FULL TITLE OF THE CLINICAL STUDY

What is the clinical experience of maintaining patient safety in hospital in patients with temporary or permanent loss of cognitive function? A Mixed Methods Study

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Short title: Clinical Experience of Maintaining Patient Safety in Hospital

Acronym: CEMPSIH

IRAS Project ID: 347285

Study Sponsor: University of Nottingham

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SYNOPSIS

Title	What is the clinical experience of maintaining patient safety in hospital in patients with temporary or permanent loss of cognitive function? A Mixed Methods Study
Short title	Clinical Experience of Maintaining Patient Safety in Hospital (CEMPSIH)
Chief Investigator	Associate Professor Alexandra Lang
Objectives	To test whether there is a universal professional experience of maintaining patient safety in hospitals, with patients who have impaired cognitive function
Study Configuration	Mixed Methods, Multi-centre, Exploratory Sequential Strategy
Setting	Secondary care - Acute Hospital Trusts
Number of participants	128 participants overall. Up to 32 participants per Hospital (16 Nursing staff, 8 Therapists and 8 Medical Doctor or associates)
Eligibility criteria	Direct patient facing healthcare workforce responsible for managing and preventing accidental falls in the NHS.
Description of interventions	Observations of participants during a simulation of an in-patient safety scenario, followed by a semi structured focus group discussion. TThe simulation will be repeated 8 times over 2 days in each participating institution. This will require up to 128 participants delivering 16 datasets.
Duration of study	The study will start on November 28th 2024 or when necessary approvals have been received. The study will be completed within 6 months of start date. Each participant will be required for a total of 4 hours in 1x 3.5 hour session and a further feedback session of 30 minutes on completion of study.
Methods of analysis	Observations will inform focus group discussion and themes and codes derived from focus group discussion will be analysed using Nvivo 14.

ABBREVIATIONS

CI	Chief Investigator overall
CDM	Critical Decision Method
CEIFP	Clinical Experience of In-patient Fall Prevention (Short study title)
CG	Clinical Guidance
CRF	Case Report Form
DMP	Data Management Plan
EPSRC	Engineering and Physical Sciences Research Council
GCP	Good Clinical Practice
MFA	Multifactorial Assessment
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PI	Principal Investigator at a local centre
PIS	Participant Information Sheet
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
PPI	Patient and Public Involvement
R&D	Research and Development department
TRL	Trial Recruitment Log (participants demographics)
UoN	University of Nottingham

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STUDY BACKGROUND INFORMATION AND RATIONALE

The National Institute for Health and Care Excellence (NICE 2013) clinical guidance CG161 recommends that all patients admitted to hospital over the age of 65 and those with specific underlying conditions between the age of 50 and 64 are considered at high risk of falls and a documented falls risk assessment is undertaken on admission. However, whilst advising the use of an appropriate multifactorial risk assessment (MFA) NICE (2013) also acknowledges that there is no evidence of the efficacy of most falls prevention methods in hospital and that high-quality randomised controlled trials (RCT) conducted in the UK are required to improve the existing evidence base (National Institute for Health and Care Excellence, 2019).

Falls are referred to as accidents but statistically they have been shown not to demonstrate a pattern of chance(Evans, 1990) which suggests a causal process (Lord, 2007). Contributing factors leading to falls have been recognised as; postural stability, gait, sensory deficit, neuromuscular impairment, psychological conditions, impact of medications, environmental risks and medical risks such as stroke and cardiac issues (Montero-Odasso et al., 2022). Significant research has been undertaken in relation to falls in the community and as such there are useful clinical guidelines published by both NICE (2019) and World Falls Guidelines (Montero-Odasso et al., 2022) for managing patients falls in their home. Whilst patients may be at less risk in their own environment, when admitted to hospital usually single or multiple risk factors apply, even if only for a limited period due to the nature of their presenting condition. It is therefore necessary to assess all patients who are admitted to hospital to establish the level of risk they face and to prescribe interventions with the goal of preventing an accidental fall.

In the UK, 30 - 50% of accidental falls in hospital lead to some injury and 1-3% of those sustain a fracture (Morris and O'Riordan, 2017). In-patient falls are a significant cause of morbidity and mortality, with an estimated 247,000 occurring annually at a cost of £2.3billion to the NHS (NHS improvement 2017; RCP 2020). In-patient falls have consistently been the biggest single category of reported incidents since the 1940's (Morgan et al., 1985). Little has changed in the 39 years since the Morgan et al.(1985) paper and with falls accounting for 85% of all hospital acquired conditions in the USA (Attenello et al., 2015) it is safe to say this is a global issue. A recent Australian study estimated that the annual cost of attempts to prevent in-hospital falls across six health services consumed AU$590 million per year in resources. The areas of greatest investment were 18% physiotherapy, 14% 24 hour observation, 12% falls assessments and 11% falls prevention alarms (Mitchell et al., 2018) and there is a lack of quality research to support their efficacy as falls prevention strategies (National Institute for Health and Care Excellence, 2019).

The generalisable level of success of these strategies is still not known (Montero-Odasso et al., 2022). It seems that health services across the world are investing time and effort in strategies for which there is an absence of evidence (Mitchell et al., 2018). The recently published World Guidelines for Falls Prevention (Montero-Odasso et al 2022) has confirmed there remains no research supporting the use of technology such as falls alarms or nonslip socks (NSS) in hospitals and as such recommends only standard falls prevention methods. As a result of increasing reimbursement costs for hospital treatments, in 2008 the Centres for Medicaid & Medicare Services, health insurance companies in the United States of America (US), removed reimbursement to hospitals for costs incurred by patient falls and any associated trauma (Shorr et al., 2018) resulting in increasing financial burden to hospitals. The impact on staff suffering 'second victim phenomena' (Kappes et al., 2021) as a result of adverse incidents and the cost to patients who suffer pain, disability, and death is incalculable (Potter et al., 2016).

STUDY OBJECTIVES AND PURPOSE

PURPOSE

- To establish the barriers to preventing accidental falls in hospital and understand what interventions are perceived to work best to prevent falls.

PRIMARY OBJECTIVE

- To disprove the null hypothesis that “there is no universal clinical experience of accidental fall prevention in hospitals with patients who have impaired cognitive function”.

SECONDARY OBJECTIVES

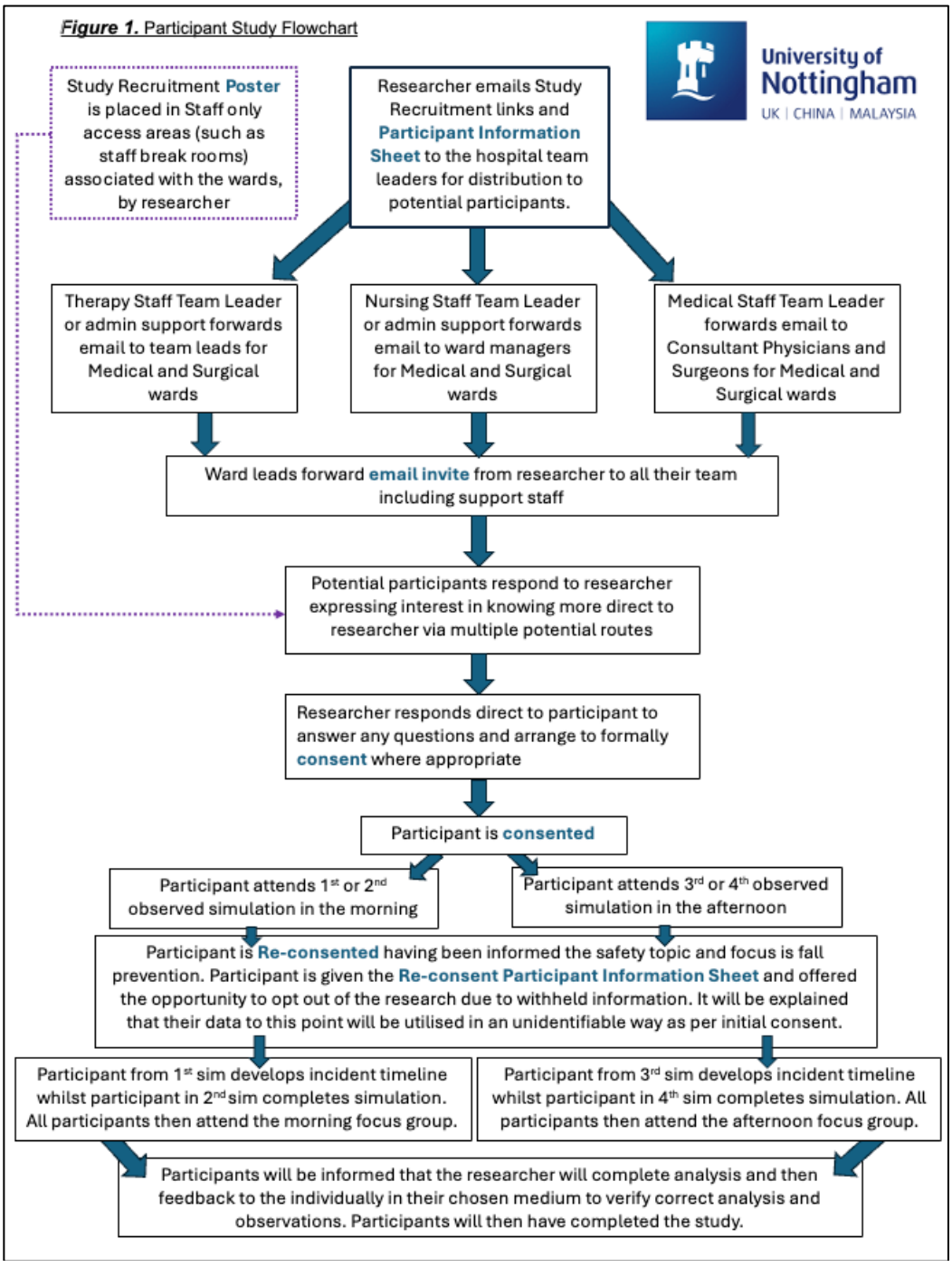
- To inductively generate a questionnaire to be distributed to healthcare professionals and care workers in a future study.
- To gather an evidence base for the co-created design and testing of fall prevention interventions as part of the longer term PhD project

The investigator has completed the HRA tools which have confirmed the study is classed as research and that it does not require NHS REC review. The investigator has also successfully undertaken the Good Clinical Practice training to provide public assurance that the rights, safety and wellbeing of research participants are protected and that research data are reliable.

STUDY DESIGN

STUDY CONFIGURATION

This is a multi-centre qualitative study utilising a purposive sampling strategy. Healthcare workers directly involved in preventing falls in hospital will be invited to contribute to the study via an email from their ward manager or clinical lead. Participants will be asked to respond directly to the researcher to indicate their interest in the study. They will be selected to ensure Medical and Surgical wards are represented to ensure generalisability of outcomes. Overall aim will be for up to 16 participants from the nursing team, registered and unregistered, up to 8 therapist participants and up to 8 doctors (*Figure 1*- Participant Study Flowchart).



This will provide up to 2 nurses, 1 therapist and 1 doctor in each simulation. This will provide 4 datasets for analysis at each hospital and this process will be repeated at up to 4 hospitals to deliver up to 16 datasets. Each group will participate in a 30 minute simulation which will simulate a patient having an accidental fall and will be recorded. Observation with notes by the investigator will inform discussion in the focus group to follow. The participant will be reconsented after the simulation as they will now be made aware that the focus is specifically on patient falls rather than all aspects of patient safety. If participants wish to withdraw they will be informed that, as per the initial consent form, their data to this point will be retained and used anonymously. In preparation for the focus group Critical Decision Method will be used to extract themes and codes to inductively generate a questionnaire for a future study. If the participant agrees to continue they will then join a larger group for the discussion around the simulation. This will be recorded for the investigators use only and the subsequent analysis will be fed back to the participants prior to publication and any further study to verify an accurate summary of the discussion. Patient and Public Involvement (PPI) representatives will be consulted on the evolving themes for their insights.

Participant numbers:-

Hospital Site	**Site 1**		**Site 2**		**Site 3**		**Site 4**		**Totals**
Morning	**Day 1**	**Day 2**	**Day 1**	**Day 2**	**Day 1**	**Day 2**	**Day 1**	**Day 2**	
1st Simulation 08.30-9.00	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	Up to 32 participants
2nd Simulation 9.30-10.00	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	Up to 32 participants
Focus Group 10.00-12.00	8 Participants from the 2 morning Simulations discuss the simulation together								Up to 8 datasets
Afternoon									
3rd Simulation 13.30-14.00	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	Up to 32 participants
4th Simulation 14.30-15.00	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	1 x Doctor 1 x Therapist 2 x Nursing Team	Up to 32 participants
Focus Group 15.00-17.00	8 Participants from the 2 afternoon Simulations discuss the simulation together								Up to 8 datasets
									Up to 128 Participants in Total
									Up to 16 datasets

Figure 2

STUDY MANAGEMENT

The investigator will lead a study management group consisting of the Chief investigator and 2 coinvestigators. The Principle investigator or delegated local collaborator from each Trust involved will be invited to join the group for updates and any concerns. The group will meet monthly to discuss progress and amendments as required.

The Chief Investigator has overall responsibility for the study and shall oversee all study management.

The data custodian will be the Chief Investigator.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration:
Enrolment to the study will begin as soon as enquiries are received from the invitations and will be completed within 6 months when up to 32 simulations and up to 16 focus groups have been analysed and collectively themed. Analysis of data will be presented back to participants to verify interpretation. The extended timeline is to account for the winter period where operational pressures in hospital may cause delays to rostering participants.

Participant Duration:
Active Involvement: Each participant will be required for a Maximum of 4 hours.

Consent:	20 mins	All on same day on an agreed date at time of consent
Simulation:	30 mins	
Reconsent:	5 min	
Focus Group:	60-90 mins	
Follow up:	30 minutes	Separate day within 2 months of Sim and focus group

End of the Study

The end of the study will be the last feedback session of the last participant.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

Participants will be recruited from medical and surgical wards at up to 4 acute Trusts (*Figure 2*). Medical and surgical wards will be selected as they have regular exposure to patients who are 65 and over and patients with specific underlying conditions between the age of 50 and 65 who are considered at high risk of falls (National Institute for Health and Care Excellence, 2019). The initial approach will be from a member of the staff's management team who will include the participant information sheet. Information will also be on display in the relevant staff only clinical areas (ie staff rest and study areas). The participants will self-select by contacting the investigator via email, whats app, QR code or phone. The QR code leads to a quick microsoft form which gives the potential participant chance to check they meet the inclusion criteria and give the Investigator their contact email address or phone number. This form is sent to the Investigator's Microsoft forms 365 account and it automatically emails me to let me know there is a response waiting for me.

The investigator will inform the participant of all aspects pertaining to participation in the study.

As the participants are all healthcare professionals or associated roles, working in the NHS there is, a requirement for them to be fluent in English both written and oral. It is reasonable, therefore, to assume they can communicate in English and therefore interpreters will not be required.

It will be explained to the potential participant that entry into the study is entirely voluntary and that their employment rights will not be affected by their decision. It will also be explained that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

Eligibility criteria

Inclusion criteria

Potential participants need to meet at least one of the inclusion criteria below:

- Any healthcare professional or associated support staff involved in the fall risk assessment of patients on admission to a standard care ward environment in hospital
- Any healthcare professional or associated support staff involved in the multifactorial assessment of patients in an acute ward environment
- Any healthcare professional or associated support staff involved in putting fall prevention measures in place in an acute ward environment
- Any healthcare professional or associated support staff involved in caring for patients and their relatives after an accidental fall in an acute ward environment
- Ability to give informed consent

Exclusion criteria

- Any healthcare worker with no medical or surgical ward experience
- Any healthcare worker under the age of 18 years old
- Any healthcare worker working exclusively in Critical Care or high dependency units or Paediatrics as countermeasures and levels of observation are different in these areas and have separate guidance and policies.

Expected duration of participant participation

Study participants will be participating in the study for a total of 4 hours over a period of 3 months.

Participant Withdrawal

Participants will withdraw from the study:-

- if consent is withdrawn
- if they become unwell
- If it is not safe for them to continue due to safety reasons outlined in the simulation risk assessment

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their employment rights. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

Informed consent

All participants will provide written informed consent. The Informed Consent Form will be signed and dated by the participant before they enter the trial. The Investigator will explain the details of the trial and provide an opportunity to go over any questions from the Participant Information Sheet that they received with the invite, ensuring that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation.

Informed consent will be collected from each participant before they participate in any part of the study. One copy of this will be kept by the participant, one will be kept by the Investigator.

Following the simulation the participants will be informed that the exact nature of the research enquiry is fall prevention in hospitals. The researcher is deliberately using the term ‘patient safety’ rather than falls prevention prior to the simulation as it is preferred that the staff are not aware of the research detail until after they participate in the simulation. Whilst it is recognised by cognitive load theory that individuals will be able to perform better with forewarning of scenarios (Cox et al., 2017) and therefore learn more easily, the intention of this simulated

scenario is to understand behaviour in the workplace. In the workplace the nurse will not always know what is going to happen next so withholding this information is a closer replication of the workplace environment and may offer a better opportunity to experience workarounds and habits as the nurse reverts to 'work as done' rather than work as 'imagined' (Hollnagel Erik, 2012). This is not totally misleading the participants as fall prevention is part of patient safety which is used as an umbrella term and is a common situation they find themselves in at work.

The investigator considered other research methods such as observational studies but a patient fall is an infrequent occurrence so having an opportunity to observe one in practice would be difficult. As the investigator is also a registered nurse they would be obliged to prevent a patient falling rather than observe it. It would also not offer a shared experience where critical decision method can be used to extract key decision points. Simulation offers a safe and comfortable alternative where staff can reflect on their actions and discuss with peers, drawing from and sharing their real life experiences keeping them safe from judgement, emotional distress, personal responsibility and blame.

All participants will be reconsented privately before the focus group but after the simulation to disclose the deliberate use of the words patient safety versus fall prevention and to allow them to withdraw from the study should they wish to do so. The participants will then be given a reconsent information sheet, offered the opportunity to withdraw and where happy to continue to the focus group the participant will be asked to sign a reconsent form with the exact nature of the research clarified. If participants wish to withdraw they will be informed that, as per the initial consent form, their data to this point will be retained and used anonymously. As the participant will be working as part of a team in the simulation it would not be possible to remove the discussions and actions from the recording and subsequent notes. The investigator will reassure them that because they will have only used their pseudonym in the simulation they will not be identifiable. The simulation is to stimulate discussion of a shared experience in the focus group and not any one persons actions or contributions, as such the main body of work will be derived from the focus group not the simulation.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the trial, continuing consent will be obtained using an amended Consent form which will be signed by the participant.

STUDY REGIMEN

1. Email invite with participant information sheet will be sent by senior team member. Posters will be displayed in clinical areas. Investigator will also attend any team meetings, where invited, to discuss the nature of the study.
2. Participant will indicate interest by contacting the investigator via email, WhatsApp, phone or QR code. The QR code leads to a quick microsoft form which gives the potential participant chance to check they meet the inclusion criteria and give the their Investigator contact email address or phone number. This form is sent to the Investigator's student Microsoft forms 365 account and it automatically emails me to let me know there is a response waiting for me.
3. Investigator will contact the prospective participant and answer any questions
4. Participant will meet the investigator in a convenient and safe location to give consent.
5. Participant will be allocated a unique study identity code number and pseudonym which will be recorded in the Trial Recruitment Log (TRL) alongside their demographic and

contact details. The TRL will be kept securely in a password protected file on UoN one drive.

6. Potential participants who choose not to go into the study will only be on the TRL as their unique identifier and their reason for not participating if they give one but they will not be asked. All personal identifying details will be deleted immediately. The investigator will not attempt to contact them again.
7. Participants who are happy to continue into the study will choose 1 of 2 dates possible for the simulation and focus group.
8. Details of location and agenda for the simulation and focus group will be sent to the participant.
9. All participants will be contacted by phone or email via their preferred form of communication identified when recruited at step 5 to remind them the day before the simulation and focus group.
10. Participants will arrive at the simulation lab and will be given a pseudonym, name badge and role card (the pseudonym is to use during the simulation and recording to protect their identity to other participants and on the recording). The pseudonym will also be recorded alongside their unique identifying number and demographics on the TRL. The TRL will be kept securely in a password protected file on UoN one drive in accordance with the data management plan (DMP).
11. The investigator will observe with notes during the simulation (30 mins). This will be recorded.
12. On completion of the simulation the investigator will re-consent the participant as they will now realise that the patient safety theme was fall prevention. (5 mins)
13. On completion of the re-consent process a guided critical decision method session will detail the timeline of events and key decisions (30 mins). This will be recorded on University of Nottingham property Dictaphones and the data securely saved as per the DMP.
14. On completion of the timeline, the semi structured focus group will begin, facilitated by the investigator. This will be recorded on University of Nottingham property Dictaphones and the data securely saved as per the DMP.
15. The investigator will close the discussion group and explain that the participant will be contacted again in order to share the analysis and themes to verify an accurate understanding of discussion. Participant will be given the option to opt out of this stage.
16. Investigator will transcribe and analyse themes evolving from the session using Nvivo14.
17. Investigator will share themed analysis for comment. Method to suit participant such as Teams meeting, email, face to face or phone call.
18. Investigator will bring together themes from all simulations and focus groups and synthesise any generalised views ensuring anonymity.

Compliance

Non-attendance of any staff member will be followed up with a phone call to number acquired during the consent process (their preferred form of communication). Participants will be offered the opportunity of an alternative date where available.

There is some contingency built into each simulation and focus group to allow for 2 participants not to turn up to their simulation. The focus group will be made up from 2 simulation groups and therefore should be a group of up to 8 for the discussion. Group numbers below 4 or with any profession not represented will not be considered quorate. In this event the investigator will attempt to organise an additional session for consented people who were unable to attend.

Criteria for terminating the study

In the unlikely event that the study is to be terminated on one or all sites the research data will be archived.

ANALYSES

Methods

The participant will be invited to play their usual professional role in a 30 minute scenario depicted by simulation and will be run 8 times over 2 separate days in each Trust using an actor. Using the safety of 'a simulation of a fall in an acute setting' rather than observations in practice the investigator will observe the participants behaviour and actions during the simulation of a patient having an accidental fall. Abdulmohdi and McVicar (2023) found there was a significant increase in deduction and analysis when using simulation compared to observations in practice. An additional advantage of a simulation is that the participants can be more confident in their discussion without the need to defend team culture compared to being observed in clinical practice. It is also easier to create the patient fall safely thereby maintaining the least powerful position for the investigator, as feedback in a hypothetical situation has not resulted in patient harm or reflected on their practice so the feeling of being judged is avoided (Humphries, 2003). There is also no compelling professionalism to require the investigator to prevent a participant causing harm to a patient or to draw attention to an omission heightening the potential power dynamic between researcher and participants (Humphries, 2003). The simulation will be held on the Trust premises to ensure ease of access for participants and minimise time away from clinical practice.

Following completion of the simulated scenario a 90 minute debrief focus group will reflect on the impact of the simulation and hear from the participants how this relates to their experience in practice. Michie et al. (2011) recommends a three-step process to investigate behaviour and this will be used as a framework for the focus group discussion alongside Critical Decision Making (CDM) (Weitzenfeld J.S, 1990). The investigator will use a semi structured design.

The focus group will be recorded, transcribed and analysed using Nvivo 14 (a software application to assist with coding) assigning meanings through essence capturing (Saldaña, 2021) by creating codes. These codes will be generated for the purpose of pattern detection to interpret data and deduct meaning (Vogt et al., 2012). This can be interpreted as imposing values or as reductionist but using constructivist principles will allow valuing multiple perspectives and will establish a deeper understanding of staff experience (Creswell, 2018). It is difficult to completely remove the investigator's values when analysis is done, but by sharing the analysis with the participants and the research team there is transparency and reflexivity, recognising the 'importance of self' (Humphries, 2003). The analyses will be discussed with the participants so any disagreement will also be recorded for the reader to consider. The primary intent of the qualitative phase is to design a measure that is grounded in issues raised by patient facing staff and PPI representatives rather than individual opinion or experience.

Sample size and justification

The investigator is seeking to involve a small number of relevant direct patient facing healthcare workers to provide in depth information about the lived experience of preventing and managing in-patient falls. By purposefully involving participants who are charged with preventing in-patient falls as part of their usual practice the investigator will be able to collect in depth knowledge of the experience and associated heuristics. 8 simulations and focus groups in 4 different hospitals on different geographical sites are planned generating 16 datasets. The investigator will continue until repeated themes suggests there is a degree of homogeneity in experiences or not (Creswell, 2018). This is with the intention of adopting a phenomenological approach but depending on the data arising sampling could continue to allow grounded theory to inform the questionnaire (Creswell, 2023). The final sample size will

not be determined until a sufficient database has been collected to develop the content of the questionnaire for a future study.

ADVERSE EVENTS

The occurrence of an adverse event as a result of participation within this study is not expected and no adverse event data will be collected.

ETHICAL AND REGULATORY ASPECTS

The incident portrayed in the simulation can evoke strong emotions either from previous professional or personal experience. Should a participant become distressed the investigator will initiate the distress protocol.

It is not anticipated that the confidentiality of participants will be breached however it is likely that participants may know each other and/or are working with or have worked with each other previously. Whilst a confidentiality agreement will be discussed with each participant and a request not to share any information outside the simulation lab and focus group room there is a chance that this will happen. In this instance the participants will be asked to report this to the investigator who will approach the relevant senior team in the hospital. Depending on the nature of the issue and the available evidence the senior management team will take appropriate action. An apology will be offered where appropriate to the affected participant.

ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) or other healthcare provider's Research & Development (R&D) department, and the Health Research Authority (HRA) if required. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice and the UK Department of Health Policy Framework for Health and Social Care, 2017.

INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator and the participant shall both sign and date the Consent Form before the person can participate in the study.

The participant will receive a copy of the signed and dated forms and the original will be retained in the Study records.

The decision regarding participation in the study is entirely voluntary. The investigator shall emphasise to them that consent regarding study participation may be withdrawn at any time without penalty or affecting their employment rights, or loss of benefits to which the participant is otherwise entitled. No study-specific interventions will be done before informed consent has been obtained.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Consent Form by the REC and use of the amended form (including for ongoing participants).

RECORDS

Case Report Forms

Each participant will be assigned a study identity code number, for use on Case Report Forms (CRF), other study documents and the electronic database. All documents and database will only use this number with the exception of the recorded consent database, where all details will be held. This document will be password protected and only accessed by the investigator.

Only the Investigator will be authorised to make entries in the CRF but the Chief investigator and co investigators can view the files if required for the purpose of guidance and supervision. All viewings and rationale for doing so will be recorded and countersigned by the investigator.

The CRF will be held on UoN One Drive and will be backed up every 24 hours to both local and remote media in encrypted format.

CRFs will be treated as confidential documents and held securely in accordance with regulations. The investigator will make a separate confidential record of the participant's name, rpseudonym and Participant Study Number, to permit identification of all participants enrolled in the study, in case additional follow-up is required. This will be held within the TRL. CRFs shall be restricted to those personnel approved by the Chief or local Investigator and recorded as such in the study records.

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated.
The Chief or local Investigator shall sign a declaration ensuring accuracy of data recorded in the CRF.

Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, study records, field notes, interview transcriptions and audio records. A CRF may also completely serve as its own source data. Only the chief and local investigator and shall have access to study documentation other than the regulatory requirements listed below.

Direct access to source data / documents

The CRF and all source documents shall be always made available for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities.

DATA PROTECTION

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 2018. The CRF will only collect the minimum required information for the purposes of the study. CRFs will be held securely in a password protected file on UoN one drive. Access to the information will be limited to the study staff and investigators and any relevant regulatory authorities (see above). Computer held data including the study database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method).

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

QUALITY ASSURANCE & AUDIT

INSURANCE AND INDEMNITY

Insurance and indemnity for clinical study participants and study staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff with both public liability insurance and clinical trials insurance in respect of claims made by research subjects.

STUDY CONDUCT

Study conduct may be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, timeliness of visits); accountability of study materials and equipment calibration logs.

The Study Coordinator/Academic Supervisor, or where required, a nominated designee of the Sponsor, shall carry out a site systems audit at least yearly and an audit report shall be made.

STUDY DATA

Monitoring of study data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The Study Coordinator/Academic Supervisor,, or where required, a nominated designee of the Sponsor, shall carry out monitoring of study data as an ongoing activity.

Entries on CRFs will be verified by inspection against the source data. A sample of CRFs (10% or as per the study risk assessment) will be checked on a regular basis for verification of all entries made. In addition the subsequent capture of the data on the study database will be checked. Where corrections are required these will carry a full audit trail and justification.

Study data and evidence of monitoring and systems audits will be made available for inspection by the REC as required.

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Code of Research Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The study documents held by the Chief Investigator (CI) on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all anonymised audio recordings, study databases and associated meta-data encryption codes.

DISCONTINUATION OF THE STUDY BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

STATEMENT OF CONFIDENTIALITY

Individual participant medical or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

Such medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

PUBLICATION AND DISSEMINATION POLICY

The study outcomes will primarily be used to design a questionnaire for a further study. This further study will be based on the outputs of this study. When both studies have been integrated and analysed the whole study will be published. This MMR study will be reported following the Good Reporting of a Mixed Methods Study guidelines (O'Cathain et al., 2008), aiming to achieve the research excellence framework criteria by November 2025. Whilst this is an extended target date it includes anticipated delays due to NHS winter pressures and publication delays, every effort will be made to achieve this ahead of this schedule. No participants or their hospitals will be identified in any publication.

Sharing of the outcomes prior to publication will be provided via infographics for research participants to consolidate good practice and lessons learned. The investigator will also share outcomes at any departmental meetings if invited to do so.

This study is part of a PhD and may be included in the published thesis and any other academic journal publications. All publications will also be shared with the participants and host institutions.

USER AND PUBLIC INVOLVEMENT

The National Rehabilitation Centre PPI group and the PPI group from the Centre for Dementia, Frail Older People and Palliative Care were consulted on all elements of the study design. They have contributed and advised accordingly and continue to do so until the end of the study with consultations every 2 months. Study progress is presented to them and any issues considered and amendments made accordingly.

STUDY FINANCES

Funding source

This study is funded by a scholarship awarded by the Engineering and Physical Sciences Research Council (EPSRC).

Participant stipends and payments

Participants will not be paid to participate in the study. There will be no additional expenses incurred by the participants.

Hot and cold drinks, fruit, pastries, biscuits and cakes will be available during the focus groups to ensure the participants enjoy their break from routine work activity and get a chance to think together with colleagues.

SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name)_____

Signature:_____

Date: _____

REFERENCES

ABDULMOHDI, N. & MCVICAR, A. 2023. Investigating the clinical decision-making of nursing students using high-fidelity simulation, observation and think aloud: A mixed methods research study. *Journal of advanced nursing,* 79**,** 811-824.

COX, J., MCGREGOR, M., GIULIANO, D. & HOWARD, L. 2017. Impact of providing case-specific knowledge in simulation: a theory based study of learning. *BMJ simulation & technology enhanced learning,* 3**,** 1-4.

CRESWELL, J. W. 2018. *Designing and conducting mixed methods research / John W. Creswell, Vicki L. Plano Clark*, Los Angeles : SAGE.

CRESWELL, J. W. 2023. *Research design : qualitative, quantitative, and mixed methods approaches / John W. Creswell, J. David Creswell*, Thousand Oaks, California : SAGE Publications, Inc.

EVANS, J. G. 1990. Fallers, Non-fallers and poisson. *Age and Ageing,* 19**,** 268-269.

HOLLNAGEL ERIK 2012. *FRAM: The Functional Resonance Analysis Method: Modelling Complex Socio-technical Systems,* ALDERSHOT, ALDERSHOT: Routledge.

HUMPHRIES, B. 2003. Arguments for an 'emancipatory' research paradigm. *In:* TRUMAN, C., MERTENS, D. M. & HUMPHRIES, B. (eds.) *Research and inequality / edited by Carole Truman, Donna M. Mertens and Beth Humphries.* London: London : Routledge.

KAPPES, M., ROMERO-GARCIA, M. & DELGADO-HITO, P. 2021. Coping strategies in health care providers as second victims: A systematic review. *International nursing review,* 68**,** 471-481.

LORD, S. R. 2007. *Falls in older people : risk factors and strategies for prevention / Stephen R. Lord ... [et al.],* Cambridge New York : Cambridge University Press.

MICHIE, S., VAN STRALEN, M. M. & WEST, R. 2011. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implementation science : IS,* 6**,** 42-42.

MITCHELL, D., RAYMOND, M., JELLETT, J., WEBB-ST MART, M., BOYD, L., BOTTI, M., STEEN, K., HUTCHINSON, A., REDLEY, B. & HAINES, T. 2018. Where are falls prevention resources allocated by hospitals and what do they cost? A cross sectional survey using semi-structured interviews of key informants at six Australian health services. *International journal of nursing studies,* 86**,** 52-59.

MONTERO-ODASSO, M., TAN, M. P., RYG, J., BLAIN, H., BOURKE, R., CAMERON, I. D., CAMICIOLI, R., CLEMSON, L., CLOSE, J., DELBAERE, K., DUAN, L., HAUSDORFF, J. M., HUNTER, S. M. W., JAUREGUI, J. R., KENNY, R. A., LAMB, S. E., LIPSITZ, L. A., LIU-AMBROSE, T., LORD, S. R., MARSH, D., MILISEN, K., MOCTEZUMA-GALLEGOS, R., MORRIS, M. E., PERRACINI, M. R., PIERUCCINI-FARIA, F., PIGHILLS, A., SAID, C., SEJDIC, E., TROEN, B. R., VERGHESE, J., VLAEYEN, E., KAUR AJIT SINGH, D., AGUILAR-NAVARRO, S. G., BARBOSA SANTOS, R., BECKER, C., BEAUCHAMP, M., BIRIMOGLU, C., BLAIN, H., BOHLKE, K., ALONZO BOUZÒN, C., GABRIEL BUENDIA, P., CAMICIOLI, R., CANNING, C., ALBERTO CANO-GUTIERREZ, C., CARLOS CARBAJAL, J., CRISTINA CARVALHO DE

ABREU, D., CERIANI, A., CHIARI, L., MANUEL CORNEJO ALEMN, L., DSOUZA, S., DYER, S., FAIRHALL, N., FREIBERGER, E., FRITH, J., GANZ, D. A., GIBER, F., FERNANDO GÓMEZ, J., MIGUEL GUTIRREZ-ROBLEDO, L., HOWE, S., JELLEMA, A., JENNI, S., KAUR AJIT SINGH, D., ANNE KENNY, R., KERSE, N., KOBUSINGYE, O., KRESSIG, R., LOGAN, P., ALVES LOURENÇO, R., MADDEN, K., MALLET, L., MARÍN-LARRAÍN, P., MARTÍNEZ PADILLA, D., MAT, S., MENANT, J., MILISEN, K., MIMENZA, A., MONTERO-ODASSO, M., MUNEEB, I., NIEUWBOER, A., NORRIS, M., OGLIARI, G., OLIVEIRA, J., PARODI, J. F., PEREZ, S., PETROVIC, M., ERNESTO PICADO OVARES, J., PIERUCCINI-FARIA, F., PIGHILLS, A., POELGEEST, E., RAMIREZ ULATE, X., ROBINSON, K., SAID, C., SCHAPIRA, M., SEPPALA, L. J., SONG, Y., SPEECHLEY, M., TODD, C., TROEN, B., VAN DER CAMMEN, T. & VERGHESE, J. 2022. World guidelines for falls prevention and management for older adults: a global initiative. *Age and ageing,* 51.

MORRIS, R. & O'RIORDAN, S. 2017. Prevention of falls in hospital. *Clinical medicine (London, England),* 17**,** 360-362.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE 2019. Falls in older people: assessing risk and prevention.

O'CATHAIN, A., MURPHY, E. & NICHOLL, J. 2008. The quality of mixed methods studies in health services research. *Journal of Health Services Research & Policy,* 13**,** 92-98.

POTTER, P., ALLEN, K., COSTANTINOU, E., KLINKENBERG, D., MALEN, J., NORRIS, T., O'CONNOR, E., RONEY, W. & TYMKEW, H. H. 2016. Anatomy of Inpatient Falls: Examining Fall Events Captured by Depth-Sensor Technology. *Joint Commission journal on quality and patient safety,* 42**,** 225-31.

SALDAÑA, J. 2021. *The coding manual for qualitative researchers / Johnny Saldaña*, London, UK SAGE Publications.

SHORR, R. I., STAGGS, V., WATERS, T. M., DANIELS, M. J., LIU, M., DUNTON, N. & MION, L. C. 2018. The effect of centers for medicare & medicaid services nonpayment on falls and physical restraint use in us hospitals. *Journal of the American Geriatrics Society,* 66**,** S134-S135.

VOGT, W. P., GARDNER, D. C. & HAEFFELE, L. M. 2012. *When to Use What Research Design,* New York, New York: Guilford Publications.

WEITZENFELD J.S, F. J. T., RIEDL T.R AND KLEIN G.A,. The critical decision method (CDM): A knowledge-mapping technique. AT&T: Behavioural Science days 1990, 1990 Lodon. AT&T.