PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Establishing the effectiveness, cost-effectiveness, and student experience of a Simulation-based education Training program On the Prevention of Falls (STOP-Falls) amongst hospitalised inpatients: A protocol for a randomised control trial.
AUTHORS	Williams, Dr Cylie; Bowles, Kelly-Ann; Kiegaldie, Debra; Maloney, Stephen; Nestel, Debra; Kaplonyi, Jessica; Haines, Terrence

VERSION 1 - REVIEW

REVIEWER	Prof Fatimah Lateef Dukes-NUS and Singapore general Hospital Singapore
REVIEW RETURNED	26-Nov-2015

GENERAL COMMENTS	1. This manuscript represents a very labourious read! even for a reviewer 2, It is too long and i have to read and turn the pages many times to search for results and what i want to know 3. the title was good and i expected to have a good focused manuscript when i saw it. This is an importnat area needing more objective studies as most in the literature are subjective ones 4. the parts on falls and simulation is not adequately explained as i did not get much besides education and briefing to patients?? 5. how was the variability in casemix in the varuious wards handled 6. How disd they handle wards with more elderly , or more of a certain type of patients or diagnoses? 7. the randomisation process: i did not get a clear idea? i read and re-read but it is nebulous to me . was there a selection pronciple? used. were there certain fall risks categories added or excluded? 8, there was a mention on communications to get the message across.. but how was this doen for those with communications issues eg dementia and this could excatly be the group prone to falls! 9. There should be a more succint Conclusion section 10. can the results be summarised as i got lost looking for them

REVIEWER	Dr Anne Tiedemann The George Institute for Global Health and University of Sydney Australia
REVIEW RETURNED	06-Mar-2016

GENERAL COMMENTS	This trial addresses a gap in research in the field of fall prevention. The protocol is well written and clear in it's methods and descriptions.

REVIEWER	Elise Omaki Johns Hopkins Center for Injury Research and Policy
REVIEW RETURNED	03-Apr-2016

GENERAL COMMENTS	This paper describes the protocol for a cluster cross-over randomized trial and cost-effectiveness study. The intervention aims to prevent inpatient falls by educating students assigned to clinical rotations in the "Safe Recovery" program using a simulated patient. Comments for the authors: The broad objective of this study is stated on page 5, but authors could be more specific with their statement about the research question. The "Safe Recovery" program was designed for and previously evaluated among patients. This protocol could benefit from a summary of that program and the results of its evaluation. Additionally, a more thorough explanation of the theory behind and the development of the intervention would be helpful. How has this been adapted for students? What are the expected competencies that students will walk away with? I found myself reading the secondary outcome measures section several times. The timing for the collection of the these measures is unclear. Authors mention surveys and interviews, but it was unclear to me when each would take place, which measures would be collected where and who would participate (all students, or just those in the intervention streams or a sub-sample?). On page 5, line 21 there is a typo -- "SBE can come be relatively expensive..."

VERSION 1 – AUTHOR RESPONSE

Comments	Response
Reviewer 1	
This manuscript represents a very labourious read! even for a reviewer. It is too long and i have to read and turn the pages many times to search for results and what i want to know. The title was good and i expected to have a good focused manuscript when i saw it. This is an importnat area needing more objective studies as most in the literature are subjective ones	We thank the reviewer for their time and wish to reiterate this is a protocol for a study, therefore are no results within this paper.
The parts on falls and simulation is not adequately explained as i did not get much besides education and briefing to patients??	The Safe Recovery program has been described in substantial detail in numerous previous papers that we have cited. We have increased our description of the Safe Recovery program to include a description of the theoretical underpinnings of the program, the process for provision, and the content of discussions. A detailed explanation of the simulation training session is provided on page 12, Paragraph 1.

How was the variability in casemix in the varuious wards handled 6. How disd they handle wards with more elderly , or more of a certain type of patients or diagnoses?	The cluster cross-over design inherently accounts for differences in case mix between wards through individual streams having both intervention and control periods. This is the great advantage of cross-over designs compared to parallel designs that do not involve cross-over.
The randomisation process: i did not get a clear idea? i read and re-read but it is nebulous to me . was there a selection pronciple? used. were there certain fall risks categories added or excluded?	We have provided a detailed description of the randomisation process on Pg 16. We randomised streams to intervention condition order, not individual patients. The stream was a ward or collection of wards under the same organizational unit and with similar patient types. Thus every patient admitted to a particular stream during a particular study period was allocated to the intervention condition that the stream was presently in. We used every stream in the health service with the exceptions of emergency, maternity and paediatrics. We excluded these streams on the basis of i) emergency patients have a length of stay too short for a face-to-face falls prevention intervention to be economically efficient, and ii) the safe recovery program is not amenable to maternity and paediatric populations. There was no recruitment of individual patients involved.
There was a mention on communications to get the message across.. but how was this doen for those with communications issues eg dementia and this could excatly be the group prone to falls!	Whilst no patient has been excluded from a student delivering the Safe Recovery Program on Falls Prevention, students are taught strategies for cognitively intact and for patients with mild cognitive delay. This program specifically excludes patients with dementia. This has been included within the manuscript within the description of the program and the theoretical development.
There should be a more succint Conclusion section 10. can the results be summarised as i got lost looking for them	At present there are no results from this study. The article is on the protocol for the study being undertaken.
Reviewer 2	
This trial addresses a gap in research in the field of fall prevention. The protocol is well written and clear in it's methods and descriptions.	We thank the reviewer for their time in reviewing the article.
Reviewer 3	
The broad objective of this study is stated on page 5, but authors could be more specific with their statement about the research question.	The aims of the study have been re-worded to: *"There are two aims of this study: Firstly, to test the effectiveness of a SP-based program to train health professional students to prevent falls amongst hospital inpatients and secondly, to undertake a health economic analysis of this training program as a falls prevention intervention."*

The "Safe Recovery" program was designed for and previously evaluated among patients. This protocol could benefit from a summary of that program and the results of its evaluation. Additionally, a more thorough explanation of the theory behind and the development of the intervention would be helpful.	The theory and history of the Safe Recovery program has been included within the manuscript on page 9.
How has this been adapted for students? What are the expected competencies that students will walk away with?	The program has not been modified for student delivery, this has been reiterated now on page 12, paragraph 1. While the students are not individually assess for competencies, the secondary outcomes that will be measured for the students are highlighted on page 14 regarding their change in practice and change in knowledge skills and attitudes. This will be collected via surveys and this has been outlined on pg 14 and again in the newly added Table 2.
I found myself reading the secondary outcome measures section several times. The timing for the collection of the these measures is unclear. Authors mention surveys and interviews, but it was unclear to me when each would take place, which measures would be collected where and who would participate (all students, or just those in the intervention streams or a sub-sample?).	The primary and secondary outcome measures have now been summarised within Table 2 within the article.
On page 5, line 21 there is a typo -- "SBE can come be relatively expensive..."	This has been amended to: *SBE can be relatively expensive with mannequins, tutors and environment set up costs exceeding $100,000.*

VERSION 2 – REVIEW

REVIEWER	ASSOC PROF FATIMAH LATEEF Associate Professor Fatimah Lateef, MBBS, FRCS(Edin)(A&E), FAMS(Em Med) Senior Consultant Dept of Emergency Medicine and Trauma Vice Chair, Academic Clinical Programme, Emergency Medicine Director, Clinical Service and Quality Director of Undergraduate Training and Education Core Faculty, Emergency Medicine Residency Programme Dept of Emergency Medicine Singapore General Hospital Director, Institute of Medical Simulation and Education Singhealth Director Singhealth Duke-NUS Institute of Medical Simulation Adjunct Associate Professor Yong Loo Lin School of Medicine National University of Singapore Associate Professor

	Duke-NUS Graduate Medical School Senior Part-time Lecturer School of Health Sciences Nanyang Polytechnic Member of Parliament Marine Parade GRC
REVIEW RETURNED	26-Apr-2016

GENERAL COMMENTS	THANKS FOR MAKING THE EDITS