

# BMJ Open Establishing the effectiveness, cost-effectiveness and student experience of a Simulation-based education Training program On the Prevention of Falls (STOP-Falls) among hospitalised inpatients: a protocol for a randomised controlled trial

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## ABSTRACT

**Introduction:** Simulation-based education (SBE) is now commonly used across health professional disciplines to teach a range of skills. The evidence base supporting the effectiveness of this approach for improving patient health outcomes is relatively narrow, focused mainly on the development of procedural skills. However, there are other simulation approaches used to support non-procedure specific skills that are in need of further investigation. This cluster, cross-over randomised controlled trial with a concurrent economic evaluation (cost per fall prevented) trial will evaluate the effectiveness, cost-effectiveness and student experience of health professional students undertaking simulation training for the prevention of falls among hospitalised inpatients. This research will target the students within the established undergraduate student placements of Monash University medicine, nursing and allied health across Peninsula Health acute and subacute inpatient wards.

**Methods and analysis:** The intervention will train the students in how to provide the Safe Recovery program, the only single intervention approach demonstrated to reduce falls in hospitals. This will involve redevelopment of the Safe Recovery program into a one-to-many participant SBE program, so that groups of students learn the communication skills and falls prevention knowledge necessary for delivery of the program. The primary outcome of this research will be patient falls across participating inpatient wards, with secondary outcomes including student satisfaction with the SBE and knowledge gain, ward-level practice change and cost of acute/rehabilitation care for each patient measured using clinical costing data.

**Ethics and dissemination:** The Human Research Ethics Committees of Peninsula Health (LRR/15/PH/11) and Monash University (CF15/3523-2015001384) have approved this research. The participant information and

consent forms provide information on privacy, storage of results and dissemination. Registration of this trial has been completed with the Australian and New Zealand Clinical Trials Registry: ACTRN12615000817549. This study protocol has been prepared according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist.

**Trial registration number:** ACTRN12615000817549; Pre-results.

## INTRODUCTION

Falls are among the most common and costly threat to patient safety in healthcare institutions. Rates as high as 20 falls per 1000 patient-days have been documented across a range of patient diagnosis groups, with higher proportions among those with cognitive impairment.<sup>1-5</sup> Approximately 30% of in-hospital falls result in physical injury, while fractures are a consequence in ~2%.<sup>1-5</sup> Fall-related fractures among hospital inpatients result in higher rates of mortality, increased length of stay in hospital and poorer rehabilitation outcomes than equivalent injury among community dwellers.<sup>6</sup> Multicentre studies from Australia have estimated the additional costs of those who fall in hospital to be between \$A7821 (when considering acute wards only)<sup>7</sup> and \$A24 927 (when considering acute and subacute/rehabilitation wards) more than those who do not fall.<sup>8</sup>

There are a number of falls prevention techniques employed widely across healthcare settings, each with little or no evidence

to support their use. One exception is providing one-to-one falls prevention education to patients, which has been repeatedly demonstrated to reduce patient falls when provided in isolation or as a part of broader, multifactorial intervention programmes.<sup>1 5 9 10</sup> A limitation with this approach is that it is likely to have questionable cost-effectiveness in settings where there is rapid turnover of patients, and there is a need to identify optimal models for cost-effective delivery of this intervention.<sup>5</sup> All previous trials of this approach have used paid staff in addition to those already present on the ward to deliver their programmes. None have yet investigated whether existing ward staff, volunteers or students could deliver them effectively.

Simulation-based education (SBE) is increasingly used as a means of teaching a range of clinical skills to health professionals and students. There are a variety of simulation modalities commonly employed in healthcare environments, including simple procedural training models, manikins and simulated patients (SPs).<sup>11</sup> Patient outcomes have been improved by SBE in technical procedure-based tasks such as catheter insertion and airway management.<sup>12</sup> SPs are well individuals trained to portray patients and offer feedback to health professionals or students on their performance.<sup>12 13</sup> SPs play a key role in raising the profile of patient perspectives, and they are characterised by their ability to demonstrate a range of emotional and mental states adding realism and facilitating participant engagement.<sup>14 15</sup>

SBE can be relatively expensive with manikins, tutors and environment set-up costs exceeding \$100 000. The real cost of SBE is often infrequently reported within studies of effectiveness.<sup>16</sup> There is a range of non-procedure-based skills learned through SBE such as interpersonal communication techniques that do not have a strong evidence base in improving the quality and safety of healthcare. Although SPs may not be as costly as manikin-based options, the relative cost of developing and delivering SP-based programmes needs to be investigated in order to justify these costs through improved patient outcomes.

There are two aims of this study: first, to test the effectiveness of an SP-based programme to train health professional students to prevent falls among hospital inpatients

and second, to undertake a health economic analysis of this training programme as a falls prevention intervention. This research is important because it will provide evidence of the efficacy of teaching communication skills and a falls prevention strategy to health professional students. It will determine whether unpaid students can effectively provide this type of education programme to inpatients with the purpose of preventing falls.

## METHODS AND ANALYSIS

### Study protocol

This study protocol was finalised on 25 May 2015. The revision chronology is displayed in [table 1](#) and on the Australian and New Zealand Clinical Trials Registry website.

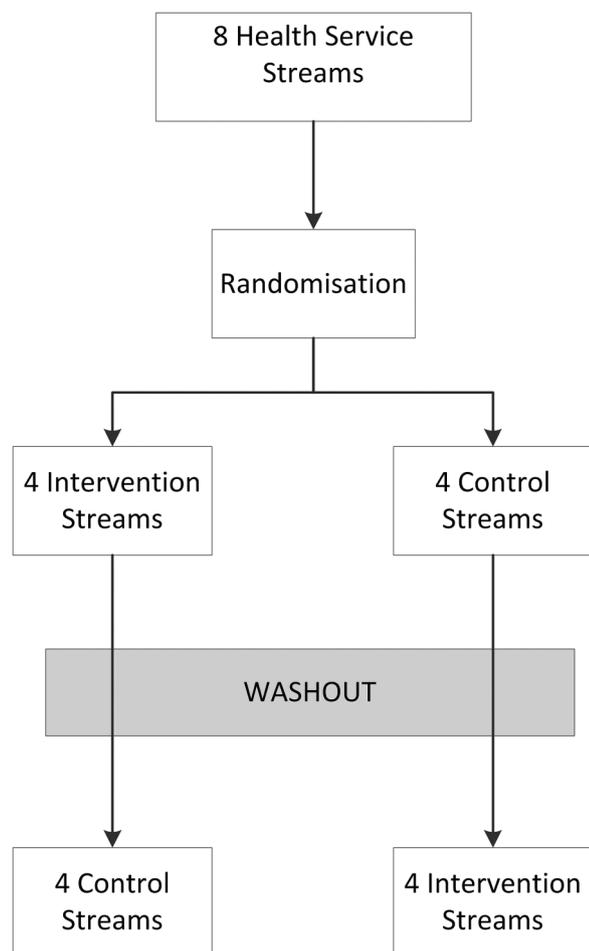
### Study design

This is a cluster, cross-over randomised controlled trial with a concurrent economic evaluation (cost per fall prevented). The trial will involve random allocation of eight health service streams within wards at Peninsula Health, Victoria, Australia, to either a 'simulation education/intervention' condition or a 'no education/control' condition. There will be a 4-month data collection period in July–December of 2015, a washout period over the December–March period of the first/second year of the project, and another 4-month data collection period from April to July 2016 in the second year of the project. The second data collection period will reverse the intervention/control allocation status of each stream so that each stream will have one 4-month control period and one 4-month intervention period ([figure 1](#)).

Use of the cluster, cross-over randomised controlled trial design minimises the risk of ward-to-ward variability in patient case mix and falls reporting cultures<sup>17</sup> from influencing results. Targeting of health professional students rather than staff was deemed necessary to enable the intervention to be washed out from the study wards. Timing the study washout period to coincide with the end of the academic year in Australia, and the commencement of the following academic year, also maximises washout of the intervention from the student

**Table 1** Protocol revision chronology

Version	Date	Action
1.0	4 May 2015	Original protocol
1.1	13 May 2015	Amendment 1: Clarifications of outcome measures, data retrieval methods from wards, sample size calculation and qualitative data analysis
1.2	18 May 2015	Amendment 2: Inclusion of background information of the patient modules and their relationship to the healthcare setting, added information on current hospital fall rates within sample size calculation
1.3	25 May 2015	Amendment 3: Clarification of secondary outcome measures collected at presimulation, postsimulation, postplacement for students on intervention wards and postplacement only for students on control wards



**Figure 1** Randomisation of health streams.

health professional participant group. Restricting the data collection period to 4 months in each year meant that students exposed to the intervention could avoid being placed in streams/wards that are in the control group at that time while still be exposed to the range of clinical experiences necessary for their education within that year.

### Participants and setting

All Monash University students studying nursing, medicine, physiotherapy, occupational therapy, social work and dietetics, which have been allocated a clinical placement on the intervention/control wards at Peninsula Health over the course of the first 2 years of the project, will be recruited as part of this research. Peninsula Health has provided ~800 medical, nursing and allied health student placements over the past year. All students allocated to an intervention ward will be trained in the Safe Recovery program as a part of their clinical education experience, unless their placement crosses over into a control ward. The Safe Recovery program seeks to enhance patient knowledge and understanding of the problem of falls, build the therapeutic alliance between patients and their healthcare professionals and enhance patients' ability to manage their emotions

which might lead to risk-taking behaviours. Making patients the central decision-maker in developing strategies to improve their safety is designed to empower them and actively engage them in falls prevention efforts. Approximately 400 students will be eligible and trained to participate in the educational evaluation component of the study. The treatment streams represent areas of care that may result in patients being admitted to one or more physical wards across Peninsula Health, and will include:

1. Gastrointestinal/General Medicine
2. Neurological/General Medicine
3. Oncology/Endocrinology
4. Orthopaedics/Plastics
5. Cardiology
6. Respiratory/Renal
7. Rehabilitation A
8. Rehabilitation B

Streams and wards that have low fall rates such as maternity and intensive care, or focus on specific patient populations unlikely to benefit from the Safe Recovery program such as paediatrics and mental health, are excluded on the basis of (i) length of stay too short for face-to-face falls prevention intervention to be economically efficient<sup>8</sup> and (ii) the Safe Recovery program not amenable to maternity, mental health and paediatric populations.

There will be multiple participant groups in this research who will be subject to different methods of evaluation. It is an unusual characteristic in simulation research that the group to whom the intervention is applied (health professional students) is different from the group from which the primary outcome is measured (patients treated within participating streams).

### Participant group 1: Patients treated within participating streams

This is the group from which the primary outcome will be measured. Routinely collected administrative data (eg, length of stay, clinical costing) for outcome measures relevant to this project for patients who receive treatment within participating study streams. As with previous investigations of falls prevention interventions that have been randomised at the ward level, these patients will not be directly recruited into this trial,<sup>9 18</sup> rather a research assistant (RA) will collect this information daily via interviews with nursing unit managers, patient files or electronic incident management systems.

### Participant group 2: Health professional students on clinical placement at intervention streams

This is the group to whom the intervention will be provided. Participating professional disciplines will include medical, nursing, physiotherapy, occupational therapy, dietetics and social work students who are the vast majority of health professional student placements at Peninsula Health. Students will be identified and contacted through the student coordinators who hold the

placement lists and can engineer changes to placement locations within Peninsula Health. This will allow the research team to ensure that students exposed to the intervention do not contaminate control streams. Each student on placement during the intervention and control periods within each stream will be invited to participate in the student-specific data collection aspects of this project.

### Intervention

The SBE program for this trial is developed as a 4-hour workshop to be undertaken within the first week of each student's clinical placement. The workshop will be provided in addition to usual practice educational seminars and events that take place at Peninsula Health and on its individual wards. This workshop will aim to teach theory and evidence of a falls prevention education programme to a multiprofessional audience while allowing students to develop patient-centred communication and interpersonal skills.

The workshop will use the Safe Recovery patient education program as the basis of its material. This program is one of the most widely investigated one-to-one patient education programmes for the prevention of falls in hospitals.<sup>1 5 8</sup> The Safe Recovery program is based on the Health Belief Model of behaviour change that has been adapted over various iterations to incorporate multimedia delivery of materials. It focuses on improving interpersonal communication between patients and staff, and makes the patient the central decision-maker in falls prevention actions they participate in. In this study, patient education on falls and falls prevention will be individually provided in face-to-face consultations with base information provided via a workbook or video to patients who have no or mild cognition issues. This base information covers the topics of (i) the problem of falls, (ii) how, where, when and why falls occur and (iii) the three simple steps to stopping falls. These materials ask patients to engage in a 'premortem' where they imagine that they were to fall while in hospital, then consider how, when, where and why they think it would most likely happen. Patients then reflect on whether they think this premortem corresponds to the data presented to the patient in the video where data relating to how, when, where and why falls occur were presented. The conversation between Safe Recovery program provider and patient will enable the patient to identify their personal risk-taking behaviours in hospital that may lead to a fall. The patient will be supported to set goals on how to reduce their own risk. Strategies will be employed to enhance patient motivation to adhere to these goals such as assisting patients to align goal behaviours with broader personal goals. For example, the patient's broader personal goal may be to return home to care for their pet. The Safe Recovery program provider would therefore discuss with the patient how not walking to the toilet without assistance will help them to

not fall over and hurt themselves, allowing them to return home to see their pet sooner. Safe Recovery program providers then revisit the patient within 3 days of goal setting to review and reset goals if needed and to promote patient accountability to goal achievement.

This program has been shown to reduce falls and fall-related injuries by over 40% in a state-wide roll-out stepped wedge trial in subacute/rehabilitation hospital settings in Western Australia.<sup>9</sup> An earlier randomised trial of this program reported a reduction of falls among cognitively intact patients in acute and rehabilitation units.<sup>1</sup> Prior to this, a formative version was used as part of a broader, multifactorial prevention programme in the first hospital-based falls prevention trial to demonstrate that falls could be prevented in this setting.<sup>1</sup>

The training workshops will be implemented by two facilitators with backgrounds in education, nursing and allied health. The Safe Recovery program has not been modified in any way for the students. Students will be provided with specific content related to falls, such as how, when and why falls occur, and current research on falls prevention. A series of prerecorded videos of a clinician implementing the program with an SP will be shown to demonstrate the three stages of the Safe Recovery program. Students will then participate in three 'live' simulations with an SP in a dedicated simulated ward environment, while the remaining students observe. The simulations will enable familiarly with the steps of the program for a patient who is 'cognitively intact' and then provide an opportunity to explore alternative communication strategies when implementing the program for a patient who displays mild delirium. In addition to the simulations, interactive discussions and practical skills role play will provide each student with the opportunity to implement the program with a student peer, and receive feedback from peers and facilitators. A maximum of 15 students will attend each workshop and where possible there will be a mix of professions. This is to ensure that there is inclusivity and in-depth discussion throughout the workshop. Students will be provided with a take-home program guide, a lanyard with prompts of the program steps, patient goal sheets and alert 'stickers' for recording in the patient notes when the program has been implemented.

Once the students are on the intervention wards, they will select appropriate patients for the Safe Recovery program based on the education they have received. If necessary, student supervisors will allocate a time each day to encourage students to regularly offer the program to inpatients. Once the program has been provided, the student will put an alert sticker within patient's health record, as well as on the Falls Risk Assessment Tool (FRAT). Regular follow-ups will occur as required to review patient goals. Students will also be regularly prompted by supervisors to undertake the intervention with suitable patients.

## Control

Health professional students placed in streams/wards that are allocated to the control condition will be exposed to usual practice educational opportunities at Peninsula Health. These may include screening for falls risk, attendance at a staff in service or implementation or ward-based falls prevention strategies involving the use of low-low beds or alarms.

## Outcome measures

### Primary outcomes

There are three primary outcomes conventionally employed for hospital-based falls prevention trials:<sup>1 9 19 5</sup>

1. Rate of falls per 1000 occupied bed days;
2. Proportion of patients who experience one or more falls;
3. Rate of falls resulting in serious injury<sup>20</sup> or death per 1000 occupied bed days.

Data on patient falls will be collected daily by the RA using computerised hospital incident reporting systems, hand searching of medical records and daily interviews with nurse unit managers. It has previously been documented that falls can be under-reported in hospital incident reporting systems by 25–50%, necessitating the use of multiple data collection strategies.<sup>21 22 23</sup> A trained RA blinded as to whether the fall occurred during the intervention or control phase of the trial will subsequently apply the WHO definition of a fall<sup>24</sup> in classifying all reported falls. This is necessary as some hospital staff report ‘near misses’ as falls on their incident reporting systems even though they do not meet the WHO definition of a fall. Data will be collected for two 16-week periods and the outcomes of all falls documented for 12 months post trial.

### Secondary outcome measures

‘Change in practice’ will be measured using the end-of-placement survey where students will be asked to report the number of occasions that they provided three different elements of the Safe Recovery program.

1. Explained to a patient the nature of falls in hospital (when, where and why they occur).
2. Assessed a patient’s self-perceived risk of falling while in hospital.
3. Assisted a patient to set their own goals to reduce their risk of falling while in hospital.

Data on barriers and enablers to students providing elements of the Safe Recovery program while on clinical placement will be collected via end-of-placement and end-of-study group interviews conducted with students. End-of-study group and key informant interviews with other health professionals will also be conducted to determine if usual care staff observed a difference in behaviour by students when their stream was in an intervention period compared with a control period.

‘Change in knowledge, skills and attitudes’ will be measured using self-report surveys which will ask students about their knowledge of when/where falls most

commonly occur, as well as their knowledge of the evidence supporting some of the most commonly employed falls prevention strategies. They will also be asked if they believe these strategies should be used. The strategies are: bed/chair alarms (two trials showing no benefit),<sup>25 26</sup> bed rails (no trials), patient sitters (no trials), face-to-face patient falls prevention education (three trials showing benefit),<sup>1 9 5</sup> giving patients falls prevention educational material but not having face-to-face education (one trial showing no benefit)<sup>1</sup> and low-low beds (one trial showing no benefit).<sup>18</sup> Finally, student participants will also be asked how confident they are to perform the three activities above using a 0–10 rating scale. Students will answer these questions at three time periods: before the training session, immediately after the training session and after their clinical placement.

At this time, students will be asked to register their interest in attending an end-of-placement group interview. Twelve students will be interviewed, and data collected on their attitudes to falls and their prevention in hospital, and their perception of the adequacy of their knowledge and skills to help prevent falls.

‘Learner reaction to the experience’ will be measured using the immediate postintervention student survey and end-of-placement group interviews with students. Participants will be asked to rate to what extent each learning objective was met and how much each simulated learning environment technique employed contributed to understanding the learning objectives. Open-ended questions will be used to identify the strengths and weaknesses of the intervention workshop and simulation techniques employed.

Additional secondary outcomes will focus on patient flow (length of stay), discharge destination (discharge to previous residence, newly admitted to residential aged care, other), readmission to hospital (within 12 months of index admission), cost of services received (from internal hospital costing data) and the labour and capital costs of providing the intervention.

A summary of the outcome measures and time points of data collection is displayed in [table 2](#).

## Procedure

The participating healthcare streams will be matched into pairs on the basis of the number of students within the stream. One stream within each pair will then be randomly allocated to the group that receives the simulated training in year 1, while the remaining member of the pair will receive the simulated training in year 2. The primary investigator will send paired mock codes linked to each stream to a separate investigator who will use a computerised random number generator to allocate the mock codes to each group. These allocations will then be sent back to the primary investigator so that the allocations to streams can be revealed. The Safe Recovery program will be redeveloped for the current research, to be suitable for delivery in an interprofessional one-to-many SBE program. It will use the

**Table 2** Primary and secondary outcomes with corresponding time points

Group	Outcome	Method of data collection	Time point
Hospital inpatients	Rate of falls per 1000 occupied bed days	Generated report from the local Victorian health incident management system for intervention wards in addition to information collected during weekday attendance at nursing handover	End of each 16-week period of falls data collection across participating wards
	Proportion of patients who experience one or more falls	Generated report from the local Victorian health incident management system for intervention wards in addition to information collected during weekday attendance at nursing handover	End of each 16-week period of falls data collection across participating wards
	Rate of falls resulting in serious injury or death (serious injury defined as major injury requiring surgery, casting, further examination, eg, for a neurological injury)	Generated report from the local Victorian health incident management system for intervention wards in addition to information collected during weekday attendance at nursing handover	End of each 16-week period of falls data collection across participating wards
	Cost of acute/rehabilitation care	Clinical costing data for all patients on intervention and non-intervention wards	End of each 16-week period of falls data collection across participating wards
	Length of stay of every patient on the intervention and non-intervention wards	Data extraction from hospital records	End of each 16-week period of falls data collection across participating wards
Students	Knowledge gain of undergraduate students who have undertaken the falls prevention simulation training	Custom-developed survey tool	Post simulation training
	Self-rated student confidence to engage in falls prevention activities and discussions with patients	Custom-developed survey tool	Data will be collected at two time points, post simulation training and post student placement
	Self-reported frequency of falls prevention engagements between student and patient	Custom-developed survey tool	Post student placement
	Learner experience of simulation training and the experience of undertaking falls prevention activities on intervention wards	Semistructured student interviews	Post student placement

techniques of standardised scenarios with an SP (actor) who is (i) cognitively intact and (ii) mildly cognitively impaired. Training sessions will see students undertake guided reflection, role modelling by an expert in the administration of the Safe Recovery program, facilitated discussions and video lectures. It will be packaged as a half-day workshop that can be delivered by one or two facilitators, for up to 15 students with one SP.

### Data analysis

Patients exposed to streams/wards from the intervention and control conditions will have their data censored from the point they left their original condition. The rate of falls will be compared between intervention and control periods using multilevel, mixed-effects generalised linear models treating patient and health service stream as a random effect, and the intervention as a fixed effect. Fall rates within each health service area will be seasonally adjusted using data from the previous 2 years. Fall and injury rates will be examined using a

negative binomial distribution, while the proportion of patients who become fallers will be examined using a Bernoulli distribution. An alternate analysis strategy will be employed if there are computational problems with this approach (such as starting values not being feasible) which cannot be resolved using proscribed strategies (Stata Statistical Software: Release 13 [program]. College Station, TX: StataCorp LP, 2013). In this circumstance, negative binomial regression with clustering of data by stream will be used to examine falls and injurious falls rate data, while logistic regression with clustering of data by stream will be used to examine the proportion of patients who become fallers. Adjustment for historical data will still be used.

We will follow current recommendations for analysis of cross-over trials that contain washout and not statistically test for cross-over effects.<sup>27</sup> Sensitivity analyses will be conducted excluding patients who presented to hospital during the data collection period and appeared on intervention and control wards.

Secondary outcomes will be compared between intervention and control periods using a similar approach. Quantitative student knowledge, skills and attitude outcomes will be compared between groups, and within the intervention group using pairwise contrasts between pre-intervention, immediately postintervention and end-of-placement assessments.

Qualitative data will be analysed thematically.<sup>28</sup> The relationship between the interviewer/s and interviewee/s will be noted and documented at the time of the interview, and considered during analysis. Researcher reflexivity will be documented, and strategies to achieve trustworthiness of data will be implemented by means of a member checking and ensuring an audit trail is traceable at all stages of the study.<sup>29</sup>

The economic evaluation will calculate the incremental cost per fall prevented from using the falls prevention SBE program (simulation learning package). Costs to be included will be the labour and capital costs of providing the program to students and patients, and costs of healthcare provision (clinical costing data). Decision tree analytic modelling will be used to conduct a net benefit analysis based on previously developed estimates of the cost of falls in hospitals.<sup>8</sup> Subgroup sensitivity analyses will be conducted for acute and subacute wards. Sensitivity analyses will also be conducted that ascribe an opportunity cost to student time spent providing the Safe Recovery program to patients. This is a contentious issue as it can be argued that providing the Safe Recovery program to patients will provide students with learning opportunities that is a valuable use of their clinical education time. They will have opportunity to understand patient frustrations experienced during their stay that lead to risk-taking behaviour<sup>30</sup> and learn how to actively manage them through participation in this program.

Conventional power analysis formulae have not previously been developed for this multilevel, cross-over design. We have therefore used a conservative cluster trial power analysis approach that considers only cluster (stream)-level data.<sup>31</sup> Individual-level falls data are normally considered to be count data analysed using a negative binomial distribution. However, these data take on Gaussian-like properties when merged across patients within streams over monthly periods. Treating stream-level outcomes as continuous and using a stream-level approach allow us to estimate sample size requirements for our study. We have calculated the sample size requirements for a conventional randomised trial that has a baseline fall rate of 7.2 falls per month per stream, an SD between streams of 6.7, an SD within streams of 3, a correlation of  $r=0.7$  for monthly falls measurements within a stream and 4 monthly follow-up measures per stream. This identified that 42 clusters per group (84 clusters in total) were required when using an analysis of covariance (ANCOVA)-style analysis approach adjusting for pretrial data. We then applied the cross-over design efficiency (DE) conversion factor of 12 to find that 8 clusters in

total were required for equivalent power in a cross-over design (acknowledging that the total number of monthly trial measurements per cluster needs to be doubled from 4 to 8 per stream). The DE conversion factor<sup>32</sup> calculation formula used was  $DE = (\text{between-stream variance} + \text{within-stream variance}) / (0.5 \times \text{within-stream variance})$ , where between-stream variance = 44.89 and within-stream variance = 9 falls per month based on the previous 2-year local data.

The author group forms the data monitoring committee will meet on a monthly basis throughout the intervention phases during the trial. A representative from the funding body, Peninsula Health management, staff, student and community representative will form the trial steering committee who will meet monthly during the intervention stages to ensure consistent communication and adherence to trial procedures.

### Adverse events

Adverse events related to students and falls will be measured and recorded through the study. It is not anticipated that this research design is likely to result in adverse events related to students undertaking the Safe Recovery program. Standard student supervision procedures will be followed at all times as per current Peninsula Health Operational Practice Guidelines. An adverse event will be recorded where a student is directly involved in a patient fall on an intervention or control ward. The current standard practice for any adverse event occurring with a student is for the senior staff member to be immediately notified. As there will be daily communication with senior staff where students are placed, this will be recorded and reported to the Human Research Ethics Committee. There will also be adverse event data collected if a staff member is directly involved or related to a fall on ward.

### Funding

Funding for this trial has been received from a 'Simulation Patient Safety Research' project funding grant from the Department of Health and Human Services, Victoria, Australia (ID3108). The Department of Health and Human Services, Victoria, Australia, approved the final protocol, and no restrictions have been placed on dissemination of findings.

### Ethics and dissemination

The Human Research Ethics Committees of Peninsula Health (LRR/15/PH/11) and Monash University (CF15/3523-2015001384) have approved this research. The participant information and consent forms can be found in the online supplementary files 1–3. These give information on privacy, storage of results and dissemination. Registration of this trial has been completed with the Australian and New Zealand Clinical Trials Registry: ACTRN12615000817549. This study protocol has been prepared according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist.<sup>33</sup>

## DISCUSSION

It is anticipated that this study will generate knowledge of importance to the following fields:

**SBE:** This project would be the first to examine the effectiveness of an interdisciplinary, SBE program for non-procedural skills on a patient safety outcome that is delivered across multiple streams of a health service. It will also contain the first economic evaluation in this field based on trial data.

**Falls prevention in hospitals:** A critical gap in this field is identification of an approach that can be used to reduce falls across a health service in a cost-effective manner. Although previous work has demonstrated that the Safe Recovery program can be used to reduce falls in acute and subacute settings, previously employed models have not been cost-effective in wards with rapid turnover of patients. The proposed model for delivering the Safe Recovery program via health professional students offers potential to be a lower cost approach that may be an optimally cost-effective model.

**Translation of research findings into practice:** An outcome of this project will be the development of an SBE program to integrate the latest and most successful falls prevention approaches into clinical practice. Such a model will likely be readily transferable to other health service simulated learning environments and permit excellent reach into undergraduate health professional curricula across multiple disciplines.

It is also acknowledged that there are limitations within this health services research. While students will be provided with time and support to undertake the intervention, intervention fidelity is difficult to measure. Mitigation measures including student supervisors allocating time each day for students to perform the Safe Recovery program, and inviting student supervisors to observe a training session to better support their students will be used to engage all relevant parties to enhance student opportunity to deliver the Safe Recovery program while still meeting placement goals.

The research team are also aware of the barriers to interprofessional learning and SBE. While simulation is becoming less challenging to implement, it still relies on contextual situations and well-trained actors for role-playing scenarios. Barriers to interprofessional education are also acknowledged and the research team are aware that the roll-out of training across a whole service with varied undergraduate health placement timetables will be logistically challenging. Often the barriers to interprofessional education have been cited as being multifactorial: scheduling, attitude differences between educators and health professionals and student engagement and perceived value. These factors have the potential to impact the planned research within Peninsula Health and all members of the research team are mindful of these at each stage. To minimise the impact of these factors, tutors from all health professionals will be engaged and student supervisors will have access to educational materials and ongoing support from the

research team. There is also an established partnership between the healthcare service and education provider, and this project will be embedded within current orientation and education packages during placement.

There is the potential for researchers to adopt this trial design and SP-based education as an intervention to measure a broader range of patient outcomes. This is particularly of interest for non-procedural tasks related to patient safety. This trial design is an innovative way to undertake a large trial while pragmatically working with students. The ability to conduct the trial with a washout period over the change-over in academic year minimises contamination within the design. This design could be used to help investigate this type of question in many other areas.

## CONCLUSION

This research seeks to investigate if the simulation-based Safe Recovery program delivered by undergraduate healthcare students is an effective and cost-effective method to prevent falls. This has implications for hospitals and education providers.

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**Contributors** CW, K-AB, SM, DN, DK and TH conceived the study design, and all authors contributed to the study concept, drafting of the manuscript, critical revision and gave approval for the manuscript to be submitted.

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