patient and public members will be involved throughout the project. They will help make sure our findings are easy to understand, and include all the important information. They will check the judgements we make about the quality of the research we find, to make sure we are being fair and clear. They will be involved in meetings to help guide us and make decisions. They will help us make a short video, which explains the findings of our research through patient experiences.

Dissemination: We will share our findings in different ways to suit different people. We will publish our report in an academic journal, with universal free access. We will present our findings at two conferences (one in England and one abroad), which have a focus on caring for older people. We will also present our results online in the form of a webinar. We will hold a half-day workshop, to which we will invite people who may find our review useful. We will produce short reports to give to people who make decisions about which flooring to use in hospitals and care homes. Finally, we will make a short online video which tells the findings of the review through the views and stories of patients as many people like to make decisions when they hear patients' or residents' views.

2. Summary of Research (abstract)

Research question: What is the clinical and cost-effectiveness of shock-absorbing flooring for fall-related injury prevention in older adults in care settings?

Background: Falls in hospitals and care homes are a major issue of international concern. Inpatient falls are the most commonly reported safety incident in the NHS, costing the NHS £630 million a year. Injurious falls are particularly life-limiting and costly. The urgency of this issue is increasing with the complex health and care needs of our ageing population. There is a growing body of evidence on shock-absorbing flooring for fall-related injury prevention (13 clinical effectiveness studies, 7 qualitative studies, and 12 economic records that we are aware of), however no systematic review exists to inform practice.

Aims and objectives: We aim to systematically review the evidence on shock-absorbing flooring use in care settings for fall-related injury prevention. Specifically we will:

1. Assess the benefits (fall-related injury prevention) and risks (falls; staff injuries) of different flooring systems.
2. Assess the extent to which these benefits and harms may be modified by different study/setting, intervention, or participant characteristics.
3. Critically appraise and summarise evidence on the resource use, costs and cost-effectiveness of shock-absorbing flooring compared with standard flooring.
4. Summarise findings on the implementation of flooring interventions.
5. Summarise the views and experiences of shock-absorbing flooring use, of patients/residents, staff, and visitors.
6. Identify gaps in the evidence.

Methods: Our project will systematically identify, appraise, and summarise studies investigating the clinical and economic effectiveness, and experiences of shock-absorbing flooring in hospitals and care homes. Our search will build on an extensive search conducted by a scoping review¹ (inception to May 2016). We will search six databases (May 2016 – present), clinical trial registries, grey literature sources, and sources for economic evidence. We will screen reference lists, conduct forward citation searches, and liaise with study researchers. We will evaluate the influence of floors on fall-related injuries, falls, and staff work-related injuries, consider economic and qualitative evidence, and implementation factors. Randomised and non-randomised studies will be included and summarised separately. We will consider risk of bias using the updated Cochrane Risk of Bias 2.0 tool² and ROBINS-I tool³. We will assess heterogeneity and explore potential effect modifiers via subgroup analyses (study type, setting, acuity of care, intervention type) and sensitivity analyses (risk of bias, analysis methods). Where appropriate we will combine studies through meta-analysis. The quality of outcomes will be evaluated using the GRADE approach⁴, and reported using Summary of Findings Tables⁵.

Timelines for delivery: 14 months.

Anticipated impact and dissemination: We will disseminate the findings via a range of outputs to suit different knowledge users. We will publish in a peer reviewed journal, give presentations (at national and international conferences, and webinar), host a stakeholder symposium, produce Knowledge-to-Action reports, and create a short video of the review findings via patient experiences. We will engage relevant stakeholders from different organisational levels throughout the project to facilitate uptake of the findings in practice and guidelines.

3. Background and Rationale

This research aligns with the ‘Complex health and care needs of older people’ priority NIHR theme, in particular by focussing on promoting healthy ageing and preventing ill health. Older people, people living with frailty, and people with multiple morbidities are at greater risk of falls and fall-related injuries⁶⁻⁹. Falls and associated injuries can lead to loss of independence following hospital discharge¹⁰⁻¹¹, and flooring interventions offer one potential solution to making healthcare environments age-friendly (and safer for those most vulnerable to harm in general), to improve health and wellbeing by preventing ill health¹. Whilst evidence in this field has been growing¹, there has been no comprehensive systematic review focussing on flooring interventions in healthcare settings for fall-related injury prevention.

Inpatient falls are the most commonly reported safety incident in NHS hospitals¹² and are of international concern¹³. Around 250,000 hospital falls occur annually in England, with about 30% resulting in injury, causing a significant burden for individuals, carers, and healthcare resources due to the costs of continued and additional care and litigation¹². The estimated costs of inpatient falls to NHS hospitals is £630 million per year¹². These costs do not account for the wider impacts to the health and social care system, related to rehabilitation, increased need for nursing/care homes, risk of recurrent falls, fear of falling, limiting activities, mobility, dependence, and the quality and longevity of life¹⁴. Hip fracture affects over 2500 people a year from NHS hospital falls¹⁵, and the proportion of hip fractures that occur in hospitals has been rising¹⁵; resulting in a 2.4 – 3.5 fold increased risk of mortality the following year¹⁶. Hip fractures are strongly associated with nursing home admission, additional formal and informal care, and further morbidity¹⁷. Whilst inpatient falls account for approximately 25%¹² of the £2.3 billion cost of falls to the NHS estimated by NICE¹⁸, falls in other care settings (e.g. nursing homes and care homes) also contribute considerably to this cost¹⁹.

Falls have a complex aetiology of intrinsic and extrinsic risk factors, affecting individuals with multiple morbidities, and no single solution effectively prevents them. The 2017 national falls audit estimates that approximately 30% of inpatient falls could be prevented, and the greatest cost savings would be realised if efforts were focussed on preventing severe falls¹². A Cochrane review on interventions for hospital falls and injury prevention²⁰ highlighted possible benefits of multifactorial interventions, vinyl (for falls prevention²¹), education, and physiotherapy. Since this review, the largest trial to date of inpatient falls (N=31411), a definitive cluster RCT of a multifactorial falls prevention intervention²², consisting of a patient risk assessment tool followed by delivery of one or more of six interventions (e.g. low-low beds), was found clinically ineffective. A Cochrane review on hip protectors for hip fractures²³ revealed that compliance with this intervention was poor due to discomfort and practicality and was a barrier to their use. Unlike hip protectors, manipulating the environment to prevent injuries is a promising intervention for reducing injurious falls as it requires no compliance from patients or staff, and can accommodate the fact that injuries occur not just to the hip. The 2013 NICE Guideline 161 on falls¹⁸, and the 2017 National Hip Fracture Database annual report¹⁵ have highlighted the pressing need to investigate environmental adaptations in older inpatients.

A recent scoping review of flooring interventions (by co-applicant CL)¹ involved a thorough search to identify the breadth of the evidence reported up until May 2016. Importantly, this scoping review did not involve a critical appraisal or systematic synthesis of the evidence, which has implications for the interpretation of the findings, as risk of bias can greatly determine the perceived effectiveness of interventions²⁴. Additionally, the findings of at least three new/ongoing studies that we are aware of, are not included in the results of this scoping review; a hospital-based trial in New Zealand and a care home study in Sweden have since been published^{25, 26}, and a cluster randomised trial (which included cost-effectiveness data) in a care home in Canada (led by our Advisory Board member DM)²⁷, is currently at the stage of data cleaning pre-analysis. From the scoping review and our networks, we are aware of five²⁸⁻³² published qualitative studies (three of which have been published since the scoping review³⁰⁻³²), and two further qualitative studies in preparation for publication (by AD and Advisory Board member AL). The scoping review identified 20 records of clinical effectiveness³³⁻⁵² (nine review articles^{33-37,43,48-50}, and 11 primary research studies of

randomised^{38,39,45} and non-randomised^{40-42,44,46,47,51,52} designs) and 12 records of cost-effectiveness^{35,36,42,45,53-60} (which require assessment for eligibility). It is critical that these studies are interpreted appropriately to inform practice, since they are in some cases small³⁸⁻³⁹, or involve observational and quasi-experimental designs^{40-42,44,47,51,52}, which are subject to inherent biases (e.g. non-comparable control groups or confounding from the different areas where flooring is laid). A systematic review of these studies, to include the new data from more recent studies^{25-27,30-32,45} will provide a more reliable basis for decision making on the use of shock-absorbing flooring in practice.

There remains an unresolved debate in lab-based research as to whether the gait of older individuals (particularly with complex health needs) may be adversely affected by softer floors^{46,54,61-70}, potentially leading to increased risk of falls. Conversely, evidence suggests that older individuals would benefit most from falling on softer floors^{54, 72-76}. The potential benefits and risks of shock-absorbing floors may vary depending on the type of patient utilising them. Further adverse effects of shock-absorbing floors may be witnessed in staff³⁹, who may experience greater effort is required to manoeuvre equipment¹, manifesting in increased staff injuries. These issues have yet to be considered in a systematic review of clinical effectiveness studies.

With the rising volume of primary research in this area, we are beginning to see evidence of shock-absorbing floors infiltrating the NHS; but their use in practice remains inconsistent. We are aware of sites which have implemented shock-absorbing flooring as an innovative measure to try and decrease fall-related injuries. Queen Alexandra Hospital in Portsmouth, opted to install a 6.5mm thick flooring, following our (non-definitive) pilot study³⁹ on an 8.3mm thick floor. A pragmatic decision was made (without knowing the clinical or cost-effectiveness) to use a mid-thickness floor in an attempt to trade-off the potential for adverse effects in staff, and in the hope that the additional thickness (in comparison to regular 2mm vinyl) will offer some degree of protection for falling patients. Other hospitals we are aware of include Bradford Hospital, and St Mary's Hospital (Isle of Wight; 8.3mm thick floor), who have invested in shock-absorbing flooring for their elderly care wards. York Hospital removed some shock-absorbing flooring due to concerns raised by staff about staff safety.

Shock-absorbing floors are more expensive than regular resilient sheet floor-coverings used in hospitals, and other hospitals (specifically Leeds, and Southend) we know, are waiting for clearer guidance as to whether a shock-absorbing floor is a good investment decision, and what type of shock-absorbing floor to select if so. When scoping out the potential viability of a definitive hospital-based cluster randomised trial in this area (in 2015), 28 NHS Trusts (over 40 wards) from our networks expressed an interest in taking part in a study should we be able to secure the funding. There is a clear appetite to explore the use of flooring for fall-related injury prevention, but current concerns exist as to whether to invest in it due to uncertainties in the evidence. The growing body of current evidence needs to be systematically assessed, with an exploration of heterogeneity of findings in different healthcare settings, and with different types of floors, to help resolve the current uncertainties, better inform NHS investment decisions, and to clearly identify the next steps for research activity (including informing the design of future studies).

Evidence explaining why this research is needed now

Fall related injuries remain a persistent and major problem in the context of our ageing population. The oldest age groups in society are the fastest growing sections of our society, with those aged 80 and over, expected to represent 20% of the older population by 2050, and the worldwide estimated 688 million people over 60 years old in 2006 projected to grow to almost two billion by 2050¹³. These projections are as pertinent in the UK as they are internationally. Innovative solutions are required to prevent avoidable morbidity and mortality from falls. This ongoing problem is of increasing concern due to our ageing population and age-associated increased risks of falls and injuries⁷⁷⁻⁷⁹. Many hospital floors are composed of a 2mm thin vinyl on concrete, which are unable to prevent injuries and may exacerbate them^{42,47,71}. Shock absorbing flooring is one potential solution¹, which could be applicable to all patients and be non-reliant on staff/patient compliance. This is a fast progressing field; the Canadian Agency for Drugs and Technologies in Health published a short report in 2010³⁵

whereby they identified no studies of clinical and cost-effectiveness of specialised shock-absorbing flooring use in healthcare settings, subsequently, albeit with differences in the search and inclusion criteria, the scoping review published in 2017 identified 20 clinical and 12 cost-effectiveness records¹, and since which at least two further clinical studies have been published^{25,26}, three further qualitative studies have been published³⁰⁻³², and another clinical and cost-effectiveness study is undergoing analysis²⁷. Practitioners in healthcare settings are keen to utilise innovative measures, such as flooring, to reduce fall-related injuries, but making sense of the evidence is prohibited due to a lack of a systematic review.

This research is important to quantify the potential benefits and harms in order to inform key stakeholders: health and social care and estates practitioners, guideline developers and others (e.g. litigation authorities, agencies focussed on care quality or environment, and the wider public).

4. Aims and objectives

We aim to systematically review the evidence on shock-absorbing flooring use in health and social care settings for fall-related injury prevention in older adults. Specifically, we will:

1. Assess the benefits (fall-related injury prevention) and risks (falls; staff injuries) of different flooring systems in care settings.
2. Assess the extent to which these benefits and harms may be modified by different study/setting, intervention, and participant characteristics.
3. Critically appraise and summarise current evidence on the resource use, costs and cost-effectiveness of shock-absorbing flooring in healthcare settings for older adults, compared with standard flooring.
4. Summarise findings on the implementation of flooring interventions in the included studies.
5. Summarise the views and experiences of shock-absorbing flooring use, of patients/residents, staff, and visitors in care settings.
6. Identify gaps in existing evidence / understanding

5. Research Plan / Methods

This systematic review will include studies aimed to address the effectiveness and/or cost-effectiveness and/or qualitative experiences of shock-absorbing flooring systems for fall-related injury prevention in care settings. We will follow the general approach set out in the Cochrane Handbook of Systematic Reviews⁸⁰, incorporating the updated Risk of Bias assessment tools (ROB 2.0 and ROBINS-I for randomised and non-randomised designs respectively^{2,3}), and the 'Grading of Recommendations, Assessment, Development and Evaluations' (GRADE) approach with Summary of Findings Tables to summarise the quality of the evidence⁵. This review will be of relevance to care settings which predominantly care for older people (hospitals, long term care/nursing settings), where patients (or residents) are at greater risk of falls and fall-related injury¹⁹.

Our interdisciplinary team comprises expertise which are subject-specific, methodological, and underpinned with personal experience. We are knowledgeable in: systematic review methodology; data synthesis; risk of bias analysis; ageing; health sciences research; health economics; estates and facilities management; characterising shock-absorbing materials; public engagement; patient perspectives; innovation in healthcare; clinical, ergonomic and human factors in falls and manual handling injury prevention.

Health technologies being assessed

'Shock-absorbing flooring systems' include floor coverings, underlays, and sub-floors considered to reduce the impact forces of falls. Alternative terminology may include variations on the terms: compliant flooring, safety flooring, soft flooring, impact absorbing flooring, energy absorbing flooring, low-impact flooring, dual stiffness flooring, low stiffness flooring, absorptive surfaces, cushioned flooring, rubber flooring, acoustic flooring, and carpet. Interventions may be flooring systems which have been purposely designed to prevent fall-related injuries (e.g. SmartCells, Sorbashock, Kradal),

thick vinyl (>5mm thick; e.g. repurposed sports floors, such as Tarkett Omnisports Excel), carpet with or without underlay, and other combination flooring systems (e.g. vinyl overlays with padded underlays, such as foam or rubber, or wooden subfloors). Fall mats will not be considered eligible as they are not permanently affixed to the floor and do not provide universal coverage or protection. We will exclude studies reporting exclusively on fall mats. We will include studies that compare different types of shock-absorbing flooring systems, or which compare one or more shock-absorbing flooring system to a standard 'rigid' floor (e.g. concrete, ≤2mm vinyl/resilient sheeting).

Search strategy

To reduce duplication of effort, this systematic review will build on the comprehensive search already conducted by co-applicant/collaborators in a scoping review¹, which had a search cut-off of 20th May 2016. The clinical (n=20), cost-effectiveness (n=12), and qualitative (n=2) records identified by the scoping review will be assessed for eligibility in this systematic review. The scoping review, which incorporated the expertise of an information scientist, involved a search of seven databases plus grey literature sources (Table 1). The search strategy of the scoping review (which also included studies exploring biomechanical efficacy and workplace safety) will be refined in scope to focus on identifying studies of clinical and cost-effectiveness, and qualitative experiences. The following electronic databases will be searched (May 2016 to present): CINAHL and MEDLINE (accessed via EBSCO, University of Portsmouth; see Appendix A for Medline strategy); AgeLine (accessed via EBSCO, Simon Fraser University, Canada); Web of Science, Scopus, and NHS Economic Evaluation Database (accessed via University of Portsmouth). Forward citation searching will be conducted on all eligible studies using Web of Science. Reference lists of any new studies identified post-May 2016 will be screened. A hand search of the tables of contents of Age and Ageing (the most predominant journal in this field to date) will be conducted from May 2016 to present. Our grey literature search will include a review of clinical trial registries, theses/dissertations, conference proceedings, and relevant websites (see Table 1), including an additional search of relevant health economics models from NICE (for cost of falls and staff injuries) and NHS Improvement (who support falls improvement and workforce initiatives within the NHS). No language restrictions will be placed on the search. We will use the extensive language expertise within the University of Portsmouth for foreign-language records which pass an initial check using Google Translate. A review author will work through the eligibility checklist (and if relevant, the data collection form) alongside someone who speaks the appropriate language. Relevant sections of the article will be translated in order to complete the data collection form; these will be checked by a second person.

Table 1. Sources of academic and grey literature: differences between the scoping review and the present systematic review.

Search type	Sources of literature included in the scoping review	Sources to be included in this systematic review
Academic search	AgeLine (EBSCO; 1978 to May 2016)	Yes (May 2016 -)
	CINAHL Complete (EBSCO; 1937 to May 2016)	Yes (May 2016 -)
	EBM Reviews (OVID; 1991 to May 2016)	Out of scope
	Ergo-Abs (EBSCO; 1985 to May 2016)	Out of scope
	MEDLINE (Ovid; 1950 to May 2016)	Yes (May 2016 -)
	SPORTDiscus (EBSCO; 1830 to May 2016)	Out of scope
	Web of Science (Thomson Reuters; 1898 to May 2016)	Yes (May 2016-)
	-	Scopus (May 2016-)
	-	NHS EED
Grey literature search (1990 to present)	Clinical trial registries:	
	<ul style="list-style-type: none"> • Clinicaltrials.gov • Controlled-trials.com 	WHO International Clinical Trials Registry Platform
	Theses/dissertations:	

<ul style="list-style-type: none"> • ProQuest Theses and Dissertations 	Yes
Abstracts/conference proceedings for target associations:	
<ul style="list-style-type: none"> • Bioengineering 	Out of scope
<ul style="list-style-type: none"> • Annual Conference of the IEEE Engineering in Medicine and Biology Society 	Out of scope
<ul style="list-style-type: none"> • ASME Summer Bioengineering Conference 	Out of scope
<i>Biomechanics</i>	
<ul style="list-style-type: none"> • Annual Conference of the American Society of Biomechanics 	Out of scope
<ul style="list-style-type: none"> • Biennial Meeting of the Canadian Society of Biomechanics 	Out of scope
<ul style="list-style-type: none"> • Congress of the International Society of Biomechanics 	Out of scope
<i>Falls prevention</i>	
<ul style="list-style-type: none"> • Biennial Conference of the Australian and New Zealand Falls Prevention Society 	Yes
<ul style="list-style-type: none"> • International Conference on Fall Prevention and Protection 	No (has not been re-run)
<ul style="list-style-type: none"> • International Society for Posture and Gait Research World Congress 	Yes
<i>Gerontology</i>	
<ul style="list-style-type: none"> • Canadian Association on Gerontology Annual Scientific and Educational Meeting 	Yes
<ul style="list-style-type: none"> • Gerontological Society of America's Annual Scientific Meeting 	Yes
<ul style="list-style-type: none"> • World Conference of Gerontechnology 	Yes
<ul style="list-style-type: none"> • World Congress of the International Association of Gerontology and Geriatrics 	Yes
Websites of target organisations:	
<ul style="list-style-type: none"> • Agency for Healthcare Research and Quality (AHRQ) 	Yes
<ul style="list-style-type: none"> • American Society for Testing and Materials (ASTM) International 	Out of scope
<ul style="list-style-type: none"> • Canadian Agency for Drugs and Technologies in Health (CADTH) 	Yes
<ul style="list-style-type: none"> • Occupational Safety and Health Administration (OSHA) 	Out of scope
<ul style="list-style-type: none"> • OpenSIGLE 	OpenGrey
<ul style="list-style-type: none"> • Parachute Canada 	Yes
<ul style="list-style-type: none"> • The National Institute for Occupational Safety and Health (NIOSH) 	Yes

	<ul style="list-style-type: none"> UK Health Technology Assessment 	Yes plus other NIHR funded programmes
	<ul style="list-style-type: none"> US Center for Health Design 	Yes
	<ul style="list-style-type: none"> WHO Health Evidence Database (HEN) 	Yes
	-	NICE guidelines
	-	NHS Improvement
Hand searching (1990 to present)	Reference lists of all eligible records	Yes
	Tables of contents of the journal 'Age and Ageing'	Yes
Consultation with experts (NA)	We will consult with content experts and the Research Advisory Panel to identify individual records not already uncovered by our academic database, grey literature and hand searches.	Yes

Review strategy and strategy for reviewing literature

All references will be imported into a reference management software, Endnote. We will manage the review strategy with the software 'Covidence'⁸¹, which supports international collaboration through sorting for duplicates, the screening, data collection, and risk of bias assessment processes, to enable tasks to be done independently in duplicate, facilitating identification and resolution of differences of opinions, and producing a PRISMA flow diagram⁸². Data will be analysed in RevMan⁸³, and Summary of Findings Tables created with GRADE Pro⁸⁴ (and guidance from the GRADE handbook).⁸⁵

Titles, abstracts, and full reports will be screened in duplicate using an eligibility checklist (based on the inclusion/exclusion criteria listed below). All records included in the clinical and cost-effectiveness sections of the scoping review will be assessed at the full report stage. From the results of the updated search, we will begin by screening titles, and those that look potentially relevant will be reviewed in abstract form. Full reports will be obtained for abstracts which appear definitely or possibly relevant. Disagreements will be resolved through discussion including a third independent arbitrator. The selection process will be documented in a PRISMA flow diagram⁸².

Risk of bias assessment will be undertaken using the updated Cochrane risk of bias tool (ROB 2.0)² for randomised trials (including individually and cluster randomised, and cross-over studies). The ROBINS-I (Risk Of Bias In Non-randomised Studies of Interventions) tool³, will be used to assess observational studies and non-randomised experimental designs. Review authors will not be blinded during risk of bias assessments, however where they have been involved in co-authoring an included study (CL, AD), assessments will be undertaken by at least two other independent reviewers (OO, BK, LF). Our public involvement members will be involved in checking the integrity and transparency of the risk of bias assessments. We will seek further information from study authors where required if there is inadequate information to form a risk of bias judgement; we will approach study authors with open-ended questions, asking to describe the relevant study processes in more detail, so to avoid overly positive answers.

Design and theoretical/conceptual framework

This systematic review will incorporate experimental, quasi-experimental, observational, and qualitative studies. Whilst randomised trials of flooring interventions are feasible (given appropriate resources), the nature and logistics of the intervention make observational and opportunistic quasi-experimental designs far more practical; therefore we will include non-randomised studies with the view to systematically report their findings and limitations, to better inform practice. To overcome variations in terminology usage, regardless of how study authors label their study designs, we will utilise the tables of study design features presented in the Cochrane Handbook⁸⁰ to classify included studies by their component design features. The following examples will be eligible:

- Randomised controlled trials, these may be randomised at the individual, or (more likely) cluster level (e.g. with the unit of allocation by room/area/facility), non-random methods of allocation (quasi-experimental studies, as per further examples below) will also be included;
- Interrupted times series (e.g. evaluating a change in trend in outcome measures before and after shock-absorbing flooring installation);
- Controlled before and after studies (e.g. non-randomised allocation to shock-absorbing flooring or control, where outcomes are measured concurrently in groups of participants residing in areas with different floors, before and after a change in floor in at least one group);
- Cohort studies (e.g. prospectively or retrospectively observing groups of patients residing in areas with or without shock-absorbing flooring);
- Case-control studies (e.g. retrospectively evaluating where patients with various classifications of fall-related injuries fell, to see the effect of flooring type on outcome).
- Partial and full economic evaluations, based on a single study or model.
- Qualitative studies involving interviews, focus groups, questionnaires or surveys, to explore experiences, attitudes, and perceptions towards flooring interventions.

Simple before and after studies measuring quantitative outcomes, with no evaluation of time trends (i.e. a series of at least three observations prior and three observations post intervention), or concurrent control, will be excluded.

The following proposed theoretical framework (Figure 1) conceptualises the causal pathway between shock-absorbing floor systems and their outcomes (falls, fall-related injuries, adverse events – staff injuries), and potential (often related) moderators of that relationship (effect modifiers). The purpose of this framework is to help direct the review process, by informing data collection, risk of bias assessment (particularly in relation to confounding), exploration of heterogeneity, and analysis of the data.

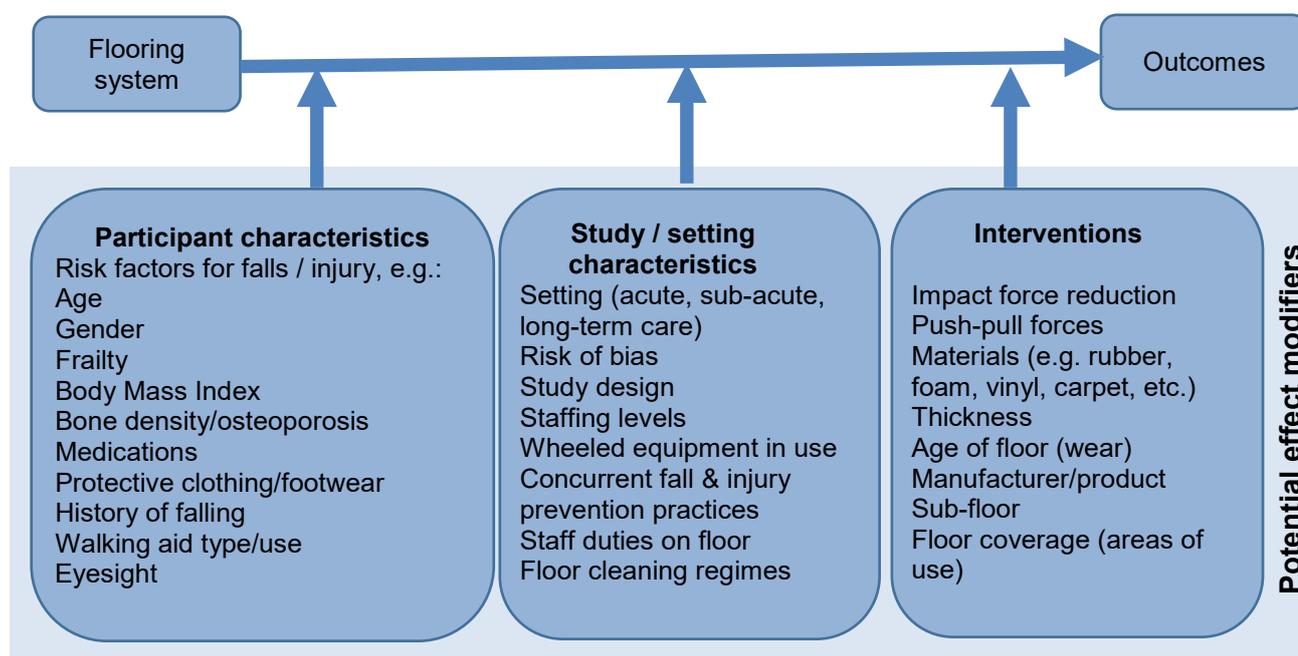


Figure 1. Theoretical framework of potential effect modifiers.

Target population

The target population for this review is broadly, older people in healthcare settings. Notably, the adverse effects may be witnessed in staff who are occupying the same environment, due to the potential for increased effort to undertake tasks (e.g. moving wheeled equipment, such as beds, trolleys, and hoists). Staff and visitors, along with patients/residents may also offer useful qualitative insights into flooring use.

Inclusion/Exclusion Criteria

Population: Studies must focus on adult populations in healthcare settings to be included in this review. Studies focussed solely on paediatric care settings will be excluded. We will be pragmatic, and open to different definitions of ‘older adults’ and will not have a set cut-off criterion for age, since it is acknowledged that chronological age may not be a good indicator of frailty^{86,87}. Due to the nature and purpose of the intervention, we anticipate that studies will largely be conducted in high risk environments where older people are the predominant population and falls are more likely.

Interventions: Studies must compare different types of flooring, with at least one intervention classifiable as a ‘shock-absorbing’ floor, as per our definition above. Studies which include flooring as one component of a package of multiple interventions, in which the effects of the floor cannot be disentangled from other concurrent interventions, will be excluded.

Outcomes: Whilst we would expect quantitative studies to report on outcomes related to falls and fall-related injuries as a minimum, the reporting of specific outcomes does not form part of the inclusion criteria for our review. Rather, we will consider the reporting of outcomes as part of our risk of bias assessments and assessment of reporting/publication bias.

Setting: Studies must have been conducted in a care setting (defined below) to be included in this review. This includes hospitals (acute, sub-acute), intermediate and long-term care settings (nursing and care homes). Studies conducted in people’s own homes, or other settings (e.g. playgrounds, sporting venues) will be excluded.

Study design: We will include primary quantitative or qualitative research studies; quantitative studies must have a concurrent control group, or an analysis of trends over time (interrupted times series) to account for seasonal effects. We will not apply a threshold for risk of bias to be included, rather, we will address the potential influence of risk of bias in the analysis and interpretation of our findings, e.g. through subgroup and sensitivity analyses where appropriate. Simple before-and-after studies will be excluded.

Setting/context

Care settings will be broadly defined as⁸⁸:

- Care home environments (a facility that meets the following criteria: provides communal living facilities for long-term care; provides overnight accommodation; provides nursing or personal care; and provides for people with illness, disability or dependence).
- Hospital environments (a facility that meets the following criteria: provides communal care where there is an expectation that this care is time limited; provides overnight accommodation; provides nursing and personal care; and provides for people with illness and disability).

Data collection

Our data collection will be underpinned by our theoretical framework of potential effect modifiers (Fig.1). We will develop and utilise a data collection form (to be piloted on three included studies, and amended as required), which will be uploaded in to the software ‘Covidence’.

Data collection will include the following key components of information, details within which will be informed by our theoretical framework:

- Study identification (and linked publications)
- Time/duration and geographical place of conduct
- Participant characteristics
- Intervention(s)
- Control(s)
- Outcome data acquisition: Falls reporting (e.g. retrospective database review; prospective daily checks of patient notes; staff recall; triangulation of sources); Classification system of

injuries; Identification of fractures (confirmation of diagnosis/type of fractures included);
Identification of adverse effects.

- Setting
- Study design characteristics
- Risk of bias assessments
- Outcomes and analyses (we will extract summary effect estimates where possible, or collect raw data to enable our own calculations if feasible).
- Patient and public involvement in the research
- Follow-up questions for study authors (Missing and unclear information will be flagged).

Assessment of risk of bias

Risk of bias assessments will be conducted using the ROB 2.0² and ROBINS-I³ tools for randomised and non-randomised studies respectively, at the level of the study results. We will focus on assessing rate and risk of injurious falls, rate and risk of falls, as well as adverse events in staff. For randomised trials, we will assess study results for risk of bias across the following five domains: (1) Bias arising from the randomization process; (2) Bias due to deviations from intended interventions; (3) Bias due to missing outcome data; (4) Bias in measurement of the outcome; (5) Bias in selection of the reported result. Cluster trials will also include an assessment of (1b) bias arising from the timing of identification and recruitment of individual participants. The results of non-randomised studies will be assessed across seven domains. The first three of these domains will replace 'bias arising from the randomisation process': (1) Bias due to confounding; (2) Bias in selection of participants into the study; (3) Bias in classification of interventions; the final four domains align with the final four domains of the ROB 2.0 tool. Supporting information and justification for judgements (high; low; some concerns) will be recorded for each domain. We will follow the guidance to derive overall summary risk of bias judgements for each outcome (high; low; some concerns), which will be used to inform our statistical analyses and GRADE assessments.

Data analysis (quantitative studies)

Assessment of reporting biases: Where possible, we will draw funnel plots with different plotting symbols to identify subgroups (as specified below). We will only test for funnel plot asymmetry if there are sufficient data (at least 10 studies to be combined), and will use visual inspection of the plots to make sense of the findings. Our aim is to reduce the risk of publication bias affecting our results by conducting a thorough search and communicating with researchers in the field.

Dealing with missing data: We will contact study authors for data missing from the reports. If missing data are from participant/cluster dropouts, we will conduct analyses based on the available data and include an assessment of the problem as part of our risk of bias judgements.

Measures of treatment effect: Rate of falls, rate of injurious falls, and rate of fracture will be reported using incidence rate ratios and 95% confidence intervals. The number of fallers, number of participants with fall-related injuries, and number of participants with fall-related fracture, will be described using risk ratios and 95% confidence intervals. Where available we will also report hazard ratios for falls (to include all falls from recurrent fallers), since this will provide a more powerful analysis of an increase in falls in the intervention group (should one exist). Where adjusted and unadjusted rates are presented in randomised trials, we will use the unadjusted figures, unless the adjustment is for clustering. For non-randomised studies, we will record the unadjusted and adjusted estimates and note the factors adjusted for. Where multiple adjusted estimates are presented, we will extract the estimate highlighted as the primary model by the authors, or where this is unclear, take the model which has adjusted for the most covariates. Where summary effect estimates (rate ratios or risk ratios) are not reported, we will calculate them where feasible using the raw data (i.e. number of falls, total length of person-time monitored, total number of participants observed in each group), or by converting any reported odds ratios using an Excel spreadsheet which has built-in the formulas provided in the Cochrane Handbook⁸⁰.

Where studies present a break-down of the severity of injuries (as ordinal outcome data, e.g. none, mild, moderate, severe, death), we will present these descriptively, and if studies have used similar categorisation systems, using figures where feasible (e.g. stacked bar graphs), since proportional odds ratios are difficult to interpret (less useful for end users of the review), and the alternative of using a cut-off point to dichotomise the data seems redundant and difficult to justify since we are already investigating injurious falls and fractures as separate outcomes. Adverse events to staff will be reported as a risk or rate ratio (per 100 working staff-days) where possible, or as the number of events observed during the follow-up period, if no clear denominator is known.

Unit of analysis issues: To avoid unit of analysis issues (including the same group of participants more than once in an analysis), we will be mindful of trials with multiple associated publications, or with multiple intervention groups; in the case of multiple study arms, we will either combine the groups (if logical) or include only one pair-wise comparison (intervention versus control) in any one analysis. Cluster randomised trials will be clearly identified in the review and the way that the data have been dealt with will be described. Where clustering has not been taken into account, we plan to adjust the estimates using an intra-cluster correlation coefficient borrowed from another similar study⁸⁰.

Assessment and investigation of heterogeneity: Where evidence exists from randomised and non-randomised studies, we will report the data separately, giving more emphasis to the findings from randomised trials. Non-randomised studies will be organised according to whether data collection was prospective or retrospective, and if controls were concurrent or historical. Where feasible, we will plot data onto forest plots, using the generic inverse variance data type in RevMan, and explore heterogeneity.

We will explore heterogeneity irrespective of whether we decide to pool studies in a meta-analysis. Heterogeneity will be assessed through a combination of visual inspection of the forest plots, along with consideration of tests for homogeneity (χ^2 with statistical significance set at $P < 0.10$), and measures for inconsistency (I^2) and heterogeneity (τ^2).

The following study and intervention characteristics will be explored via subgroups, where feasible:

- Study design (randomised, type of non-randomised study)
- Study setting (hospital, care home)
- Acuity of care (acute, sub-acute, intermediate, long-term care)
- Flooring type (novel shock-absorbing flooring, thick vinyl/vinyl & underlay, carpet, wooden subfloor)

We will not explore patient level characteristics via subgroups as this level of data is more suited to individual-patient data meta-analysis, which is beyond the scope of this review. However, we anticipate that study level characteristics related to setting and the acuity level of care provided, will overlap with differences in patient-level factors, which we will assess and comment upon qualitatively by reviewing the Tables of Included Studies.

Sensitivity analyses: Sensitivity analyses will be undertaken to determine the influence of:

- risk of bias (removing studies at high risk of bias);
- choice of effect estimates (e.g. where multiple adjusted estimates are presented in observational studies, the analysis will be run on the most optimistic and pessimistic scenarios).
- Adjustment for clustering where an intra-cluster correlation coefficient has been borrowed from another similar study; we will assess the impact of opting for more or less conservative adjustments.

Data synthesis: Should meta-analysis be viable, we will opt to combine studies using a random-effects model, assuming that intervention effects are likely to vary across studies (based on our theoretical framework of potential effect modifiers; Figure 1). If appropriate, we will combine the data from RCTs and non-RCTs to provide an overall summary effect estimate.

Measurement of costs and outcomes

There is no core outcome set for shock-absorbing flooring interventions specifically, however a common outcome data set for fall injury prevention trials has been developed⁸⁹, albeit with a focus on community-dwelling populations. This consensus statement provides a definition for a fall as “an unexpected event in which the participants come to rest on the ground, floor, or lower level”. It recommends falls be summarised by trialists as number of falls, number of fallers / non-fallers / frequent fallers, fall rate per person year, and time to first fall. For injuries, the recommended measure is the number of radiologically confirmed peripheral fracture events per person year (to include the limbs and limb girdles). It is recommended that investigators summarise injury data as peripheral fracture rate per person-year of follow-up, number of peripheral fractures, number of people sustaining peripheral fractures, and number of people sustaining multiple events. It is recommended that primary analyses of fall and injury data should not be adjusted for physical activity, and reporting should include the absolute risk difference. It is recommended⁸⁹ that the psychological consequences of falling (defined as “the degree of confidence a person has in performing common activities of daily living without falling”) are measured using the modified Falls Efficacy Scale, and health related quality of life is measured with the Short Form 12 (SF12) version 2 and European Quality of Life Instrument (EuroQoL EQ-5D).

An international consensus statement for trials on hip protectors⁹⁰ proposes the outcomes of: hip fractures (defined as proximal femoral fractures to include subtrochanteric fractures, and periprosthetic fractures, but not femoral shaft fractures), adherence, falls (total and injurious), quality of life, adverse effects, other fractures, cost–effectiveness and cost–utility analyses.

There are some key differences to consider in relation with the present review and these core outcome sets, namely: (1) it is more common for rates of falls and injuries to be presented in terms of 1000 patient bed-days in institutional settings (versus person-years in the community); (2) a number of the items on the Falls Efficacy Scale have limited applicability to individuals in institutional settings, so it is unlikely to be used in this context; (3) hip protectors target a more specific area of the body than shock-absorbing flooring, so trials on flooring are likely going to want to capture broader effects. Taking into consideration these related core outcome sets, and their differences in foci with the current review, and through discussion with our public involvement group, and wider stakeholder engagement we have undertaken in the field⁹¹, we plan to focus on the following outcome measures:

Primary outcomes:

- (1) Injurious falls rate per 1000 patient-bed days;
- (2) Falls rate per 1000 patient-bed days.

Secondary outcomes:

- (1) Fractures per 1000 patient bed days;
- (2) Hip fractures per 1000 patient bed days;
- (3) No. of fallers;
- (4) No. of fallers with injuries (none, minor, moderate, severe, death);
- (5) No. of adverse events (staff injuries);
- (6) No. of fractures;
- (7) No. of hip fractures;
- (8) Qualitative outcomes (e.g. staff, patients/residents, and visitors attitudes, views, and experiences).
- (9) Economic outcomes (to include assessments of quality-adjusted life years);
- (10) Process outcomes (e.g. ease of, or problems with, flooring installation).

Economic evaluation

We shall align our approach for the incorporation of costs data to an exemplar systematic review by Garrison and colleagues⁹². One reviewer (LF) will extract all data from included economic evaluations, which will be checked by an expert reviewer (JR). The data extraction form for economic evaluations will be based on the format and guidelines used to produce structured abstracts of full economic evaluations for inclusion in the NHS Economic Evaluation Database, adapted to reflect specific design features of this review. Data extraction will include general study characteristics (e.g. country, settings, aims) and methodological aspects related to economic evaluations. We will collect the following economic variables, if reported: costs of flooring (purchasing, installation,

maintenance); costs of falls based on injury, such as hospital resources (e.g., increased length of stay, additional surgery needs), post-discharge healthcare costs (e.g. hospital readmission, outpatient visits); utility measures, such as quality of life, life years and quality adjusted life years; and summary measures, including incremental cost-effectiveness ratios (ICERs), net monetary benefits, and value of information (Vol).

Data extraction will include items on economic study type, analytic perspective, study population, modelling and statistical extrapolation, setting, dates to which data relate/time horizon of costs and effects, clinical and epidemiological data, data sources, methods used to obtain data, link between effectiveness and cost data, details and methods of associated effectiveness studies, source(s) of unit cost data, currency, resource use and costs, methods used to allow for uncertainty, synthesis of costs and benefits, incremental cost-effectiveness results, authors conclusions, comments.

Economic evaluations will be classified by type (*Partial evaluations*: ‘outcome description’, ‘cost description’, ‘cost-outcome description’, ‘efficacy or effectiveness evaluation’, or ‘cost-analysis’; *Full economic evaluations*: ‘cost-effectiveness analysis’, ‘cost-utility analysis’, or ‘cost-benefit analysis’) and as either an economic evaluation based on a single study or a model-based economic evaluation. Where necessary, we will seek additional information from study authors.

We will assess the methodological quality of included economic evaluations through the use of the risk of bias tool and recognised checklists⁹² based on guidelines for authors and peer reviewers of economic submissions to the British Medical Journal (for economic evaluations based on a single study), and for quality assessment in economic decision-analytic models (for model-based economic evaluations). Checklists will be completed independently by two reviewers (JR and LF) and disagreements will be resolved through discussion.

We will tabulate and summarise the results of included economic evaluations narratively in the text. We will adjust all costs to 2019 Pound Sterling values using Gross Domestic Product deflators, and use relevant exchange rates for international comparisons.

Qualitative evaluation

We will incorporate qualitative evidence into the review using a meta-aggregative approach to qualitative synthesis (following the guidance of the Joanna Briggs Institute⁹⁵). An appealing feature underpinning this approach, is that it seeks to derive generalizable statements, in the form of recommendations that can be used to guide end-users (practitioners and policy makers). Studies will be assessed using the Joanna Briggs Institute’s critical appraisal tool for qualitative research⁹⁵ and data will be extracted by two independent reviewers (LF and AD) and using a third reviewer for arbitration if required (and to ensure duplicate independent quality assessment of AD’s paper).

Data to be considered ‘findings’ for the purposes of the review, will be the themes/metaphors presented in the results sections (and discussion sections, if relevant), defined as “a verbatim extract of the authors analytic interpretation accompanied by either a participant voice, or fieldwork observations or other data”. Synthesis will follow a three-step process (1. Extraction of all findings from included papers, with an accompanying illustration and rated level of credibility; 2. Developing categories for findings which are sufficiently similar; 3. Developing one or more synthesized findings of at least two categories). Qualitative study selection will be supported via Covidence, as with our other study types. Data analyses will be conducted using QSR NVivo software (which we have utilised for qualitative synthesis previously⁹⁶).

Confidence in Cumulative Evidence

Quantitative Evidence: We will assess the quality of evidence across the included studies at outcome level for each comparison using GRADE⁸⁴, and incorporate these assessments into ‘Grade profile’ and Summary of Findings (SoF) Tables using the GRADEpro software⁸⁵. Our main comparison will be ‘shock-absorbing flooring (all types) versus standard flooring’, and we will include separate SoF tables for hospitals and care homes. Supplementary SoF tables will be developed for different types of shock-absorbing flooring (e.g. specially designed ‘health’ floors; sports floors in care settings; carpet / wooden subfloors) versus standard flooring (e.g. ≤2mm resilient sheet vinyl/lino on concrete or wooden subfloor), and for head-to-head comparisons of different shock-absorbing flooring interventions.

We will include the following outcomes: (1) injurious falls rate per 1000 patient-bed days, (2) falls rate per 1000 patient-bed days, (3) fractures per 1000 patient bed days, (4) hip fractures per 1000 patient bed days; (5) number of fallers, (6) number of fallers with injuries (none, minor, moderate, severe), and (7) number of adverse events (e.g. staff injuries). The GRADE system provides a grade of the overall quality of the evidence for each outcome on one of four levels: high, moderate, low, very low.

We will use the following five GRADE criteria to assess the quality of evidence: risk of bias; indirectness of evidence; inconsistency of effect (heterogeneity); imprecision of the effect estimates; and risk of publication bias⁸⁰. In the first instance, two review authors will independently assess the GRADE criteria for all the above outcomes in a purposefully designed form. We will justify each grading decision. We will then compare the independent assessments of both the authors, with the aim to resolve any discrepancies in the decisions by discussion and as appropriate, by consulting a third review author. Once a consensus is reached, one review author (LF) will transfer the agreed data to the GRADEpro table, using the GRADEproGDT software (GRADEproGDT), and create the SoF table.

The Summary of findings (SoF) tables will include a brief description of the population, settings, intervention and the comparison intervention, in addition to:

1. A measure of the typical burden of the outcomes such as illustrative risk based on data derived from the studies (control groups) included in the review;;
2. Absolute and relative magnitude of effect;
3. Numbers of participants, and studies addressing each outcome;
4. A GRADE assessment of the overall quality of the body of evidence for each outcome;
5. Comments such as interpretation of the quality of evidence, and clinical relevance;
6. Explanations to support upgrading or downgrading decisions of the grade assessment.

We will provide supplementary ‘Evidence Profile’ tables to breakdown the quality assessments in a clear and transparent format⁵.

Qualitative Evidence: We will follow the CERQual group’s recommendations to assess the quality of qualitative evidence included in the review⁹⁷. We will assess each review finding based on methodological limitations, coherence, adequacy of data, and relevance⁹⁸. We will make an overall assessment of confidence for each review finding on one of the four levels: high, moderate, low, very low. We will create ‘CERQual Evidence Profile’, and ‘Summary of Qualitative Findings (SoQF)’ tables.

We will include the following information in the Evidence Profile: i) a summary of each review finding; ii) an explanation of the assessment made for each component for each review finding; iii) an overall CERQual assessment for each individual review finding; iv) an explanation of the overall CERQual assessments; v) reference to the studies contributing data to the review findings. SoQF will summarise the key review findings, and we will include the following three elements in the table: i)

summary of each review finding; ii) an overall CERQual for each review finding; iii) reference to the studies contributing data to the review finding.

6. Dissemination, Outputs and anticipated Impact

Our approach is underpinned by the Knowledge to Action Framework⁹⁹, and will ensure involvement of knowledge users with researchers throughout the research process. A previous stakeholder symposium⁹¹ has informed the identified problems to be addressed in this review (namely: addressing questions of clinical and cost-effectiveness, to address concerns with the perceived financial barriers as well as barriers to installation), and we will continue to engage with stakeholders to ensure our outputs can be adapted to local contexts, barriers to uptake are considered, and knowledge use can be monitored.

What do we intend to produce from our research?

The following outputs will be produced from this research:

- A peer-reviewed, (gold) open access journal publication of the review findings
- A presentation at an international conference (e.g. Biennial Global Ageing Conference)
- A presentation at a national conference (e.g. British Geriatrics Society Autumn Meeting)
- A webinar presentation
- A peer-reviewed, (green) open access journal publication of the review protocol
- A registration entry on the PROSPERO database
- Press release/social media with an item in relevant media outlets (e.g. The Conversation; The HEFMA Pulse magazine) generating national/international media attention with Creative Commons License for re-use
- A half-day stakeholder symposium, the outputs of which will be made available online
- A short video distilling the review findings via patient stories
- Knowledge-To-Action Reports tailored to NHS Chief Executives, care home managers, and estates/facilities managers, healthcare designers and builders.

How will we inform and engage patients, NHS and the wider population about our work?

We will consult with key stakeholders and a range of potential knowledge users at each stage of our review (i.e. small group meetings, one-to-one discussions, videoconferences, teleconferences, and email). Our Advisory Board includes the following knowledge users: Falls in older people NICE Guideline Developer; Safety and Improvement Clinical Lead; director/chairman of the Health Estates and Facilities Management Association; public members; shock-absorbing flooring researchers from health sciences and engineering disciplines). Collectively, members of the Panel possess the relevant expertise and decision-making authority to critically evaluate and implement shock-absorbing flooring systems in high-risk environments such as hospitals and long-term care, and utilise systematic review evidence to inform future research.

An interactive process of communication between researchers and the Advisory Board will be used throughout all stages of the review process. We will involve the Board in a number of important ways: (1) in providing input on the design and implementation of the review; (2) as members of the project team who attend project meetings and inform us of emerging primary research evidence; (3) in the interpretation of findings and identification of research gaps; and (4) in the packaging and dissemination of the review's findings in a form that is relevant, practical and easily interpreted by other decision-makers and knowledge users.

We also plan to engage with targeted and wider members (falls prevention / safety clinical leads; nursing home managers; NHS hospital executives; members of the public; NHS estates managers) of our broader networks at the outset, mid-point, and conclusion of the grant period, to incorporate their information needs, keep them engaged, and provide a broader base for knowledge translation at regional, national, and international levels. We recognise the importance of professional, organisational, and systems level influences in the uptake of innovations, and that there are preferences for different types of evidence across professional groups¹⁰⁰. Our engagement strategy

therefore targets individuals and organisations at these different levels of influence, and our dissemination plan includes the reframing of our findings into different formats (academic publications; conference presentations; Knowledge-to-Action Reports; video depicting patient stories and need; webinar; a half-day symposium; and social media and press).

Our end-of-grant dissemination plan matches knowledge translation strategies to each of our target audiences to support the advancement of health-related knowledge. To disseminate findings to stakeholders from a range of sectors, and to capitalise on the power of in-person communication, we will host a half-day Stakeholder Symposium to which we will invite individuals representing healthcare, occupational health, building design and construction, government, housing, flooring manufacturers, and research. This approach has been successfully implemented in Canada as part of the project related to the scoping review⁹¹.

To disseminate findings to a broader geographic audience of stakeholders from a range of sectors, we will host a webinar and produce and distribute Knowledge-to-Action Reports. To reach academic stakeholders, we will prepare and submit both a conference abstract and open-access peer-reviewed journal article with the study results. It has been highlighted that service commissioners draw on a range of evidence, including alternative evidence such as patient stories⁹⁷. With this in mind, we will work with our public involvement group (and other members of the public as required) to produce a short video, which incorporates compelling patient narratives that elaborate upon the bottom line evidence found in the systematic review. We will produce this video in our state-of-the-art simulation in health care centre (ward and care home environment), and with the expertise of the University of Portsmouth Media Production Centre. This video will be accessible to the public and linked to our other dissemination outputs, including social media and press releases. Our press release will include submission of an article to The Conversation (<https://theconversation.com/uk>), an independent media outlet which many national newspapers and other media sources (across the world) re-use content from under their Creative Commons License. Publishing via The Conversation also enables authors to track the readership numbers and wider dissemination of the article. We will evaluate the success of our end-of-grant dissemination efforts through a variety of means, such as tracking event attendance, event evaluation forms, downloads and citations of our scientific journal article, and distribution numbers for the Knowledge-to-Action Reports. The review's findings and outputs will be made openly available via the Open Science Framework and will help decision-makers understand the current evidence base on shock-absorbing flooring that aims to prevent fall-related injuries.

Our engagement plan with stakeholders throughout this review will better enable us to adapt the presentation of the review findings to different stakeholders and contexts. Aside from our regular Advisory Board meetings and Public Involvement meetings, we will seek to engage with key parties through the use of our extensive personal and professional networks, for example:

- AD manages the University of Portsmouth Ageing Network >520 internal and external members (including NHS, local authorities, nursing and care homes, voluntary sector organisations) and >120 public engagement members;
- AD sits on two expert advisory groups and a community of practice for the Healthy Ageing Programme run by the Wessex Academic Health Science Network (AHSN). The Wessex AHSN also disseminates information to 3000 members regionally and has extensive links with AHSNs across the country.
- AD maintains a list of 86 stakeholders (from NHS, public, and wider organisations, including: NHS Property Services Ltd; Architects for Health; Office of Quality and Patient Safety, The Joint Commission, USA; and Canadian Patient Safety Institute) who have expressed a specific interest of being kept up-to-date with shock-absorbing flooring research;
- JW regularly communicates with four regional falls networks across the country (approximately 250 members);
- JW is on the Steering Group for the National Inpatient Falls Audit at the Royal College of Physicians, which links with Chief Executives of the 19 Trusts registered to the audit.

- Together, we share contact information with members of the flooring industry who have an interest in operating in this field (e.g. Tarkett, Polyflor, Altro, Gerflor, Kradal, SmartCells).

Further key parties will be identified via the networks above (by asking key individuals to link us in with their networks) and through facilities such as the CHAIN Network (<http://www.chain-network.org.uk/>) and social media (LinkedIn, Twitter).

Our collaborator KFS is the External Promotion and Liaison Lead, for the School of Health Sciences and Social Work, and she will oversee our engagement plan, beginning at the start of the project by disseminating news of our work, inviting feedback, and updating our contacts database with the details of interested parties. A newsletter with a brief preferences survey will be disseminated mid-way through the project, to help us shape our dissemination products, and invite people to attend the stakeholder symposium. As well as a means to disseminating the findings, the stakeholder symposium will include workshop activities to enable stakeholders to discuss the barriers to uptake of the research findings, how the findings will need to be tailored to their contexts, and to look for solutions to issues raised.

How will our outputs enter our health and care system or society as a whole?

We anticipate our outputs to be incorporated into clinical guidelines (updates to the NICE CG161), and other practice guidelines internationally, e.g. in the USA, the Eastern Association for the Surgery of Trauma has issued practice guidelines in this area, noting our research¹⁰¹. We will engage with NHS Property Services to facilitate the uptake of the outputs into decision-making for refurbishment schedules of their 3500 properties large estate and new-building works. Our engagement with clinical falls specialists, Chief Executives, estates and facilities managers, nursing home managers, and Academic Health Science Networks, and higher level organisations (e.g. NHS Improvement; Joint Commission, USA; Canadian Patient Safety Institute) will facilitate the spread of knowledge, from bottom-up and top-down perspectives.

What further funding or support will be required if this research is successful?

We plan to carry forward the work of this review with future primary research to address gaps and uncertainties highlighted by the evidence (we may approach NIHR, UKRI, industry, or charities for such funding). Should the review highlight clinical effectiveness for particular groups or contexts, we will next seek to address the barriers to implementation that will be discussed at our stakeholder symposium. We anticipate one potential barrier to implementation to be related to staff concerns over the use of wheeled equipment on the floor. This may be tackled through, for example, working with industry to improve the rolling resistance of shock-absorbing flooring products, exploring the use of wheeled equipment within the system (e.g. are there more appropriate products with larger wheels, assistive technologies); looking at the policies and staffing factors surrounding manual handling to see where improvements could be made.

What are the possible barriers for further research, development, adoption and implementation?

A potential barrier to uptake is the possibility for inconclusive findings of the review, or uncertainty around the trade-off between potential benefits and harms of the intervention. We hope this risk will be somewhat mitigated by the emerging evidence which will be incorporated into this review, and our attempt to meta-analyse results where feasible and appropriate. In addition, the incorporation of economic data we hope will aid decision making, should a potential for harm be demonstrated. Whatever findings arise from this review, it will still lead to better available information to inform decisions than is currently available, and the findings will therefore be valuable to practice.

One concern raised at our previous stakeholder symposium⁹¹ was around feasibility of installation. To address this concern we will include process outcomes in the review, to detail any issues experienced by others with the installation process and how they were overcome. Further concerns relate to the acceptability of the intervention from a staffing perspective, given the potential for increased effort required when wheeling objects. We will address this outcome in the review, to try

and quantify the extent of the problem, as well as summarise the qualitative findings around these issues. Decision-makers will have to balance this risk against the potential benefits for patient outcomes, and consider ways the risk to staff can be managed (e.g. through type of equipment in use, manual handling policies, staffing levels, area to implement a shock-absorbing floor). We aim to present the evidence in such a way as to help decision-makers apply the new knowledge to their specific contexts and make an informed choice.

Financing an innovative floor may be a barrier, particularly in situations where the estates and facilities budget may be handled separately to budgets used for clinical care (an overspend in one budget may lead to savings in another), or where short-term financial pressures outweigh the potential long-term gains. Through our review process we will be seeking to engage with stakeholders from estates and clinical care, as well as Chief Executives and managers, and we hope that by targeting these different areas and levels of influence, we will help generate a shared understanding to influence future change.

What do we think the impact of our research will be and for whom?

The findings of this review will help inform decisions to influence patient benefit (falls and injuries prevention in hospitals and care homes), staff wellbeing (injury prevention), care environments (flooring choices), all leading to efficiency savings for the NHS in the longer term. The wider repercussions of improving inpatient falls/injuries for public wellbeing include: reducing the extent of post-discharge formal and informal care requirements and increasing independence. The most direct result of this project will be to inform decisions on care environments (depending on the direction of results - the uptake or otherwise of shock-absorbing floors). Our Advisory Board and wider stakeholder engagement will be integral to helping us realise our ambitions for impact. Through our engagement with a working member of the CG161 NICE Guideline on falls in older people¹⁸, we anticipate that evidence from this review will be incorporated into future updates of the NICE Guideline (estimated 2020). Our stakeholder organisations include NHS Property Services Ltd, which oversees the refurbishment (and new building works) of 3500 NHS buildings (10% of the NHS estate), and the Health Estates and Facilities Management Association, which is made up of 8 regional branches across England and the membership includes 380 Directors and Senior Managers of Estates and Facilities working in the NHS; we hope the results of this review will help inform future investment decisions in the NHS estate (from 2020), and more widely into care home and nursing homes (communicating through, e.g. the National Care Association, and Registered Nursing Home Association). These more immediate effects may mature over time as the innovation becomes embedded into practice, and uptake is seen more widely. Should the findings of the review prove positive, flooring companies may experience a commercial return on their products, contributing to economic growth. From an NHS savings point of view, should shock-absorbing flooring reduce injuries and not increase falls or overly effect staffing, the cost of refurbishing a ward could be easily balanced against the savings of preventing one hip fracture; further consider that the initial outlay for refurbishment is for a product that may remain in situ for 15 years and all the injuries and potential litigation proceedings that could be prevented over that time. The potential long-term impacts are vast. Should the outcomes of the review prove negative, we hope it will help avoid costly mistaken decisions (or help with disinvestment), and for areas of the review with inconclusive findings, we will seek to address the gaps through further primary research in the next 5 years and onwards.

7. Project / research timetable

Milestones	Study identification			Data collection and assessment			Data analysis and summarising				Write-up and dissemination			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Project Month														
Calendar Month	Feb-19	Mar-19	Apr-19	May-19	Jun-19	Jul-19	Aug-19	Sep-19	Oct-19	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20
Register protocol on PROSPERO	☑													
Submit protocol for publication		☑												
Project management set-up (Covidence, meetings)														
Produce eligibility checklist														
Database & grey literature search														
Screening & study selection														
Forward citation search & reference list screening														
Develop & pilot data collection form														
Data collection / risk of bias														
Contact authors for missing info														
Data analysis / qualitative synthesis														
GRADE / Summary of Findings														
Review write-up														
Submit review for publication														
Stakeholder engagement /symposium (☑)														
Produce patient experience video														
Knowledge-to-action reports														
International / national conference														
MEETINGS														
Advisory Group	☑			☑			☑				☑			
PPI meeting		☑				☑				☑		☑		
Team meetings	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑

8. Project management

This project will be managed from the University of Portsmouth (AD). We will establish collaboration agreements with our partners (CL, JR, BK, OO), to facilitate our shared understanding of the project and deliverables. We will utilise the software 'Covidence' to facilitate collaboration across institutions. The project team will meet via teleconference at least once a month, and fortnightly during the more intense phase of study selection and data collection. Fortnightly meetings will allow us to resolve any disagreements which have arisen from the independent screening, data collection and study assessment, as well as establishing targets to ensure project timescales are met. We also anticipate at least one physical meeting between the researchers at Portsmouth and the health economist in Southampton, to discuss the quality, findings, and synthesis of the economic studies.

Public involvement meetings, and wider stakeholder engagement, will be co-ordinated by KFS, who will ensure there is independent representation of public opinions at each key stage in the review process. Advisory panel meetings (which will also include a public representative) will take place every three to four months (four times over project period), to monitor progress and help resolve any issues. Team meetings and Advisory Panel meetings will take place via Go-To-Meeting due to geographic dispersion, and dates will be scheduled from the start of the project. Public involvement meetings will take place in person at the University of Portsmouth. We will regularly communicate with all collaborators via email, to summarise key decisions made in meetings, update on progress, and ensure everyone understands the next steps. Draft publications will be shared with all collaborators via Google Docs to enable individuals to make simultaneous contributions whilst maintaining version control.

9. Ethics

We do not need to obtain ethical review, as this is an evidence synthesis. Nonetheless, our ethical considerations¹⁰² will relate to: (1) appropriateness of authorship on the final works; (2) avoidance of duplication in the publication of the findings – we will be seeking to publish the review in a peer-reviewed open access journal, and any other media outputs (e.g. blogs, summaries) will be cross-referenced with the full report; (3) avoiding plagiarism by ensuring that all reported findings are sufficiently cited and attributable to the source material; (4) transparency, in the form of acknowledging all contributions and competing interests ; (5) having due rigour in the data collection and reporting phases of the review (e.g. duplicate screening and extraction, identifying duplicate publications) to ensure the accuracy of the findings; and (6) flagging suspected fraudulent or plagiarised research to the publishing journals.

10. Patient and Public Involvement

We held a public involvement meeting on 26th February 2018, with three public members. Our public members are all retired, they have personal experience of caring, nursing, falls, hospitals, patient and public involvement (PPI) in research, research participation, writing, editing, and involvement in filming for educational videos. In this meeting we discussed the draft proposal and PPI over the course of the project. As a result, we made changes to our list of secondary outcomes, which settings to include in the review, further developed the theoretical framework underpinning the review, and discussed how our public members would like to remain engaged during the project (e.g. how many meetings, format of the meeting, representation on other meetings).

Specifically, public involvement members emphasised the importance of listing 'all fractures' as a separate outcome to 'hip fractures'. It was felt that use of the term 'peripheral fractures' was confusing, and unclear as to whether it included hip fractures, and since spinal fractures are unlikely to be a result of a fall, for any study which measures fall-related injuries, the term 'fractures' will suitably capture all relevant fractures that may be seen as a result of a fall. The group still felt it worthy to consider hip fractures as a separate outcome, due to the associated costs and life-expectancy associated with this specific event.

In discussing the settings to be included in the review, our public involvement members helped refine our focus to hospitals and care homes, as the healthcare settings to be included. We discussed the idea of other community settings, for example community centres which may be used as venues by voluntary sector organisations involved in the delivery of support groups, and GP surgeries. Our public involvement members felt that hospitals and care homes (including nursing homes) were the most important venues to focus on, as the places that are more likely to be high risk for falls and that have physical areas more focussed on caring for the complex health and care needs of older people, where compliant flooring could prove a useful investment. Public involvement members also highlighted the importance of eyesight, footwear, giddiness (orthostatic hypotension), and stroke, as potential modifiers of the relationship between compliant flooring and outcomes.

Our group felt that meeting in person at the University would be beneficial, at regular intervals throughout the project, and were receptive to the idea of joining the Advisory Board meetings via teleconference in the evenings (to accommodate the time zone variations with our Canadian collaborators). One member suggested we use the platform 'Go-to-Meeting' as they had experienced better reception with this than Skype, when engaging with previous projects. Subsequent to this meeting, the draft proposal was circulated to the PPI group who provided feedback on matters of clarity and comprehensiveness. Suggestions were made on how to reduce the length of the report, and whilst it was felt that the main proposal contained some necessary technical information, feedback was provided on the plain language summary, to the point where group members felt the plain language summary was easy to read and understand.

Our public and patient involvement group will be involved throughout the project life cycle. They will be integral to assuring the transparency and fairness of judgements made throughout the review process (in conjunction with risk of bias and GRADE assessments), helping to prioritise outcomes and how the findings are set out in Summary of Findings Tables, improving the clarity and the appropriate level of comprehensiveness of review outputs, as well as making the findings accessible via alternative outputs (including a video involving patient perspectives, and content of the Stakeholder Symposium).

We are planning five specific PPI meetings over the course of the project. Each meeting will include a brief training session to explain the stage of the review the project is at, and the processes and tasks involved. AD/Senior Research Associate will deliver the training. Specific ways in which PPI members will be involved at each stage of the review, to coincide with these five meetings include:

- 1) Commenting on the clarity and comprehensiveness of the protocol (with the opportunity to contribute as an author);
- 2) Providing an independent judgement as to the fairness, transparency, and consistency of risk of bias judgements made by the project team;
- 3) Providing an independent judgement as to the fairness, transparency, and consistency of GRADE judgements made by the project team;
- 4) Informing the Summary of Findings Tables, by commenting on the clarity of the information presented, and informing the importance ratings given to outcomes, and the order and presentation of comparisons and subgroups listed in the tables.
- 5) Providing feedback on the clarity, comprehensiveness, and presentation of the project outputs (including the Plain English Summary).

In between meetings our PPI members will be given time to review and comment on documents, so thoughts that occur to members after the physical meeting can be fed back to the team. Additionally our PPI members will be involved in the creation of a video, where they will help translate the key

messages from the review into stories from a patient perspective. This will involve at least two additional meetings, electronic exchanges, and a day for the set-up and filming. They will also be involved in the planning of the Stakeholder Symposium and are likely to be involved in presenting some information at this event, such as the importance of the research from a public perspective, and helping to facilitate some of the discussions by for example, taking key notes.

Supplementary to these meetings, our PPI members will have positions on the Advisory Board. We will aim to have at least one or more members of the PPI team at these meetings, which will take place in the evening via teleconference. Members in need of additional support to join these meetings will be welcome to physically meet with the lead applicant (AD) so they can call in together.

Our PPI members will be appropriately compensated and recognised for their time in the project via payments, authorship, and acknowledgements. All of our PPI members have access to a computer, however they will be given the option to receive documents in hard or electronic copy, and any printing will be covered by the University of Portsmouth.

Our PPI members all support the involvement plan. There may be unforeseen times when not every member will be available to provide input into a specific activity. Our aim is to ensure we have one or more PPI members contribute in each of the ways we have outlined, but with no obligation on any one person to contribute at any one time. We feel our PPI team is large enough to meet this aim, but we will recruit additional members if required.

11. Project / research expertise

Lambert Felix has been recruited as a Senior Research Associate. He is a Chartered Physiotherapist, and currently undertaking a postgraduate diploma in health economics and health policy at the University of Birmingham. LF has more than 11 years' of research experience in systematic reviews of healthcare interventions. He worked for a brief period as a Community Physiotherapist with the NHS and had an opportunity to support the falls prevention service. He will be full-time for the 14 month project period, and will be responsible for the day-to-day running of the project. He will be involved in every aspect of the review, and will screen, extract data from all relevant records, undertake data analysis, write the report, and participate in dissemination activities.

Dr. Amy Drahota will oversee the project as Principal Investigator (PI). She is an experienced supervisor and PI, has led primary research on shock-absorbing flooring in hospitals, and had various roles in Cochrane (author, trainer, methodologist, and consultant), providing a sound knowledge-base in systematic reviews. She will supervise the Senior Research Associate, provide expertise in systematic review methods and shock-absorbing flooring research (from a health sciences perspective), and will undertake key tasks that require doing independently in duplicate, contribute to data analyses, the interpretation of findings, and the research outputs. She will be contributing 39 days to this project.

Dr. Bethany Keenan (BK), Dr. Chantelle Lachance (CL), and Dr. Olanrewaju Okunribido (OO) will all undertake key tasks that require doing independently in duplicate, they will be involved in the data collection form development and piloting, and contribute to the interpretation of findings and the research outputs. They each will attend team meetings and Advisory Board meetings and be contributing 10 days to the project.

BK provides expertise in biomechanics and materials, to include characterising flooring interventions (from an engineering perspective). She has been involved in the development of an international standard for shock-absorbency testing and has been working with AD to provide the engineering expertise to help characterise and select suitable floors for use in clinical research.

CL provides expertise on systematic reviews, knowledge translation, and shock-absorbing flooring research (from a health science perspective). She led on the scoping review which forms the

foundation for this systematic review, and has undertaken primary research in this field. CL has been a Postdoctoral Fellow in the Knowledge Synthesis Team at St Michael's Hospital, Canada, and she will be contributing 10 days of her time to this project in kind.

OO is a Senior Ergonomics and Human Factors Specialist providing expertise on manual handling injuries during push-pull tasks as well as falls prevention. OO has led on the development of a risk assessment tool for staff roles involving push-pull tasks, has undertaken research to help understand contributing factors to manual handling injuries, and is involved in accident investigations and guidance formation. The Health & Safety Laboratory are contributing 10 days of OOs time to the project in kind.

Ms. Kirsten Farrell-Savage is a qualified radiographer (with expertise in fracture diagnostics) and is the External Promotion and Liaison Lead for the School of Health Sciences and Social Work, bringing experience in public and stakeholder involvement. She will co-ordinate our public involvement and stakeholder engagement activities alongside contributing to some of the review processes (study selection, data collection, quality assessments) by helping to resolve disagreements, interpret the findings, and contribute to the research outputs. She will contribute 15 days to this project.

Prof James Raftery is a health economist, and Professor of Health Technology Assessment (working part-time for the University of Southampton). He is a former chair of the NIHR Evaluation Trials and Studies Coordinating Centre (NETSCC) and has led several research projects including an update of the literature on assessing the impact of the HTA programme, and assessment of funding expenditure in relation to disease burden. He has led the economic elements of an extensive range of projects, including in clinical trials, systematic reviews, and the political economy of healthcare. He will lead on the methodological aspects of synthesising economic studies, reviewing all of the economic studies, collecting data on them, undertaking quality assessments, and informing the interpretation and summary of the economic findings. He will contribute six days to this project.

Ms Julie Windsor is a registered nurse by background, and the Patient Safety Clinical Lead - Medical Specialties/Older People for NHS Improvement, with a leading role in falls prevention activities across England. She sits on the NICE Clinical Guidelines panel for falls prevention in older people, and is extensively networked with knowledge users relevant to this review. Her role in the project as an Advisory Board member, will be related to shaping the protocol, interpretation of findings, contributing to the research outputs, and facilitating the uptake of findings.

Prof. Dawn Mackey (DM) is the Director of the Aging and Population Health Laboratory at Simon Fraser University, Canada. She is a PI on a shock-absorbing flooring clinical and cost-effectiveness study (FLIP study) currently undergoing analysis⁴⁵. She secured funding for and supervised the scoping review on shock-absorbing flooring¹. Her research incorporates techniques from epidemiology and biostatistics, including clinical trials, longitudinal cohort studies, knowledge synthesis, and meta-analysis, as well as laboratory-based studies. As an Advisory Board member she will be involved in providing guidance on designing the protocol, supplying supplementary evidence from primary research, interpreting the findings, and contributing to research outputs.

Prof. Andrew Laing is the Director of the Injury Biomechanics and Aging Laboratory at the University of Waterloo, Canada, with expertise in musculoskeletal biomechanics related to human health, mobility, and injury prevention. His research interests centre on fall-related tissue trauma (including hip fractures, spinal cord injuries, and traumatic brain injuries), balance and mobility issues that could increase the risk of fall-related injuries, and workplace musculoskeletal disorders. He is a PI on the FLIP study⁴⁵ with DM and involved in the development of an international standard for shock-absorbency testing with BK. As an Advisory Board member, he will be involved in providing guidance on designing the protocol, interpreting the findings, and contributing to research outputs.

Alison Cracknell (AC; Consultant in Medicine for Older People) and Anna Winfield (AW; Speciality Doctor Elderly Medicine) from Leeds Teaching Hospitals NHS Trust are further clinical

representatives and will be members of our Advisory Board. AC is Associate Medical Director for Quality Improvement at Leeds Teaching Hospitals, and Clinical Lead for the Yorkshire and Humber Patient Safety Collaborative. She is an active researcher and experienced in patient safety, improvement, and implementing innovations into frontline clinical practice. AC, working with AW, led the Health Foundation Scaling up Improvement Grant: “Huddle Up for Safer Healthcare”, working with >150 frontline teams across three acute Trusts, to combine a huddle with improving patient safety and team working. In 2014 AC was named as one of the HSJ (Health Service Journal) Top Innovators in Healthcare.

AW is a Specialty Doctor in Elderly Medicine at Leeds Teaching Hospitals, a Clinical Lead for Quality Improvement (QI) at the Yorkshire and Humber AHSN Improvement Academy and Clinical Tutor for Speciality and Associate Specialist (SAS) doctors across the Trust. She is extremely passionate about leading frontline teams in QI and improving patient safety. One of her major interests is inpatient falls and she is the Clinical Lead for the 'Falls QI Collaborative' at Leeds Teaching Hospitals. Alongside her colleague, she was 'runner up' for the NHS Improvement Sir Peter Carr Award. She has led multiple QI work and is experienced in embedding evidence based innovations into clinical practice. As Advisory Board members, AC and AW will be involved in providing guidance on designing the protocol, interpreting the findings, and contributing to research outputs.

Mrs. Margaret Bell, Ms Joleen Tobias, and Ms. Liz Burden are public involvement members, contributing as described in the PPI section above.

Mr Jonathan Stewart (JS) is the National Chairman for the Health Estates and Facilities Management Association (HEFMA), and Director of HEFMA Ltd., and is highly experienced as an independent estates and facilities management consultant. HEFMA represents many of the Estates and Facilities professionals working within the NHS. JS can provide access to the HEFMA membership for the purposes of our stakeholder engagement plan and for disseminating research findings. JS will also facilitate dissemination via the HEFMA magazine, which has wide readership across the health sector and suppliers. JS will be an Advisory Board member, providing guidance on interpreting the findings, contributing to research outputs, and facilitating the uptake of findings into practice.

Nadra Ahmed (NA), who received an OBE in 2006 for services to social care, has been Chairman of the National Care Association since 2001. She has been involved in the field of social care for over 35 years and until 2005 was the Registered Manager of two private care homes for older people, having developed and run services since 1981. NA has served on numerous government task forces and she was the Vice Chairman of Skills for Care for 11 years. NA is a trustee of Parkinson's UK among other charities, the Deputy Lord Lieutenant of Kent and a Kent Ambassador. She is a regular contributor to journals and speaks at national and international conferences. She is also regularly called upon by the major media networks to represent the views of social care providers. NA is driven by a desire to ensure the delivery of quality services to the most vulnerable members of our society. She works across a number of government departments which have an impact on the social care world giving evidence and expert advice to parliamentarians. NA will be an Advisory Board member, representing the views of social care providers, providing guidance on interpreting the findings, contributing to research outputs, and facilitating the uptake of findings into practice via her networks.

12. Success criteria and barriers to proposed work

Our success criteria are aligned to our ten project outputs (described above) and project schedule. More so than submitting timely articles and creating the outputs by the end of the project period, we wish to document the interest and where possible the uptake of the findings to demonstrate tangible impacts. This measurement, will by necessity, extend beyond the end of the grant funding period. We plan to establish mechanisms which will support our ongoing engagement with potential knowledge users, by maintaining a secure database of their contact details (established over the course of the project period, which includes their communication preferences). We will use this

information to keep our stakeholders updated of our progress in this field, extending beyond the period of the project grant, and to continue to invite feedback from them to keep us abreast of any actions people are taking on the basis of the review findings.

Risks to the project include running over schedule and lack of cohesion of the project team. We will mitigate against these risks through regular virtual meetings to keep us on track and maintain an open dialogue. Alongside considering the estimated size of our review, we have taken time to develop a realistic project schedule, which takes into consideration the steps involved in the systematic review process, which can take time regardless of the number of studies included. Our collaborative team, includes leading international researchers in the field, and through this review, we will be building upon our working relationships and joint track-record, which we envisage will lead to stronger, future interdisciplinary bids, to address some of the challenges facing the field. All members of the team are ambitious and keen to make this project a success, as demonstrated through the offers of people's time we have had approved (10 days of CL, 10 days of OO), and time offered by our Advisory Board members in kind.

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Appendix A: Medline search, accessed via EBSCO

1	MH "Wounds and Injuries+
2	MH "Accidental Falls/PC"
3	MH "Hip Fractures+/PC"
4	fall\$
5	faller\$
6	S1 OR S2 OR S3 OR S4 OR S5
7	MH "Aged+"
8	MH "Middle Aged"
9	Older
10	Senior\$
11	elderly
12	S7 OR S8 OR S9 OR S10 OR S11
13	S6 AND S12
14	MH "Residential Facilities+"
15	MH "Long-Term Care"
16	MH "Institutionalization"
17	MH "Hospitalization"
18	MH "Subacute Care"
19	MH "Hospitals+"
20	MH "Hospital Units"
21	MH "Rehabilitation Centers"
22	MH "Inpatients"
23	MH "Geriatric Assessment"
24	("long stay" or "long term" or "acute" or "sub-acute" or "subacute" or "residential" or "hospital") N3 (care or ward# or hospital)
25	(rehabilitation or geriatric) N1 (ward# or hospital# or unit# or department#)
26	hostel\$ or nursing home\$
27	inpatient
28	resident\$
29	institution\$
30	S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29
31	S13 and S30
32	floor* NOT (pelvic floor OR sinus OR mouth)
33	carpet*
34	ground surface\$
35	smartcell*
36	tarkett
37	softile
38	sorbashock
39	forbo
40	kradal
41	noraplan
42	MH "Floors and Floorcoverings"
43	S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42
44	S31 AND S43
45	MH "Animals+"
46	MH "Humans"
47	S45 NOT S46
48	S44 NOT S47
49	S44 NOT S47
	Limiters - Date of Publication: 2016-05-01-