Effectiveness of the Wearable Sensor based Ambient Intelligent Geriatric Management System (AmbIGeM) in Preventing Falls in Older People in Hospitals

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ABSTRACT

Background: The AmbIGeM system augments best practice and involves a novel wearable sensor (accelerometer and gyroscope) worn by patients where the data captured by the sensor is interpreted by algorithms to trigger alerts on clinician handheld mobile devices when risk movements are detected.

Methods: A 3-cluster stepped wedge pragmatic trial investigating the effect on the primary outcome of falls rate and secondary outcome of injurious fall and proportion of fallers. Three wards across two states were included. Patients aged ≥65 years were eligible. Patients requiring palliative care were excluded. The trial was registered with the Australia and New Zealand Clinical Trials registry, number 12617000981325.

Results: 4924 older patients were admitted to the study wards with 1076 excluded and 3240 (1995 control, 1245 intervention) enrolled. The median proportion of study duration with valid readings per patient was 49% (IQR 25-67%). There was no significant difference between intervention and control relating to the falls rate (ARR=1.41, 95% CI (0.85, 2.34; p=0.192)), proportion of fallers (OR=1.54, 95% CI (0.91, 2.61); p=0.105) and injurious falls rate (ARR=0.90, 95% CI (0.38, 2.14); p=0.807). In a post hoc analysis, falls and injurious falls rate were reduced in the Geriatric Evaluation and Management Unit (GEMU) wards when the intervention period was compared to the control period.
Conclusion: The AmbIGeM system did not reduce the rate of falls, rate of injurious falls or proportion of fallers. There remains a case for further exploration and refinement of this technology given the post hoc analysis findings with the GEMU wards.

Keywords: hospital related, morbidity, preventative healthcare
INTRODUCTION

Falls in hospital are a major contributor to adverse events leading to deaths, with the incidence increasing by 14% over the decade between 2006/07 and 2015/16 (1). Falls remain common in Australian hospitals, occurring in more than 34,000 separations at a rate of 3.2 per 1000 separations in the 2015/16 financial year (2). Falls are costly resulting in additional hospital costs of AUD $6669 (95% CI, $3888-9450) (3). Importantly, falls also have functional and psychological consequences, resulting in loss of independence and premature institutionalization (4,5).

Research evidence for effective interventions to reduce falls among older people in hospitals remains limited (6). In the most recent Cochrane review, multi-factorial interventions were shown to have stronger evidence of effect than single interventions, and there was stronger evidence in sub-acute compared to acute hospital wards (6). Further, there remains an evidence gap for falls prevention for hospitalized patients with dementia (7), despite a high proportion of falls in hospitals involving people with dementia or delirium (8).

Although widely used, research evaluating pressure sensor alarms on beds and chairs have produced disappointing results (6). Despite this lack of evidence, the desire to keep patients safe drives ongoing reliance on such devices (9,10). Wearable sensors may offer advantages over bed and chair pressure alarm systems because they allow for monitoring of multiple risk activities, across multiple locations in multiple patients together with the ability to individualize alarms to patient care needs. Furthermore, there is rapid progress in the field of wearable sensors, moving towards a future where real time physiological monitoring of patients...
is integrated with electronic medical records (11).

A new wearable sensor approach called the Ambient Intelligent Geriatric Management (AmbIGeM) system, encompassing patient worn sensors and movement recognition and location tracking algorithms to trigger alert messages to staff when risk movements occur, was co-designed by our research team and hospital staff with feedback from patients. Preliminary research by our team demonstrated data to support that a wearable sensor system could be accurate and acceptable to patients (12). We hypothesized that such a system would enable staff to intervene before a fall and reduce falls rates and injuries.

The study objective therefore was to investigate the AmbIGeM system in three wards across two different states whilst evaluating the effectiveness of the technology in reducing the falls rate, the proportion of fallers, and the injurious falls rate in older people in hospital.

METHODS

Trial Design and Participants
The implementation research incorporated a concurrent mixed methods design combining a pragmatic stepped-wedge cluster trial (SWCT) with a survey and qualitative process to gather information from patients and clinical staff on the acceptability and safety of the study. The study protocol has been published but is briefly described here (13).
Participants and Consent

Patients who were 65 years and older and admitted to participating wards were eligible whilst those receiving palliative care as well as those previously enrolled in the study during the same admission (e.g. transfers between wards) were excluded. Supporting inclusiveness of those with dementia, an opt-out consent process was in place in South Australia (SA) whilst a consent waiver process was in place in Western Australia (WA). Opt-out consent is where participants are provided with information about the research and unless they opt out (decline to participate), it is presumed they will participate. A consent waiver, waives the requirement to obtain informed consent. In the study wards, patients and families were informed about the study by placing posters around the ward and giving patients written information about the study. If patients (or person responsible) did not want to participate, they withdrew (WA study site) by telling the clinical or research staff or opted out (SA study site) by signing the form or telling the clinical or research staff within three days of entering the ward.

Sample Size

Assuming a falls rate of 7.7 per 1000 participant bed days (PBD) and the average length of stay (ALOS) of 12.3 days, we calculated that 924 patients would be needed in a patient-level pragmatic trial to achieve 80% power at 5% significance level to detect a relative reduction in falls of 0.53 (i.e. a 47% reduction in the falls rate). To account for the clustered nature of the stepped wedge design, an ICC of 0.0027 and an average cluster size of 800 patients over the 100 weeks of the study (excluding the three weeks technology testing period prior to the first intervention block) was assumed, resulting in a design effect of 2.6. The study required a total
of 2400 patients (1200 in control and 1200 in intervention). The sample size arrived at was guided by pragmatism as well as the study by Dykes et al. where the adjusted fall rate in the control unit was 4.75 (3.44-6.54) per 1000 patient days compared to 2.66 (1.87-3.80) per 1000 patient bed days (14).

**Allocation and Blinding**

The intervention was not blinded and was delivered across three clusters (wards) in two hospitals in two Australian states: SA and WA. The AmbIGeM trial commenced on the 10th of July 2017 and after 103 weeks including 3 weeks of technology testing prior to the first active wedge (commenced 22nd of January 2018), the study completed on the 30th of June 2019.

All wards initially spent 25 weeks in the control period, with one ward then changing to an intervention ward each subsequent 25 weeks wedge. The following pragmatic order of transitioning from control to intervention wedge was used to support deployment of the technology from SA: (1) South Ground (28-32 beds) at The Queen Elizabeth Hospital (TQEH), SA, (2) followed by the 14 bed Geriatric Evaluation and Management Unit (GEMU) at Sir Charles Gairdner Hospital (SCGH) in WA, and (3) the 32 bed General Medicine (GM) ward at SCGH. Whilst South Ground frequently flexed up from the 28 beds GEMU to a 32 beds ward with the 4 additional beds occupied by general medical patients, this ward is referred to as GEMU in this paper. The GM ward admitted patients of all ages. Summer bed closures affected the WA GEMU (control period) for 16 weeks, from the 22nd of December 2017 to the 16th of April 2018.

**Best Practice**

Best practice consistent with the Australian falls prevention guidelines for hospitals was in place and continued throughout the study (15). The New South Wales Clinical Excellence Commission Falls Audit Tool-Ward Level was administered during the first week of each wedge to provide a record of best practice falls prevention activity within the wards (16). This best practice framework remained consistent throughout the study.
Intervention

Patients wore a cotton singlet with an encased wearable Bluetooth Low Energy (BLE) sensor device with integrated triaxial accelerometer and gyroscope sensors. The sensor weighed 15 grams (Figure 1) and was positioned in a customized pocket over the sternum. Wearable sensors were cleaned and reused. A protocol with radiology was developed to ensure the wearable sensor was removed prior to Magnetic Resonance Imaging (MRI).

Wireless signals transmitted from the wearable sensor containing the triaxial accelerometer, gyroscope and unique sensor ID data were collected by base stations attached to the ceiling of patient rooms. Base stations were positioned above patient beds, toilets and room doors exits. Data from the base stations were processed and transmitted over a local area network (LAN) to a server. Software developed by our team interpreted the data using algorithms. The three categories of key software changes made during the study were: a) changes to improve usability of the software by making modification to the user-interface based on staff feedback; b) updates to the algorithms used to determine patient activities; and c) system upgrades to improve performance and software maintenance. It is possible that the
changes to the algorithms and system upgrades could have improved performance but this was not assessed.

Staff selected patient risk for the day and night periods and it was possible that for some patients, no risk was identified. When patient specific risk movements were inferred, staff were alerted using vibration or sound or both modes with messages generated by the server software. These were transmitted through the ward Wi-Fi network to the Mobile Apps on Android smartphones to alert staff using vibration or sound or both modes. Unless the staff was adjacent to the patient and had selected to sound, patients would not hear the alerts. The goal was to provide staff an opportunity to intervene and prevent a fall but no record of staff response was recorded. In the intervention phase, the smartphones were provided to all nursing staff in participating wards, and were provided to allied health staff in WA. The AmbIGeM system was allocated a dedicated Wi-Fi network using existing Wi-Fi infrastructure in WA but relied on the health system Wi-Fi network in SA.

The AmbIGeM Mobile App deployed on smartphones allowed staff to define individual patient risk movements for translation by the system to generate a bedside poster and for determining the rules for activation of relevant patient specific alarms. The risk movement selection facilitated setting individual patient alarm activations by the system for any or all of the following risk movements, and the selections could be updated any time:

- Sitting up after lying on the bed;
- Getting out of from bed or chair;
- Walking out of the room including to the toilet; and
Walking without an aid where the aid was considered necessary for safety.

The Mobile App allowed staff to deactivate the alert whilst the alert displayed the patient, time, location and risk movement. The intention was to provide staff the opportunity to attend to the patient as quickly as possible. Sensors were also attached to participant walking aids to detect movement without an aid where an aid was required for safe mobility.

A Desktop App for falls management was also available at the nurse station to support patient enrolment, bed swaps and discharge as well as alert staff towards the need for sensor replacements due to an impending depletion of a sensor battery (lasted median 23 days) for individual sensors. Updates on patient activity and alerts were available on the Desktop App and the alarm could also be deactivated from the Desktop App.

**Program Fidelity**

To ensure program fidelity, protocols were used for staff training, detailing definition and reporting of a fall, use of the Mobile App, putting on the singlet, changing the singlet, enrolling a sensor, use of the Desktop App and how to respond to the alerts, delivered to the Mobile App. Two weeks prior to the study commencement on each ward, in-service programs were conducted with ward staff to ensure staff understood the definition of a fall including a video designed to assist staff define what constitutes a fall, were familiar with best practice and were aware how falls should be reported (hospital incident reporting system and patient medical records) (17). In the week before the commencement of the intervention, an in-service program to train ward staff occurred where details of the intervention were provided.
Information describing the system was also available in printed form. Once the intervention had commenced, in-service sessions of 15 minutes duration on the use of the technology were provided daily for the first week and then weekly in the first month to maintain staff knowledge with regards to the use of the intervention and support trouble-shooting.
Technology Adherence

For the purpose of estimating adherence, the percentage of time with valid sensor data was evaluated and defined as (duration with valid sensor data/duration enrolled in study) \times 100\%. Data were present when the following conditions were met: i) the participant enrolled into the system and assigned a sensor and ii) the sample rate of the data (number of unique data packets sent by the assigned sensor and received by the system) exceeded 240 samples per minute. Subsequently, for a given 1-minute period to be counted as a “duration with valid sensor data”, it must satisfy the conditions of: i) a correctly calibrated sensor; ii) a sensor worn by a patient (e.g. not accidently left on a table); and iii) a sensor worn in the correct orientation. The admission day was assumed to be from 1200-2359 (24 hour clock) whilst the discharge day was 0000-1200. In this study, daytime was defined as 0701-2059. Based on other falls research, the adherence threshold was set at 63\% in this study (18).

Outcomes

The primary outcome measure in this study was falls rate, calculated as the number of falls divided by the number of participant bed days in the participating wards during the control and intervention blocks, and expressed as falls per 1000 participant bed days. A fall in this study was defined as an ‘event which results in a person coming to rest inadvertently on the ground or floor or other lower level’ (19). Research personnel collected falls data (location, injury, time) from three sources: i) health systems computerized incident reports; ii) daily enquiry of falls from ward team leaders; and iii) hand searching of patient medical notes or electronic health records in order to maximise accuracy of falls data (20).
The secondary outcome measures in this study were: i) proportion of participants falling; and ii) rate of injurious in-patient falls per 1000 participant bed days.

In this study injurious falls refer to those that cause bruising, laceration, fracture, loss of consciousness or if the patient reports persistent pain (17,21). Moderate injurious falls were recorded when bruising, sprains, cuts, abrasions, seeking medical attention, or a decrease in physical function for a period of 3 days or more were noted (21). Serious injurious falls were when fractures (with radiological confirmation (22)) and sutures were required. As part of hospital policy, clinical staff record any fall in the incident reporting system and medical records and no structured protocol was in place. When it came to recording of falls for this research, where research staff were uncertain, the senior investigators (RV and KH) adjudicated.

Other Assessments

Research staff entered patient demographic information (hospital identifier, date of birth, gender, living arrangements pre-hospitalisation) within 72 hours of admission. At discharge and predominantly from the discharge summary, the primary reason for admission, post hospital discharge destination, the Charlson Co-morbidity Index (23), delirium present during admission or as a primary or complicating diagnosis, if patient was admitted with a fall (within seven days of admission), if fracture was a primary or complicating diagnosis of this admission, and number of regular medications were recorded. Information relating to recruitment, withdrawal and adverse events was also recorded.
Data Safety Monitoring

Guided by a charter, a chair and four others including representatives from both hospital falls prevention committees formed the independent Data and Safety Monitoring Committee, and reports were provided for their consideration. They met on 23rd August 2017, 10th November 2017, 14th August 2018, and 12th March 2019 to ensure the safety of patients over the course of the study.
Ethics

Ethics and governance approval were achieved from TQEHLyell McEwin Hospital (LMH)/Modbury Hospital (MH) (HREC/15/TQEH/17) and Curtin University (HRE2017-0449)/SCGH (PRN 2015-110). Funded by the National Health and Medical Research Council of Australia (APP1082197), the trial was registered with the Australian and New Zealand Clinical Trial Registry (ANZCTR): ACTRN 12617000981325.

Statistical Methods

All analyses were conducted using intention to treat principles and while blinded to trial phase (intervention or control). The planned analysis of the primary outcome of falls rate was using a Poisson generalised linear regression model including fixed effects for intervention, ward and time period. Due to over-dispersion and non-convergence of some models, negative binomial models are reported as adjusted rate ratios (ARR) and 95% confidence intervals (CI). The secondary outcome of the rate of injurious falls was analysed similarly. The proportion of participants falling was analysed by binary logistic regression, accounting for ward and time period effects. The Charlson Comorbidity Index was included as a pre-specified covariate. Patients recruited to the study during a control period were censored when the ward transitioned to the intervention (or technology testing period for SA), with falls and length of stay data only collected up until the time of transition. A planned subgroup analysis of the effect of the intervention within patients with and without dementia and delirium was conducted, by including the presence of dementia and delirium diagnoses at discharge as an interaction effect. A planned subgroup analysis by time of fall (day 0700-1959/night 2000-0659) was also conducted, but due to non-convergence of the repeated outcomes model, results are reported for day and night falls rates separately. Significance was determined at the 5% level for all analyses. No imputation of missing outcome data was conducted.
RESULTS

Participant Flow and Recruitment

Of the 4924 patients eligible (Figure 2), 3848 met the inclusion criteria and 1076 were excluded. Finally 3240 patients were enrolled with 1995 control patients and 1244 intervention patients included in the intention to treat population.

Mean recruitment rates were higher in the control period when compared to the intervention period (SA GEMU 13.4/week vs. 9.3/week; WA GEMU 8.7/week vs. 7.5/week; WA GM 17.7/week vs. 6.8/week) with the greatest reduction (62%) seen in WA GM.

The higher falls rate observed (10.3/1000 participant bed days) compared to the a priori assumed (7.7/1000 participant bed days), increased the theoretical power to approximately 89% but the lower length of stay observed (11.1 days) compared to assumed (12.3 days) reduced the final theoretical power to 86%.

Baseline Characteristics

There was a larger proportion of GEMU patients (86%) in the intervention group and larger proportion of GM patients (67%) in the control group. The mean age of the study population was 82.7 years (standard deviation [SD] 8.2) with patients in the intervention arm (84.0 [7.9]) being older than those in the control arm (81.9 [8.3]). Patients in the intervention group were more likely to be admitted from the community when compared to the control group (96 vs. 89%) and had longer average length of stay (16 vs. 11 days). Twenty-two percent
of patients were admitted with delirium and 17% with dementia (Table 1), with a slightly higher proportion in the intervention compared to control (delirium 27 vs. 20%; dementia 19 vs. 16%). The proportion admitted with a history of falls with or without fracture was higher in the intervention arm at 41% compared to control at 23%. Mortality and discharge to community rates were similar for both groups. There were more patients admitted primarily for infection (35% vs. 29%) and more transferred to rehabilitation (inpatient or community; 19% vs. 15%) with less discharged home (43% vs. 48%) in the intervention period compared to control, when the GM ward was considered on its own.

Outcomes and Estimation

There were a total of 371 falls from 273 patients in this study. Injuries were seen in 122 falls with a quarter (n=103) being classified as moderate or severe and a further 5% (n=19) as mild injury. Two hundred and fifty-four (69%) of the falls were recorded from the incident reporting system. Twenty-three percent of falls occurred in wet areas with the majority of falls occurring in the patient rooms (68%).

The overall falls rate increased during the intervention (ARR=1.41, 95% CI (0.85, 2.34)) period, but was not statistically significant (p=0.192) (Table 2). Similarly, the proportion of fallers was non-statistically significantly increased during the intervention period (OR=1.54, 95% CI (0.91, 2.61); p=0.105) period (Table 2). The injurious falls rate was similar between the two periods (ARR=0.90, 95% CI (0.38, 2.14); p=0.807) (Table 2).

In an exploratory, unplanned subgroup analysis, all outcomes (Table 3) indicated a different effect of treatment in the GEM wards compared to GM (all interaction p<0.05), with the intervention being associated with better outcomes than control in the GEM wards, but worse outcomes in GM.
Withdrawal

Overall there were 33 withdrawals during the control period. There were 153 withdrawals during the intervention period (Supplementary Table 1a). The majority of withdrawals during the intervention period were related to the singlet (n=111; 73%) (Supplementary Table 1b). There were 19 withdrawals relating to the sensor (Supplementary Table 1b). Three patients pulled apart the sensor and as a result of this staff were advised to not enroll patients (mostly with dementia) who were agitated or fidgety and where already enrolled, to withdraw those patients from the study. To further reduce the risk, the sensor casing was subsequently re-designed without a rivet and enlarged to support a snugger fit in the singlet pocket. A tool was also fabricated to ensure the correct installation of a battery by inserting the battery all the way into the casing and thus ensuring the protections provided by the casing made it difficult for participants to remove the battery.

Adverse Events

There were 24 adverse events recorded during the intervention period with multiple consequences selected for each. The consequences predominantly related to the skin [pressure (n=2), irritation (n=10), rash (n=7), redness (n=7) and itchiness (n=8)] and participant [discomfort (n=1), pulling at sensor (1) and pulling sensor apart (n=3)].

Technology Adherence

The first intervention wedge was impacted by a delay to technology deployment at the start lasting almost 2 weeks and then multiple technical issues relating to the network
connectivity between systems at the SA GEMU. Subsequently, there were three major technical issues: i) relating to the Wi-Fi system where the smartphones were unable to connect to the network reliably while roaming; ii) relating to the introduction of new smartphone models; and iii) due to the SA GEMU network administrators re-configuring the LAN and inadvertently disconnecting the server in the process. Two minor events (i.e. <1 day) relating to system maintenance contributed to downtime.

Wearable sensor data was available for 1196 (of 1244) subjects. The overall median proportion of duration with valid readings was 49% (IQR 25-67%), similar to that seen at night (median 50%; IQR 25-71%). In SA GEMU, the median percentage of study time with valid data (Supplementary Table 3) reduced with successive wedges from 53% (IQR 35-69%) to 40% (IQR 19-62%) and then 38% (IQR 16-60%). In WA GEMU, the median percentage of time with valid data remained similar (58%; IQR 44-72% vs. 60%; IQR 38-72%) across the two wedges. The lowest median was seen with WA GM (32%; IQR 14-59%). Interestingly in WA GM, the falls rate in those with high adherence (defined as ≥63% median percentage time with valid reading) was treble (i.e. 33.6 falls/1000 patient bed days vs. 11.0 falls/1000 patient bed days) that seen in those with lower adherence.

Bed and chair pressure sensors or pull cord alarm systems were used for a small number of patients throughout the study given staff previous practice and their fear of relying only on the AmbIGeM system only for some patients. These were not recorded but an audit in the final intervention wedge revealed that 11 patients in SA wore a pull cord alarm whilst 25 patients in the WA GEMU and 21 patients in WA GM used a pressure sensor mat.
No differences in rates were seen when daytime was compared to nighttime (Supplementary Table 4) or when those with dementia/delirium were compared to those without (Supplementary Table 5). The effect of the intervention when adherence to the intervention was deemed high was similar to the intention to treat analysis.
DISCUSSION

The use of the AmbIGeM technology system in GEMU and GM wards did not significantly reduce falls rate, number of fallers and injurious falls rate. A posthoc analysis by wards suggested a trend towards reduction in falls and injurious falls rates in the GEMU wards but an increase in those rates in the GM ward. The research is the first time wearable sensor technology involving a large sample of inpatients has been trialed to prevent rather than detect falls and there were few adverse events related to the technology. However, adherence to the technology in terms of the availability of valid data was sub-optimal and appeared related to ward size and turnover as well as the duration of time in the intervention as part of research.

Similar to other research when investigated in real world settings, the intervention did not benefit patient outcomes (9,10). Similar to that noted by Timmons and colleagues who investigated pressure sensor alarm system, we noted that the intervention and the outcome (falls) could not be separated from the broader context of the clinical staff, their established work practices, the ward environment, the organizational culture and patient or carer expectations. In this research (not published), participants and families viewed the intervention as a useful backup for staff and participants found it acceptable. Staff reported at times that false alerts contributed to ignoring of alerts whilst delayed alerts did not provide staff with sufficient time to intervene. The intervention was an additional workload for staff that they were willing to undertake if the system was beneficial. Whilst we attempted to overcome potential limitations by co-designing the technology to meet staff and patient needs and gain
support for the roll out of the technology, it was difficult to anticipate and respond to all arising requirements in a timely manner given the variability of requirements between staff and also the limited funding and resources available for the conduct of this project. The introduction of new technology into any healthcare setting introduces new workflow and where there are competing demands, as is the norm, it is more than likely that what is characterized, as research of an unproven intervention is viewed as less of a priority (24). Acceptability of the system from patient, carer and staff perspectives is planned to be reported separately (13).

Whilst the falls and injurious falls rate increased in the GM ward, the reduced falls and injurious falls rate noted in the GEMU wards provided evidence for further exploration of this technology concept. These findings are also consistent with those reported in a recent Cochrane review that multi-factorial interventions appear more effective in reducing falls rates in sub-acute settings (Relative Adjusted Risk 0.67, 95%CI 0.54 to 0.83) when contrasted to acute or mixed settings (6). Therefore, the quest for an effective strategy for the acute setting continues. A health economic analysis is planned to assess the value of further clinical trials in this area (13).

The recruitment rate was lower in the intervention period compared to the control period. Implementation fatigue is a real risk to lengthy studies and the mean recruitment rate dropped off over the 75 weeks of intervention in the SA GEMU. The largest difference in recruitment rate however was seen with the larger acute GM ward that had a greater patient turnover given shorter median length of stay whilst caring for patients of all ages. The least change in recruitment rate was noted for the smallest ward providing sub-acute GEM care
(WA) to only older people. Therefore, selection bias possibly contributed to the unusual finding in the GM ward. A limitation of this study was that we did not have approval to investigate the differences between those who enrolled in the trial and those who did not. It has been reported elsewhere that clinical staff sometimes over-ride the random allocation of patients to sensor related interventions where they subscribe to a view that they know which patients are more likely to fall (25) or are under competing work pressures and it is possible that staff prioritized the intervention to those they identified as being most at risk thus introducing a selection bias.

Our previous research investigating the use of health information technology to assess falls risk also demonstrated a lower rate of use (70 vs. 61%; p=0.08) in the acute medical ward compared to the GEMU (26). The counter-argument that the technology intervention somehow contributed to a higher risk of falling in the general medicine ward is less likely unless the availability of the system to those most at-risk resulted in automation complacency (27) reducing staff alertness in this particular busy environment as that association was not seen with the sub-acute GEM wards.

Reduced adherence to the intervention was recently cited as a major reason why a nurse led multi-factorial falls prevention intervention incorporating assessment and care planning in primary care did not lower the rate of a first adjudicated serious fall injury when compared to enhanced usual care (28). Non-adherence to intervention in clinical trials is common and our response to calls for adherence to be reported is a major strength of this study (29). Our interrogation of sensor data on the use of the sensor revealed that the percentage of time with valid data reading was highest in the smaller sub-acute ward (WA GEMU) but lowest in the
larger acute general medicine ward with 28% deterioration over the 75 weeks of intervention in the SA GEMU. Potentially, and in line with the hypothesis that staff in the general medicine ward were focused on those with greater risk of falls, higher falls rate (33.6/1000 vs. 11.0/1000 participant bed days) were seen in those with high adherence (i.e. >63%) compared to those with lower adherence with this pattern less noticeable with the GEMU wards.

In this research, a singlet was used to host the sensor but most adverse events and withdrawals related to the use of the singlet. Sensor technology is fast advancing with patch sensors with multiple capabilities more likely to be used in the future (30), removing the need for a singlet. Interest in investigating the effectiveness of wearable patch sensors in improving clinical care is increasing with one recent study of intensive care unit patients providing some evidence that wearable sensors guiding patient repositioning including alerting staff to the need, can reduce hospital acquired pressure injuries when compared to usual care (31). Our research adds to the growing body of knowledge and intense interest in this field.
Conclusion

The AmbIGeM system consisting of a movement sensor alarm system was not shown to prevent falls in this adequately powered research. However, our pragmatic trial and comprehensive deployment of a new wearable sensor technology based intervention in three wards across two sites in two states generated knowledge, novel observations and new findings. The successful implementation and findings from post-hoc analysis paves the way to define future intervention trials investigating novel wearable sensor technologies in hospitals to improve patient outcomes, especially given the rapid advancements in the wearable technology field.
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Contributors

RV and KDH equally contributed to the study design, selecting participating sites, conducting the research, data collection, data interpretation and drafting of the manuscripts. DCR contributed to the technology design and implementation, conducting the research, data collection, data interpretation and drafting of the manuscript. KL designed and conducted the statistical analysis and contributed also to interpretation and drafting of the manuscript. AW and JK contributed to study design, data interpretation and drafting of manuscript. KI and SH were clinician leads involved in selecting participating sites, conducting the research, data collection, data interpretation and drafting of the manuscript. JD, EB, KJ, MC were research fellows with the study that were involved in the conduct of the study, data collection, data interpretation and drafting the manuscript. CP is involved in the analysis and contributed to the drafting of the manuscript.
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Conflicts of interest

Previously, there was a patent filed (mid 2013) by A/Prof Ranasinghe and Professor Visvanathan titled system, method, software application and data signal for determining movement but this has since lapsed. Professor Visvanathan is the Head of Unit of the Aged & Extended Care Services at the Queen Elizabeth Hospital in South Australia within which the GEM Unit is a service for which, Mr Stephen Hoskins is the Nurse Manager. Dr Kate Ingram is the Falls Lead at Sir Charles Gairdner Hospital in Western Australia.
Data Sharing

Requests for data should be directed to the lead author (reenuka.visvanathan@adelaide.edu.au) and include a collaboration with at least one of the Chief Investigators (RV, KH or DR). Any request will be assessed for scientific rigour (by a panel consisting of RV, KH, DR and KL) and given the involvement of hospital patient data, the request must meet ethics request guidelines and be approved by the ethics committees of TQEIH/Lyell McEwin Hospital (LMH)/Modbury Hospital (MH), Curtin University and SCGH. The requestor will be responsible for preparing documentation to the standard required to meet the requirements of the various ethics committees. A data sharing agreement will likely be necessary. Given the multiple analyses planned as well as underway currently, data sharing is at this stage embargoed for a further two years.
REFERENCES

1. Beck B, Smith K, Mercier E, et al. Differences in the epidemiology of out-of-hospital and in-hospital trauma deaths. *PLoS One.* 2019;14(6):e0217158. doi.org/10.1371/journal.pone.0217158

2. Australian Institute of Health and Welfare. *Australia’s health 2018.* Canberra: AIHW;2018. Accessed 1st June 2021 <https://www.aihw.gov.au/reports/australias-health/australias-health-2018/contents/indicators-of-australias-health/falls-resulting-in-patient-harm-in-hospitals>.

3. Morello RT, Barker AL, Watts JJ, et al. The extra resource burden of in-hospital falls: a cost of falls study. *Med J Aust.* 2015;203(9):367. https://doi.org/10.5694/mja15.00296

4. Tinetti ME, Williams CS. Falls, injuries due to falls, and the risk of admission to a nursing home. *N Engl J Med.* 1997;337(18):1279-1284. https://doi.org/10.1056/NEJM199710303371806

5. Cumming RG, Salkeld G, Thomas M, Szonyi G. Prospective study of the impact of fear of falling on activities of daily living, SF-36 scores, and nursing home admission. *J Gerontol A Biol Sci Med Sci.* 2000;55(5):M299-305. https://doi.org/10.1093/gerona/55.5.m299
6. Cameron ID, Dyer SM, Panagoda CE, et al. Interventions for preventing falls in older people in care facilities and hospitals. *Cochrane Database Syst Rev.* 2018;9(9):Cd005465. https://doi.org/10.1002/14651858.CD005465.pub4

7. Cumming RG, Sherrington C, Lord SR, et al. Cluster randomised trial of a targeted multifactorial intervention to prevent falls among older people in hospital. *BMJ.* 2008;336(7647):758-760. https://doi.org/10.1136/bmj.39499.546030.BE

8. Hitcho EB, Krauss MJ, Birge S, et al. Characteristics and circumstances of falls in a hospital setting: a prospective analysis. *J Gen Intern Med.* 2004;19(7):732-739. https://doi.org/10.1111/j.1525-1497.2004.30387.x

9. Sahota O, Drummond A, Kendrick D, et al. REFINE (REducing Falls in In-patieNt Elderly) using bed and bedside chair pressure sensors linked to radio-pagers in acute hospital care: a randomised controlled trial. *Age Ageing.* 2014;43(2):247-253. https://doi.org/10.1093/ageing/aft155

10. Shorr RI, Chandler AM, Mion LC, et al. Effects of an intervention to increase bed alarm use to prevent falls in hospitalized patients: a cluster randomized trial. *Ann Intern Med.* 2012;157(10):692-699. https://doi.org/10.7326/0003-4819-157-10-201211200-00005

11. Xu H, Li P, Yang Z, et al. Construction and application of a medical-grade wireless monitoring system for physiological signals at general wards. *J Med Syst.* 2020;44(10):182. https://doi.org/10.1007/s10916-020-01653-z
12. Ranasinghe DC, Shinmoto Torres RL, Hill K, Visvanathan R. Low cost and batteryless sensor-enabled radio frequency identification tag based approaches to identify patient bed entry and exit posture transitions. *Gait Posture*. 2014;39(1):118-123. https://doi.org/10.1016/j.gaitpost.2013.06.009

13. Visvanthan R, Ranasinghe DC, Wilson A, et al. 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. *Inj Prev*. 2019;25(3):157-165. https://doi.org/10.1136/injuryprev-2017-042507

14. Dykes PC, Carroll DL, Hurley A, et al. Fall prevention in acute care hospitals: a randomized trial. *JAMA*. 2010;304(17):1912-1918. https://doi.org/10.1001/jama.2010.1567

15. Australian Commission on Safety and Quality in Healthcare. *Preventing falls and harm from falls in older people: best practice guidelines for Australian hospitals*. Commonwealth of Australia;2009. Accessed 1st June 2021 <https://www.safetyandquality.gov.au/sites/default/files/migrated/Guidelines-HOSP1.pdf>.

16. The New South Wales Clinical Excellence Commission. *CEC Falls audit tool-ward level*. Accessed 1st June 2021 <https://docsbay.net/cec-falls-audit-tool-ward-levelaudit-no>.
17. Haines TP, Massey B, Varghese P, Fleming J, Gray L. Inconsistency in classification and reporting of in-hospital falls. *J Am Geriatr Soc.* 2009;57(3):517-523. 
https://doi.org/10.1111/j.1532-5415.2008.02142.x

18. Morello RT, Barker AL, Ayton DR, et al. Implementation fidelity of a nurse-led falls prevention program in acute hospitals during the 6-PACK trial. *BMC Health Serv Res.* 2017;17(1):383. https://doi.org/10.1186/s12913-017-2315-z

19. World Health Organization. *WHO Global Report on falls prevention in older age.* Geneva: World Health Organization; 2007. Accessed 1st June 2021 <https://extranet.who.int/agefriendlyworld/wp-content/uploads/2014/06/WHO-Global-report-on-falls-prevention-in-older-age.pdf>.

20. Hill AM, Hoffmann T, Hill K, et al. Measuring falls events in acute hospitals-a comparison of three reporting methods to identify missing data in the hospital reporting system. *J Am Geriatr Soc.* 2010;58(7):1347-1352. https://doi.org/10.1111/j.1532-5415.2010.02856.x

21. Campbell AJ, Robertson MC, Gardner MM, Norton RN, Tilyard MW, Buchner DM. Randomised controlled trial of a general practice programme of home based exercise to prevent falls in elderly women. *BMJ.* 1997;315(7115):1065-1069.
https://doi.org/10.1136/bmj.315.7115.1065
• 22. Schwenk M, Lauenroth A, Stock C, et al. Definitions and methods of measuring and reporting on injurious falls in randomised controlled fall prevention trials: a systematic review. *BMC Med Res Methodol.* 2012;12:50. https://doi.org/10.1186/1471-2288-12-50

• 23. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis.* 1987;40(5):373-383. https://doi.org/10.1016/0021-9681(87)90171-8

• 24. Timmons S, Vezridis P, Sahota O. Trialling technologies to reduce hospital in-patient falls: an agential realist analysis. *Sociol Health Illn.* 2019;41(6):1104-1119. https://doi.org/10.1111/1467-9566.12889

• 25. Meyer G, Köpke S, Haastert B, Mühlhauser I. Comparison of a fall risk assessment tool with nurses' judgement alone: a cluster-randomised controlled trial. *Age Ageing.* 2009;38(4):417-423. https://doi.org/10.1093/ageing/afp049

• 26. Teh RC, Visvanathan R, Ranasinghe D, Wilson A. Evaluation and refinement of a handheld health information technology tool to support the timely update of bedside visual cues to prevent falls in hospitals. *Int J Evid Based Healthc.* 2018;16(2):90-100. https://doi.org/10.1097/XEB.0000000000000129
27. Campbell EM, Sittig DF, Guappone KP, Dykstra RH, Ash JS. Overdependence on technology: an unintended adverse consequence of computerized provider order entry. *AMIA Annu Symp Proc.* 2007;2007:94-98.

28. Bhasin S, Gill TM, Reuben DB, et al. A randomized trial of a multifactorial strategy to prevent serious fall injuries. *N Engl J Med.* 2020;383(2):129-140. https://doi.org/10.1056/NEJMoa2002183

29. Dodd S, White IR, Williamson P. Nonadherence to treatment protocol in published randomised controlled trials: a review. *Trials.* 2012;13:84.

30. Boroojerdi B, Ghaffari R, Mahadevan N, et al. Clinical feasibility of a wearable, conformable sensor patch to monitor motor symptoms in Parkinson's disease. *Parkinsonism Relat Disord.* 2019; 61: 70-76. https://doi.org/10.1016/j.parkreldis.2018.11.024

31. Pickham D, Berte N, Pihulic M, Valdez A, Mayer B, Desai M. Effect of a wearable patient sensor on care delivery for preventing pressure injuries in acutely ill adults: A pragmatic randomized clinical trial (LS-HAPI study). *Int J Nurs Stud.* 2018;80:12-19. https://doi.org/10.1016/j.ijnurstu.2017.12.012
Figure 1: The sensor diameter and the sensor casing dimension

Figure 2: CONSORT diagram
Table 1: Patient characteristics

|                                      | Control (N=1995) | Intervention (N=1244) | Total (N=3239) |
|--------------------------------------|------------------|------------------------|----------------|
| Age, years (mean (SD))               | 81.9 (8.3)       | 84.0 (7.9)             | 82.7 (8.2)     |
| Female (n [%])                       | 1074 (54%)       | 716 (58%)              | 1790 (55%)     |
| Living in the community pre hospitalization (n [%]) | 1772 (89%)       | 1196 (96%)             | 2968 (92%)     |
| Charlson’s Co-Morbidity Index Score (median (IQR))* | 2 [1-4]          | 2 [1-4]                | 2 [1-4]        |
| Proportion with dementia or delirium (n [%])**^ | 582 (30%)        | 422 (37%)              | 1004 (32%)     |
| Admitted with falls with or without fractures (n [%])**^ | 441 (23%)        | 470 (41%)              | 911 (29%)      |
| Hospital length of stay, days (median [IQR]) * | | | |
| Total                                 | 11 [7-18]        | 16 [11-24]             | 13 [8-21]      |
| SA GEM                                | 17 [12-27]       | 19 [13-28]             | 18 [13-27]     |
| WA GEM                                | 15 [11-22]       | 15 [11-21]             | 15 [11-21]     |
| WA Gen Med                            | 9 [6-14]         | 9 [7-15]               | 9 [6-14]       |
| Death during admission (n [%])**      | 107 (5%)         | 18 (2%)                | 125 (4%)       |
| Discharge destination (n [%])         | | | |
| Community                             | 1013 (52%)       | 606 (53%)              | 1619 (52%)     |
| Residential aged care (permanent)     | 193 (10%)        | 62 (5%)                | 255 (8%)       |
| Rehabilitation                        | 164 (8%)         | 104 (9%)               | 268 (9%)       |
| Transitional care program             | 173 (9%)         | 98 (9%)                | 271 (9%)       |
| Died in hospital                      | 107 (5%)         | 18 (2%)                | 125 (4%)       |
| Others                                | 312 (16%)        | 264 (23%)              | 576 (18%)      |

*Data was obtained from discharge summary and is not available for subjects who withdrew from study during admission and did not grant permission for further data collection. Remaining sample size is 1962 in Control and 1152 in Intervention.

^Excludes three subjects in Control for whom data was unavailable
### Table 2: Falls outcomes

|                          | Intervention (N=1152) | Control (N=1962) | Total (N=3114) | Adjusted rate ratio (95% CI), P Value |
|--------------------------|-----------------------|------------------|----------------|-------------------------------------|
| Falls, rate per 1000 participant bed days (95% CI) | 9.3 (7.0, 12.5)       | 6.6 (4.9, 9.0)   | 7.9 (6.8, 9.2) | 1.41 (0.85, 2.34), p=0.192          |
| N patients with falls    | 130                   | 128              | 258            |                                     |
| Injurious falls, rate per 1000 participant bed days (95% CI) | 2.5 (1.5, 4.1)       | 2.8 (1.7, 4.5)   | 2.6 (2.0, 3.3) | 0.90 (0.38, 2.14), p=0.807          |
| N patients with injurious falls | 50                    | 52               | 102            |                                     |
| N serious falls          | 8                     | 4                | 12             |                                     |
| N patients with serious falls | 8                     | 4                | 12             |                                     |
| Proportion of fallers, having one or more falls (95% CI) | 8.9 (6.8, 11.7)       | 6.0 (4.5, 8.0)   | 7.3 (6.3, 8.4) | OR = 1.54 (0.91, 2.61), p=0.105    |

* Rates, proportions and confidence intervals (CIs) are model-based estimates adjusted for ward, time period and Charlson’s Comorbidity Index.
### Table 3: Falls outcomes by ward

|                                | Intervention (N=1152) | Control (N=1962) | Total (N=3114) | Adjusted rate ratio (95% CI) | P     |
|--------------------------------|-----------------------|------------------|----------------|-----------------------------|-------|
| **Falls, rate per 1000**      |                       |                  |                |                             |       |
| participant bed days (95% CI) |                       |                  |                |                             |       |
| GEM                            | 7.1 (4.9, 10.4)       | 11.1 (6.0, 20.5) | 8.9 (7.1, 11.2)| 0.64 (0.27, 1.68)           | 0.002 |
| Gen Med                        | 14.3 (8.6, 23.7)      | 5.7 (4.4, 7.5)   | 9.1 (6.8, 12.1)| 2.13 (1.10, 4.10)           |       |
| **Injurious falls, rate per 1000** participant bed days (95% CI) |                       |                  |                |                             |       |
| GEM                            | 2.3 (1.3, 4.0)        | 6.7 (3.2, 14.1)  | 3.9 (2.9, 5.3) | 0.34 (0.11, 1.15)           | 0.018 |
| Gen Med                        | 3.4 (1.3, 8.8)        | 1.1 (0.6, 2.0)   | 2.0 (1.1, 3.5) | 2.23 (0.61, 7.90)           |       |
| **Proportion of fallers, having one or more falls (95% CI)** |                       |                  |                |                             |       |
| GEM                            | 8.2 (5.7, 11.6)       | 9.6 (5.5, 16.4)  | 8.9 (7.2, 11.0)| 0.84 (0.35, 2.19)           | 0.003 |
| Gen Med                        | 10.0 (6.1, 15.9)      | 4.3 (3.3, 5.6)   | 6.6 (5.0, 8.7) | 2.21 (1.09, 4.38)           |       |

*Rates, proportions and confidence intervals (CIs) are model-based estimates adjusted for time period and Charlson’s Comorbidity Index.

P is the p-value for the intervention by ward interaction.
4924 patients admitted to ward

1076 met ≥1 exclusion criteria

3848 patients met all inclusion criteria

608 were eligible but not enrolled
- 220 opted out (SA)
- 368 declined (WA)
- 20 other

3240 patients enrolled

1995 patients in control period (WA GEMU closed 22/12/17 to 16/4/18)

1245 patients in intervention period

0 excluded from ITT population

1 excluded from ITT population
- 1 withdrew consent and permission to use data

1995 in ITT population
- SA GEMU n=334
- WA GEMU n=331
- WA GM n=1330

1244 in ITT population
- SA GEMU n=699
- WA GEMU n=375
- WA GM n=170

33 without Charlson's Comorbidity Index
- the following withdrawn
  - 33, palliative care

92 without Charlson's Comorbidity Index
- the following withdrawn
  - 5, palliative care
  - 61, patient's choice
  - 22, staff decision
  - 1, patient & staff choice
  - 3, other reason

1962 included in primary analysis

1152 included in primary analysis

Note. ITT - Intention to Treat
GM - General Medicine
GEMU - Geriatric Evaluation and Management Unit
SA - South Australia
WA - Western Australia