Effectiveness of an Ambient Intelligent Geriatric Management system (AmbIGeM) to prevent falls in older people in hospitals: protocol for the AmbIGeM stepped wedge pragmatic trial

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ABSTRACT
Background Although current best practice recommendations contribute to falls prevention in hospital, falls and injury rates remain high. There is a need to explore new interventions to reduce falls rates, especially in geriatric and general medical wards where older patients and those with cognitive impairment are managed.

Design and methods A three-cluster stepped wedge pragmatic trial, with an embedded qualitative process, of the Ambient Intelligent Geriatric Management (AmbIGeM) system (wearable sensor device to alert staff of the Ambient Intelligent Geriatric Management) system (wearable sensor device to alert staff of patients undertaking at-risk activities), for preventing falls in older patients compared with standard care. The trial will occur on three acute/subacute wards in two hospitals in Adelaide and Perth, Australia.

Participants Patients aged ≥65 years admitted to study wards. A waiver (Perth) and opt-out of consent (Adelaide) was obtained for this study. Patients requiring palliative care will be excluded.

Outcomes The primary outcome is falls rate; secondary outcome measures are: (1) proportion of participants falling; (2) rate of injurious inpatient falls/1000 participant bed-days; (3) acceptability and safety of the interventions from patients and clinical staff perspectives; and (4) hospital costs, mortality and use of residential care to 3 months postdischarge.

Discussion This study investigates a novel technological approach to preventing falls in hospitalised older people. We hypothesise that the AmbIGeM intervention will reduce falls and injury rates, with an economic benefit attributable to the intervention. If successful, the AmbIGeM system will be a useful addition to falls prevention in the hospital setting reported limited evidence that single interventions to prevent falls in hospital are effective.10 This review also included four hospital studies investigating multicomponent interventions and concluded that there was a reduction in falls rate predominantly from just two studies—one involving a subacute ward with the effect more obvious after 45 days, and the other an orthopaedic service where comprehensive geriatric assessment was the intervention.10–12 More recently, a patient education programme (visual and written) in Australian acute and subacute hospital units, supported with additional clinician time focusing on individualised information regarding falls risk management (median additional time 30 min), reduced the falls rate only in cognitively intact individuals.13 However, for patients with cognitive impairment, this intervention increased the rate of injurious falls. Another Australian trial of patient education (for cognitively intact patients) and staff fractures and about 450 other fractures. Falls in hospitals have been reported to result in approximately doubling of hospitalisation costs compared with costs for non-fallers.1,3 In addition to the physical injuries reported, the psychological consequences of falls to the individual include anxiety, depression, loss of confidence and fear of falling and ultimately a downward spiral of decline in health.4,5

Falls are most common in the oldest patients (ie, age >80 years).1 Older people with cognitive impairment are particularly at risk of falling in acute care settings.1 A 2013 audit of in-hospital fallers within the Division of Medicine at The Queen Elizabeth Hospital (TQE) in Adelaide, South Australia, found that 68% of falls occurred in those aged >75 years and almost half had cognitive impairment.6 The audit confirmed that high falls rates were most common in wards where large numbers of older patients and patients with dementia were managed, that is, in geriatric evaluation and management units (GEMUs) and general medicine wards. In hospitals, falls commonly occur around the patients’ beds, in the corridor, bathroom or the toilet.7,8 Many falls occur at night when nurse staffing levels are lowest and patient confusion is common.9 Furthermore, many falls are not witnessed.7

The most recent Cochrane review of falls prevention in the hospital setting reported limited evidence that single interventions to prevent falls in hospital are effective.10 This review also included four hospital studies investigating multicomponent interventions and concluded that there was a reduction in falls rate predominantly from just two studies—one involving a subacute ward with the effect more obvious after 45 days, and the other an orthopaedic service where comprehensive geriatric assessment was the intervention.10–12 More recently, a patient education programme (visual and written) in Australian acute and subacute hospital units, supported with additional clinician time focusing on individualised information regarding falls risk management (median additional time 30 min), reduced the falls rate only in cognitively intact individuals.13 However, for patients with cognitive impairment, this intervention increased the rate of injurious falls. Another Australian trial of patient education (for cognitively intact patients) and staff

INTRODUCTION
Background and rationale Falls in hospitals are common and costly.1 A UK report examining 200,000 incident reports over 12 months found that inpatient falls were the most common type of safety incident (40%).1,2 being directly responsible for 26 patient deaths, 530 hip

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education in rehabilitation hospitals reduced falls for cognitively intact patients and demonstrated a strong trend towards reduced falls in the cognitively impaired patient group.14

Even with current best practice, falls rates in hospitals remain unacceptably high,13 especially in wards where there are a large number of older people including those with cognitive impairment. Technology may be one avenue to augment best practice falls prevention. An American study investigating a multi-component intervention in acute wards demonstrated the falls prevention toolkit (FPTK) reduced falls rate, with the intervention units reporting a falls rate of 3.15/1000 occupied bed days (OBDs) compared with the control units rate of 4.18/1000 OBDs (p=0.04).16 The FPTK software included the Morse Falls Scale for risk assessment, management plan for medication review, use of bed/chair alarms and assistance in at-risk circumstances, with generation of a bedside poster for each patient. Commercially available pressure sensor alarms for use on floor, beds or chairs are used by hospitals and aged care facilities despite the lack of trial evidence for effectiveness.17 19 An individual patient randomised controlled trial (RCT) in the UK (n=1839 older patients) investigated the use of pressure sensor alarm mats and found no significant difference in falls rate between the two study groups.20 Another cluster RCT in the USA aimed at increasing the use of pressure bed alarm systems also found that although use was increased with education, training and technical support, falls rate did not reduce, and the study was thought to be possibly underpowered.17 Both studies identified high ‘false alarms’ as a major reason for negative results. Two papers have reported significantly different false alarm rates with one suggesting that observed false alarm rates were >99%19 and another recording a false alarm report rate of 16% with pressure sensors (may have been impacted by under-reporting).20 A recent review also recommended that alarm systems should monitor for multiple risk activities in multiple locations and suggests that wearable sensors may be better able to meet this need.21 The effectiveness, usability and acceptability of technology interventions require further investigation before routine implementation into clinical practice will be possible.21 The limited success of previous falls prevention studies in hospital, in particular those using sensor-related systems, indicates a need for innovative changes to the methods of technology that may improve acceptability, reduce false alarm rates and reduce falls. A novel intervention is required that does not rely on the patient using the call bell, does not rely on the nurse being present and is able to monitor multiple risk activities automatically and immediately alerts staff that supervision is required. The intervention described in this paper aims to address these needs and overcome the limitations of existing approaches.

Furthermore, few falls prevention studies in hospitals have investigated cost-effectiveness. There is a need to identify cost-effective intervention strategies for acutely admitted medical patients with short lengths of stay, including suitable and effective strategies for those with cognitive impairment such as dementia or delirium.22

The purpose of this paper is to describe the methodology of the AmbiGeM pragmatic stepped wedge cluster trial. The primary objective of this study is to determine if the AmbiGeM system reduces falls rate in older people in hospital. The secondary objectives are to (1) determine if the AmbiGeM system reduces the proportion of fallers and injurious falls rate in older people in hospital, (2) to determine the acceptability and safety of the intervention with patients and clinical staff and (3) to determine if the intervention is cost-effective.

**METHODS**

**Design, blinding and study setting**

The trial incorporates a concurrent mixed methods design combining a pragmatic stepped wedge cluster trial with a qualitative process to gather information from patients and clinical staff on the acceptability and safety of the study. Figure 1 provides a diagrammatic representation of the mixed methods design.

The AmbiGeM study will be delivered across three clusters (wards) in two hospitals in two states of Australia (South Australia (SA) and Western Australia (WA)). It will take 103 weeks to complete, with one ward crossing over from control

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**Figure 1** Ambience Intelligence Geriatric Management System (AmbiGeM) stepped wedge pragmatic controlled trial study process. (Every fifth participating patient for survey and every seventh for interview). A&S, acceptability and safety; GEM, geriatric evaluation and management; GM, general medicine; TQE, The Queen Elizabeth Hospital.

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to intervention every 25 weeks until all wards have experienced one or more time blocks exposed to the intervention (figure 2). A 3-week period after the first 25-week control block is included concomitantly across all three sites to test the technology prior to the commencement of the first intervention period in SA. To aid in the implementation of the technology required for the intervention, the order that the wards will cross over from control to intervention was predefined as the single SA GEMU ward at TQEH first, followed by the smaller WA GEMU ward, and finally the larger general medicine WA ward at the Sir Charles Gairdner Hospital (SCGH). It was logistically impractical to deploy the technology across all wards simultaneously, and so a patient-level RCT was not feasible. There will be no blinding to the intervention of staff or patients. These wards were chosen as they have primarily older patients and high falls rates in the clinical setting.8 The three study wards will have a mix of single-bed, double-bed and four-bed rooms with a total of 28 beds in SA and 46 beds in WA.

Ethics and recruitment

All patients aged 65 years and older admitted to the participating wards are eligible with the only exclusion criteria being those receiving palliative treatment.

The project has received ethics and governance approvals from the two participating hospitals (TQEH and SCGH) and received approvals from management of both hospitals for the conduct of the research. For the stepped wedge trial, the SCGH Human Research Ethics Committee (HREC) approved a waiver of consent for the SCGH and the HREC (TQEH/Lyell McEwin Hospital (LMH)/Modbury Hospital (MH)) then approved an opt-out consent for TQEH. As requested by the SCGH HREC and TQEH/LMH/MH HREC, the researchers developed posters for display in the wards and flyers to be placed on all patient bed side lockers for participants, family and or carers, to inform them and staff of the research activities and provide key contact details where they can seek further information. The poster and flyers also notify patients, family and or carers that they are free to choose not to participate (opt out or withdraw) by notifying the ward staff or the research team. When a TQEH patient opts out, an opt-out form is completed either by the patient, their person responsible or the research staff. Patients in both hospitals will be made aware that care will be provided as usual, with no negative consequences for declining to participate in or withdrawing from the project.

A subset of the patients recruited into the stepped wedge trial and clinical staff who have worked on the study wards during the intervention periods will be invited to participate in preintervention/postintervention acceptability and safety studies. All patients recruited for this aspect in WA will need to provide consent as third party consent is not approved in WA. In SA, for those patients unable to provide informed consent, a person responsible will be invited to complete the preintervention/postintervention surveys and interview.

Intervention

The AmbiGeM intervention includes a wearable Bluetooth low energy (BLE) device with integrated sensors worn by patients in a singlet. The wearable device (figure 3) is positioned in a pocket in the singlet over the sternum for the purpose of transmitting movement signals, where these signals are collected by base stations and interpreted by software that identifies risk circumstances and responds ‘intelligently’ (tailored response) to those activities of a patient leading to situations of increased falls risk.22,23 When a risk circumstance is identified by the system, clinical staff will be alerted via a hand-held mobile device that they will wear or carry. A selected combination of vibrations and/or an alarm sound from the mobile device will alert staff. The alert will describe the patient, location and risk movement. Staff may then intervene and provide supervision to the patient.

Figure 2 Stepped wedge trial design indicating the three clusters (each cluster represents one ward) and the four study periods or wedges (grey shaded area indicates the intervention phase and non-shaded area indicates the control phase). Note: Test=3 weeks prior to first ward commencing intervention, the technology will be tested. GEMU, geriatric evaluation and management unit; Gen Med, general medicine; SCGH, Sir Charles Gairdner Hospital (Western Australia); TQEH, The Queen Elizabeth Hospital (South Australia).

Figure 3 The Bluetooth low energy (BLE) device with integrated sensors to be evaluated in the study.
where required. The research team has taken care to customise this intervention with feedback from consumers and staff. In a previous pilot study, participants found a radio frequency ID-based sensor technology worn over clothing and on the sternum area, easy to wear and did not report any discomfort.

1. The wearable device and singlet
The wearable device (figure 3) used in the trial has a number of inertial sensors (eg, triaxial accelerometer) as well as sensors for measuring elevation above ground. It is low cost and uses a replaceable coin cell battery to power the device (typical operational life of the battery will be approximately 30 days). The wearable embodiment is achieved using a plastic encasing. The encasing will be comfortable for the patient to wear, will protect the device and will ensure the on board sensor orientation on the patient is deterministic. The encasing is black on one side and white on the other to allow nursing staff to easily determine the correct placement of the wearable device in a singlet pocket. A nurse will place the wearable device within an ‘envelope type’ pocket on the inner side of the sensor system vest (singlet), which the patient will wear under their hospital or own clothing, at the position of the sternum (figure 4). Singlets will be changed as needed. One wearable device will be used per patient and can be disposed of once a participant completes participation in the study. If a sensor is lost or misplaced during the study, it will be replaced.

A further device embodiment in an encasing will be attached to patient walking aids, for patients who are classified as not requiring supervision for transfers out of bed and chair but being risk takers who are unsafe in mobilising without their walking aid (see ‘The AmbIGeM System’ section below) during the admission.

Wearable devices will capture the participants’ physical orientation and movement information and wirelessly transmit these data. Different movements between the wearable device and the device attached to walking aids will allow detection that the walking aid is not being used by the patient.

2. The modified hospital room environments
To capture the data from wearable devices worn by patients and devices on walking aids, small form factor, BLE-enabled, single-board computer-based listening devices (base stations) are installed on ceiling locations above each bed and door exit. This will provide adequate coverage for various configurations of one, two and four bed rooms. Base stations will collect and preprocess data from wearable devices worn by patients and forward these data for analysis by the backend AmbIGeM software to identify risky movements. Each base station will communicate with backend AmbIGeM systems over a local area network.

3. The AmbIGeM system
Activity recognition algorithms in the backend systems will process and analyse the data from all the wearable devices forwarded from the base stations and in the context of the personalised information entered on the system by the staff (see below), determine whether an alarm should be triggered, in real-time. The backend AmbIGeM systems will alert clinical staff when an assessed patient is undertaking high falls risk activities (eg, walking into the bathroom by themselves when this activity has been set as requiring staff supervision), and it is hypothesised that the facilitation of timely staff supervision opportunity might potentially prevent a fall.

We have developed an electronic interface, capable of being run on a mobile hand-held device for clinical staff. The AmbIGeM mobile app will be executed on an Android smartphone carried by staff during the intervention phase of the trial. Using this app, nursing staff, at the beginning of every shift, will select the patients allocated to their care and determine the movement circumstances of individual patients where there is a risk of falling and the app will record this information onto the AmbIGeM system (figure 5), where the information collected will be used: (1) to generate and print an individualised falls risk poster for display by the bedside, which will also act as a visual aid for falls prevention; and (2) to activate an alarm when a movement pattern indicating the identified risk movement occurs. Other clinical staff on participating wards, such as physiotherapists, will also carry the mobile hand-held device and be alerted if a patient is undertaking falls risk-related movements.

The process employed to activate the alarm system is illustrated in figure 6. Alert notifications from the AmbIGeM server monitoring patient activities will be sent over the existing Wi-Fi network in the wards in which the trial is conducted and will be received by the mobile app executing on the mobile hand-held devices carried by staff. The staff carrying the mobile hand-held device running the app will then attend and assist the patient with the aim to mitigate the risk of falling through timely supervision. The alert notification received will include the following information: (1) the identity of the patient (who); (2) the physical location of the patient (where); (3) the type of high-risk activity (what); and (4) a timestamp of when the high-risk activity was detected (when). Risky movements that will be detectable and may be set to activate the alarm include:
- sitting up from lying on the bed
- standing up from bed or chair
- walking (can be limited to a specific area, ie, may be set up to allow walking in the room but not out of the room)
- walking without a required gait aid (ie, if a patient is identified as safe to walk with their frame but is considered not safe without their frame, starts walking without the frame the system can alarm, through the gait aid being tagged).

Figure 4  Sensor in singlet.

Central features include the user-centric nature of the intervention, its psychometric properties, feasibility of use and utility. The evaluation of the usefulness and feasibility of the AmbIGeM system-based approach is based on analysing the improvements realised by using the intervention, a survey to measure the experiences of the users of the intervention and to ask their recommendations for improvement.

Patient preintervention/postintervention surveys and interviews
Of the patients who participate in the stepped wedge pragmatic trial, every fifth participant will be invited to participate in the preintervention and postintervention survey and every seventh participant (up to a maximum of 30 participants) will be invited to participate in a postintervention interview of their experience with the sensor system. The interview will take no longer than 15 min. Survey and interview data will be linked with other data collected such as age, gender and falls history.

Clinical staff focus group
All clinical staff who work on each cluster during the intervention periods will be eligible to be included in a focus group conducted after at least 20 weeks’ exposure to the intervention (figure 1). A list of clinical staff working on the clusters during the AmbIGeM trial will be requested from unit managers. Individuals will be sent an internal mail invitation to participate. The focus group will seek information from clinical staff about their overall experience with AmbIGeM, their perspectives of the positive and negative aspects of AmbIGeM, the implementation of AmbIGeM and any recommendations for improvements of the intervention. With participants’ permission, the session will be audio recorded.

Clinical staff survey
All clinical staff working in the clusters will be invited to complete an acceptability and safety survey (figure 1). The survey will explore users’ experience of the intervention, opinions on its acceptability and suggestions for improvement. Items for the survey will be developed from themes identified in the clinical staff focus group. Ethics approval will be sought once the survey is developed.

Throughout the project, staff will be provided an opportunity to provide feedback anonymously about any aspect of the project and technology into a feedback box situated outside the ward environment.

Programme fidelity
To ensure programme fidelity, protocols will be used for staff training about definition and reporting of a fall, use of the mobile app, putting on the singlet, changing the singlet, changing the sensor or battery, use of the desktop app and how to respond to the AmbIGeM mobile alarm. Two weeks prior to the study commencement on each ward, in-service programmes will be conducted with ward staff to ensure staff understand the definition of a fall, are familiar with best practice and are aware how falls should be reported (hospital incident reporting system and patient medical records).18 This will include a video designed specifically for this purpose. An in-service programme to train staff with details of the intervention will occur 1 week before the commencement of the intervention. An online webpage describing the system and the process to activate it will be on the hospital intranet and available in printed form. Once the intervention is commenced, in-service sessions of 15 min duration on the use of the technology will be provided daily for the first

Staff will be able to deactivate the alarm from the same mobile app. The staff will also be able to record if an incident was a false alarm or true alarm and what they noted when they attended the patient. During the intervention period, the AmbIGeM system will replace other sensor alarms for all study participants.

A dedicated desktop falls management application (AmbIGeM desktop app) at the nurses’ station will provide the capability to: (1) enrol patients in the trial by assigning a wearable device to a patient; (2) visualise real-time updates of patient activity and current alarm information as well as a log of past alarms for individual patients; (3) discharge patients or unenrol patients as may be required; (4) provide a facility for nurse managers to alter alert settings including sensitivity of alerts; (5) visually observe when falls risk-related movements need updating based on user defined expiry times; and (6) provide warnings where a battery replacement is required due to a patient stay lasting longer than the typical operational life of a battery.

Assessing intervention acceptability and safety
To evaluate the usefulness and feasibility of the AmbIGeM system, quantitative and qualitative data will be collected using surveys, focus groups and interviews. Assessment may increase the likelihood of intervention implementation and usefulness.

![Figure 5 Example of AmbIGeM mobile screen of movements and locations to trigger alarm for night-time for an individual patient.](image)
Study protocol

Outcome measures

The primary outcome measure for this study will be the falls rate, calculated as the number of falls divided by the number of participant bed days (PBDs) in the participating wards during the control and intervention blocks. The fall definition already in use at the participating hospitals will be used for the study. A fall in this study is defined as ‘an event which results in a person coming to rest inadvertently on the ground or floor or other lower level’.26 Research personnel will collect falls data (location, injury and time) from three sources: health systems computerised incident reports, daily enquiry of falls from ward team leader and hand searching of patient medical notes or electronic health records. Secondary outcome measures include: (1) proportion of participants falling; and (2) rate of injurious inpatient falls per 1000 PBDs. Injurious falls are those that cause bruising, laceration, fracture, loss of consciousness or if the patient reports persistent pain.13, 27 Fractures will be confirmed by radiological confirmation.28

Research staff will collate data and enter it on an online custom developed data management system that should enhance data reliability and completeness.

Other assessments

Best practice

Standard practice (control and intervention blocks): for the duration of the study, staff will continue with best practice within their current resources. TQE and SCGH have in place routine best practice falls prevention activities consistent with Australian falls prevention guidelines for hospitals,29 including falls risk screening and assessment, environment assessment, implementation of interventions for identified risk factors, such as appropriate positioning of call bells and mobility aids, adequate lighting, bed/chair sensor alarms for patients with high risk of

Figure 6 Process for individualising settings for circumstances of alarm being activated.
falling, reduced clutter and compliance with restraint policies. The only aspect of usual care that will not be in place during the intervention blocks for participants in the trial is the use of bed and chair alarm pressure sensors (ie, only one sensor system will be used for a single participant (the AmbiGeM system or standard bed/chair alarm). The New South Wales Clinical Excellence Commission Falls Audit Tool-Ward Level will be administered at the first week of each block to provide a record of best practice within the wards.\textsuperscript{10} This tool audits for appropriate use and timing of risk screening, assessment and management. A culture of incident reporting will be encouraged throughout the study period.\textsuperscript{31}

**Patient-related measurements**

Within 72 hours of admission to the participating wards, research staff will gather patient information in relation to demographic details (date of birth, gender and living arrangements prehospitalisation).

At discharge, the reason for primary admission, the Charlson Co-morbidity Index,\textsuperscript{32} diagnoses of dementia and delirium and medication list will be recorded from the medical discharge summary. If a patient is still in rehabilitation or a residential transition care programme at 3 months postdischarge from the study ward, this will be recorded as a discharge to residential care.

**Data on resource use**

Data collection for an economic analysis will include capital cost, installation cost, maintenance cost, sensor replacement costs, sinlets (for wearing the sensor), the cost of responding to sensor alarms and technology support costs. The frequency of alerts and response time by staff will be recorded. Throughout the study period, a record of staffing levels including the use of additional staff will be maintained, as staffing constraints may contribute to increased falls rates. In-service training and advice requirements will also be noted. Where a fall has occurred, the injuries, laboratory and radiology investigations immediately following and related to the fall, and any surgical interventions to treat injury related to the fall will be recorded. Data will be obtained from the medical records, and costs of investigations and interventions will be obtained from the finance departments of participating hospitals.

Health systems data held by the State Departments of Health in SA and WA will be linked to the study inpatient data to inform prestudy ward, study ward and poststudy ward types and lengths of hospital stay and discharge destination. Use of hospital services including rehabilitation, emergency department presentations and readmissions and mortality data will be collated to 3 months postdischarge from the study ward (with an extended analysis planned for 12 months postdischarge).

**Statistical analysis**

**Sample size and statistical power**

Assuming a baseline falls rate of 7.7 per 1000 PBDs and an average length of stay of 12.3 days (based on earlier data from participating wards), then 924 patients are needed in a patient-level randomised trial to achieve 80% power at 5% significance level to detect a relative reduction in falls to 0.53 (ie, a 47% reduction in the falls rate). Accounting for the clustered nature of the stepped wedge design requires increasing the sample size by a factor of the expected intracluster correlation coefficient (ICC). Assuming an ICC of 0.002\textsuperscript{15} and an average cluster size of 800 patients over the 100 weeks of the study (excluding the 3-week technology testing period prior to the first intervention block) gives a design effect of 2.6 and so requires a total of 2400 patients. This requires an average of 24 eligible patients admitted across the three wards (74 beds in total) per week.

**Statistical methods**

The statistical analysis will be blinded regarding the trial phase participants were involved in (intervention or control block). All analyses will be conducted using intention-to-treat principles. The primary outcome of the falls rate will be analysed using a Poisson generalised linear regression model including effects for intervention, ward and time period to account for the clustered, stepped wedge design of the study. Patients recruited to the study during a control period will be censored when the ward transitions to the intervention, with falls and length of stay data only collected up until the time of transition. The secondary outcome of the rates of injurious falls will be analysed similarly. All Poisson models will be examined for overdispersion and underdispersion. The proportion of participants falling will be analysed by binary logistic regression, accounting for ward and time period effects. The Charlson Comorbidity Index will be used as a covariate to adjust analyses for baseline differences between the control and intervention groups. A subgroup analysis of the effect of the intervention within patients with and without dementia and delirium will also be conducted, by including the presence of dementia and delirium diagnoses at discharge as an interaction effect in a secondary model. For all analyses, significance will be determined at the 5% level. No imputation of missing outcome data will be conducted.

**Health economic analysis**

The cost-effectiveness analysis will include patient-level cost estimates comprising intervention costs (estimated as fixed and variable costs, converted to a daily equivalent cost, with the fixed costs annuitised over the expected lifetime of the intervention); daily ward costs (allocated by dividing the aggregate daily ward cost, based on recorded staffing levels, by the number of patients on the ward on each day); and costs relating to falls, based on recorded hospital activity for eligible patients (eg, imaging and surgical procedures). Costs incurred in the 3-month period postdischarge from the study ward will represent time spent on other hospital wards, the receipt of other hospital-based services (eg, home-based rehabilitation services) and residential care costs incurred by the Australian federal and/or state governments using discharge destination data.

Within the trial, cost-effectiveness will be represented as the incremental cost per fall avoided, per fall-free separation and per avoidance of discharge to residential care. Extrapolation of the longer term costs and consequences of observed differences in reported outcomes will be considered, for example, with reference to models of the long-term costs and effects of frailty.\textsuperscript{34}

**Safety and acceptability analysis**

Two members of the research team will independently undertake analysis of data pertaining to assessing the intervention acceptability and safety.

Text data from interviews and focus groups will be transcribed. Transcriptions will be read multiple times to obtain a sense of the whole meanings. Notes taken during meetings will help to clarify discussion points in the recordings. Data from anonymous feedback boxes will be collated and added to the transcriptions. Date will be analysed using NVivo software.

A process of Open Coding where focus group data and text data from surveys is marked and labelled with a code describing
its content will be undertaken. Once the initial codes are generated, they will be discussed and analysed to form ‘nodes’. The ‘nodes’ relating to each other will be grouped together, forming ‘concepts’. ‘Concepts’ that have similar meaning will be merged together forming the ‘categories’. The main questions used in the interview guide will be used to label the main categories as this allows reporting of participants’ responses to individual questions separately. Separate categories may be created for the coded content that does not fall under the main questions.

Numerical data from patient and clinical staff surveys will be analysed using descriptive frequencies and integrated into the focus group and interview data analysis to provide an in-depth analysis of the feasibility and acceptability of the intervention.

**Data safety monitoring**

An independent data and safety monitoring committee will be established consisting of a chair and four others including representatives from the hospital falls prevention committee of each participating centre. The data and safety monitoring committee will ensure the safety of patients during the study period. Reports will be provided to this committee 6 monthly.

**DISCUSSION**

The AmbiGeM trial focuses on the pressing challenge of reducing falls among older people admitted to hospital. Falls in hospitals remain an international problem and are a leading cause of reduced quality of life, impairment and injury, and death. Even with current best practice, falls rates in hospitals remain unacceptably high despite local, state and national activities. With an ageing population in Australia and internationally, the number of falls will increase especially in the wards that preferentially manage older people, many frail and many with dementia. Given the increasing demands on the already limited healthcare budget, more needs to be done to prevent falls in hospitalised older people. There is an imperative to explore alternative interventions, including technological solutions, which have the potential to prevent falls and so reduce health and aged care expenditure when implemented to augment best practice. The setting of the study provides the opportunity to evaluate the effectiveness of a novel, technological approach incorporating Bluetooth technology aiming to reduce falls in hospitalised older people. Furthermore, the study aims to include participants from culturally and linguistically diverse background and participants with cognitive impairment. Major methodological strengths of the trial include external, non-invasive electronic monitoring, the inclusion of health professionals and partnership with health providers.

Falls rates in wards where frail older people, many with cognitive impairment, are managed are higher (eg, 8 per 1000 OBDs in the proposed study wards) than the total hospital average (eg, 4.8 falls per 1000 OBDs). Current best practice falls prevention programme in hospitals are of limited effect, with falls rates in Victoria (Australia) increasing over the past 10 years, despite local, state and national activities over this time aiming to reduce falls. Inaction is not economically or morally sustainable, given the increasing demands on the already limited healthcare budget and the populations’ expectations of healthcare.

The research team has developed an innovative ambient intelligent system incorporating wearable sensors and the latest BLE technology. A pragmatic stepped wedge trial is proposed to determine the effectiveness and cost-effectiveness of this technology system on falls rate in hospitals. This novel system brings some key innovations. It will monitor multiple patients in multiple locations. The wearable sensor is a completely different approach to deploying powered pressure mats on beds or pressure sensors on chairs because multiple patient activities in multiple locations will be able to be automatically monitored. The sensor can be worn 24 hours a day and will monitor patients receiving interventions and realarm if necessary. If the alarm is not deactivated by a staff member attending the at-risk patient within a short preset time, the alarm will be triggered again. The system also provides a novel strategy to reduce false alarms, which is a key differentiator in relation to previously trialled approaches in the literature. Alarms can be individualised to patient needs and discretely (through vibration mode) sent to allocated staff via the mobile app or to a central console via the desktop app. Furthermore, fine grain analysis of patient movements by human activity recognition algorithms executing in backend systems that can be customised to patients provides more accurate and timely determination of alarm events. These differences in approach to currently available technology-related monitoring systems helps reduce ‘nuisance’ effects by avoiding unnecessary alarms. Lastly, this system is relatively low cost.

We hypothesise that the AmbiGeM intervention will reduce the falls and injury rate of hospitalised older patients. Utilising a mixed methods research approach provides broader, deeper and/or more useful information, providing strengths that offset the weaknesses of single research approaches. We also anticipate that the patients and clinical staff will find the AmbiGeM system acceptable. If the AmbiGeM intervention is successful in reducing falls, is cost effective and acceptable to staff and patients, the intervention will be able to augment best practice falls prevention in hospital in wards that have many older people and people with cognitive impairment. Furthermore, there is potential for its use in non-hospital settings. The outcomes of this research will therefore be of international significance given the novelty of the proposed technological solution and the potential cost-effectiveness.

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**Contributors**

RV, DCR, KH, AW, KL and JK provided substantial contribution to the conception and design of the work and obtaining funding, drafting and revising the work and final approval of the version to be published. JD, EB, ER, SM, KI, SP and SH have provided substantial contribution to the refinement of the design of the work, drafting and revising the work and final approval of the version to be published. All authors agree to be accountable for all aspects of the work.

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**Competing interests**

None declared.

**Patient consent**

Waiver of consent received for Western Australia and opt-out consent received for South Australia.

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TQEH/Lyell McEwin Hospital (LMH)/Modbury Hospital (MH) and SCGH HREC.

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