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Impact of acute care physician's age on crisis management performance and learning after simulation-based education: protocol for a prospective cohort trial

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Manuscripts

Title

Impact of acute care physician's age on crisis management performance and learning after simulation-based education: protocol for a prospective cohort trial

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Ageing; Continuing Education and Training; Patient Safety; Randomized Controlled Trial; Simulation Education

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Abstract

Introduction: The proportion of older acute care physicians (ACPs) has been steadily increasing. Ageing is associated with physiological changes and prospective research investigating how such age-related physiological changes affect clinical performance, including crisis resource management (CRM) skills, is lacking. There is a gap in the literature on whether physicians' age influences baseline CRM performance and also learning from simulation. We aim to investigate whether ageing is associated with baseline CRM skills of ACPs (emergency, critical care, anesthesia) using simulated crisis scenarios and to assess whether ageing influences learning from simulation-based education.

Methods and Analysis: This is a prospective cohort multicenter study recruiting ACPs from the Universities of Toronto and Ottawa, Canada. Each participant will manage an Advanced Cardiovascular Life Support (ACLS) crisis simulated scenario (pre-test) and then be debriefed on their CRM skills. They will then manage another simulated crisis scenario (immediate post-test). Three months after, participants will return to manage a third simulated crisis scenario (retention post-test). The relationship between biological age and chronological age will be assessed by measuring the participants CRM skills and their ability to learn from high-fidelity simulation.

Ethics and Dissemination: This protocol was approved by Sunnybrook Health Sciences Centre Research Ethics Board (REB Number 140-2015) and the Ottawa Health Science Network Research Ethics Board (#20150173-01H). The results will be disseminated in a peer reviewed journal, and at scientific meetings.

Trial Registration: NCT02683447; Pre-results

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Strengths and Limitations of the Study:

- Acute care physicians are recruited from various institutions across Ontario from three specialties
- Participants are immediately debriefed by experts on their crisis resource management performance
- Simulation environment for each scenario is tailored to the participant's specialty
- Ageing physicians likely did not train with mannequin-based simulation compared to physicians who recently completed their certification

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Introduction

The proportion of older acute care physicians (ACPs) has been steadily increasing.[1] Within Canada, approximately 32% - 39% of anesthesiologists are over the age of 55. A survey of members of the American Society of Anesthesiologists in 2013 revealed that a greater percentage of members are older (>55) in 2013 compared to 2007. These numbers are similar for emergency and critical care physicians, where the proportion of the workforce over 55 years of age is also 33% - 40%.[2] This shift in the demographics may be explained by various factors. It can partially be attributed to the recent economic crisis leading to delayed retirement. Also, in the early 1990s, there was a reduction of residency positions, likely explaining the smaller population of middle aged ACPs and hence, increasing demand for the older population to meet the needs of the healthcare system.[3, 4] Recent studies have also reported an overall shortage of healthcare providers of all ages with conditions varying by region. This is also another reason for a greater number of older ACPs currently working, as it calls upon delayed retirement of the older physicians to meet the demands of the healthcare system secondary to this shortage.[5-7]

Acute care specialties such as critical care, emergency medicine and anesthesiology, require its providers to both excel at technical and non-technical skills (e.g. teamwork, communication and leadership) and function at a high cognitive level in a fast-paced environment that requires quick decision-making and problem solving. Ageing is associated with physiological changes, which in turn can influence both a physician's clinical and decision-making abilities. The time required for processing information is prolonged and decision-making can be compromised in physicians as they age.[8, 10, 11, 14] Physiological stress impacts the ageing physician to great extent with potential consequences on performance. The prevalence of stress, illness, fatigue, and dementia increases as one age.[3, 8-11] Manual dexterity can also be affected with the onset of arthritis and alterations in visual acuity.[3, 12] Siu and colleagues

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found that anesthesiologists' age and years from residency were associated with decreased simulated cricothyroidotomy proficiency.[5, 13]

Research investigating how such ageing-related physiological changes affect clinical performance and patient safety is limited.[12, 15] The common idea that ageing physicians compensate through experience and pattern recognition from previous similar clinical situations[13, 14] has been called into question. First, physiological studies have shown that neural compensation mechanisms to ageing are limited and cannot prevent a certain amount of cognitive decline in the long-term.[16] Secondly, Duclos *et al*. found that older surgeons had an increased rate of patient complications after thyroid surgery.[17] In addition, 10 years of litigation data shows that anesthesiologists in British Columbia, Ontario, and Quebec who are older than 65 have 1.5 times the risk of being involved in litigation compared with those aged less than 51, with the settlements being generally larger.[12, 13] For all specialties, disciplinary incidents involving physicians are likely to occur later in practice, increasing with each 10-year interval since first getting a license.[14, 15, 18] Moreover, the degree of injury identified in the claims of physicians 65 years of age or older was of greater severity.[14] Lastly, studies have shown that long term medical knowledge retention can be negatively impacted with increasing age as well [19]. Overall, human physiology, previous investigations, litigation, disciplinary and critical event data strongly suggests that ageing effects among physicians are not compensated by greater experience as previously thought.

Crisis Resource Management (CRM) skills are essential clinical skills within acute care specialties, and are vital for patient safety. CRM encompasses technical skills (e.g. defibrillation, drug preparation, intubation), as well as a rapid and structured approach to non-technical, cognitive skills such as decision-making, task management, situational awareness and team

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management. CRM skills are crucial during life threatening crises and are precisely the type of processing and decision making skills that may decline as one ages, thus contributing to patient safety concerns described above.

Evidence shows that high-fidelity simulation-based education is effective for learning CRM, transferring skills to the clinical setting, and improving patient outcomes.[20] However, the effectiveness of simulation-based education for teaching CRM has mainly focused on undergraduate and post-graduate learners, whereas limited data is available for the ageing physician population.[21] Despite the limited evidence to support claims that simulation for continuing professional development actually improves learning,[22] simulation-based education has been recommended as a tool to train and assess ACPs.[12, 23] Thus, there is a need to investigate if physicians' age influences baseline CRM performance or learning from simulation-based education.

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Methods and Analysis

Aim:

Our research aims are to investigate whether ageing is correlated with baseline CRM skills in acute care physicians and to determine whether ageing influences CRM skill learning from high fidelity simulation and debriefing.

We hypothesize that ACPs' baseline CRM performance as assessed using high-fidelity, simulation-based scenarios decline as physician age increase. Our secondary hypothesis is that although ACPs' CRM performance will increase immediately following simulation-based practice scenarios with feedback, increasing physician age will negatively impact the retention of CRM skills.

Design:

This study is a prospective cohort multicenter interventional study. This study has been registered on **ClinicalTrials.gov (**NCT02683447) and this manuscript follows the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) reporting guidelines.[24]

Ethics:

This study will recruit from two large, university-affiliated tertiary centres in Toronto and Ottawa, Canada. Ethical approval was received from the Ottawa Health Science Network Research Ethics Board (#20150173-01H) (Ottawa, ON) and the Sunnybrook Health Sciences Centre, Research Ethics and Human Research Protections Program (#140-2015) (Toronto, ON). Written informed consent and a confidentiality agreement will be obtained from all participants by a trained research assistant or a study investigator. ACPs from the academic affiliated sites of

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both universities will be approached for recruitment, with data collection being conducted locally in each center. Throughout the study and upon completion of the trial, all data will be stored on secure servers at each sites institution. Data will be transferred using secure, encrypted, protected file transfer software.

Participant Characteristics:

Practicing emergency, critical care and anesthesia staff with a minimum of 5 years of clinical practice post-certification will be approached for participation. Participants will not be scheduled for a study session on a post-call day. Participants will be recruited from both academic and community sites. In Toronto, a formal simulation training curriculum for faculty does not exist. In Ottawa, a curriculum is in development and is in its infancy when it comes to implementation.

Simulation Scenario Development:

The core concepts pertaining to CRM skills and subsequent management of pulseless electrical activity (PEA) arrest will be consolidated into one document by the principal investigators (FA and SB) and then sent out to three faculty acute care physicians (one from each specialty involved) from Universities not involved in the recruitment, who are trained advanced cardiovascular life support (ACLS) instructors, for review and revisions. Once core concepts are agreed upon, the three simulation scenarios will be developed. Each scenario will then be piloted before recruitment to ensure an equal degree of difficulty.

Data Collection:

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Research personnel at Sunnybrook Health Sciences Centre will generate computer-based randomization of scenarios for all participants. Study participants will be blinded to their randomization assignment and un-blinding will not occur. The simulation environment for each scenario will be tailored to their respective specialty (i.e. Intensive Care Unit, Operating Room, and Emergency Room). Scenarios will be designed by an interdisciplinary group and will be piloted before recruitment to ensure an equal degree of difficulty. It will consist of a unique inciting event and will result in PEA arrests.

Study visits for all participants are listed in Table 1. On day one, participants will complete a demographic questionnaire to *quantify potential confounding factors,* such as previous simulation, ACLS and crisis management experience and a life expectancy questionnaire online to determine subject's biological versus chronological age (www.projectbiglife.ca). Depending on certain lifestyle factors, a person might have a 'younger or older' biological age when compared to their stated chronological age.[25] Next, a standardized structured orientation session will be held for each participant, including a non-crisis simulated scenario for familiarization with the simulation environment. The scenario will be an induction of general anesthesia using rapid sequence induction (a common technique performed by all three acute care specialties in this study).

Participants will manage three distinct scenarios for this study. All three scenarios will be matched for difficulty. The first will be a PEA arrest scenario (pre-test), followed by a 20 minute facilitator-led debrief on their CRM performance. They will then manage another PEA crisis scenario (immediate post-test). Three months later, participants will return and manage a third PEA arrest scenario (retention post-test) in addition to a questionnaire to assess whether they have recently completed ACLS training. The retention post-test can be completed starting

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at 3 months (up to 6 months) following the initial pre-test. These scenarios will all be video-recorded and all data will be stored on encrypted devices in compliance with local privacy policies, at each institution. Following a pre-written standard script, confederates will serve as a respiratory technician and nurse to be directed by the participant, but they will not provide tips or guidance in terms of how to manage the crisis. Two raters who have not worked with the participants, blinded to the study hypotheses and test phase will evaluate the participant's performance using validated assessment tools stated below.

Performance Measures:

The Ottawa Global Rating Scale (GRS) is a tool that has shown validity and reliability evidence for measuring non-technical CRM skills.[26] It assesses each of the following categories on a 7-point anchored scale: situational awareness, leadership, problem solving, communication, resource utilization and overall performance.

A simple checklist that has been shown to be a reliable tool for PEA arrest published by the Heart and Stroke Foundation will be used to assess for adherence to ACLS algorithm (technical skills) in addition to the quality of cardiopulmonary resuscitation.[27] Within each category, the participant gets a dichotomous option ("yes" or 'no") for each item required and the final score will be determined by tallying up the "yes" scores.

Outcome measures:

We will assess the relationship of biological and chronological age with:

- CRM skills (Primary Outcome), as measured by the total Ottawa GRS[26] score and the Heart and Stroke ACLS checklist for PEA.[27]

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- Learning from high-fidelity simulation education (Secondary Outcome), measured by change in performance *from pre-test, immediate post-test,* and *retention post-test* using the Ottawa GRS scale[26] and the ACLS checklist for PEA.[27]

Statistical Analysis:

Descriptive statistics will be calculated for all variables of interest. Continuous measures such as age will be summarized using means and standard deviations whereas categorical measures will be summarized using counts and percentages.

To test the first hypothesis, the association between CRM skills and age measured using the Ottawa GRS and ACLS checklist, we will use a Pearson correlation (or Spearman correlation for non-normal data). We will then conduct a multivariable linear regression model analysis including demographic variables of interest (i.e. past simulation experience, previous ACLS management) and time of retention test (i.e., between 3-6 months following initial post-test) as predictor variables. This model will also adjust for the correlation among observations taken from the same site.

The secondary outcome of change in the Ottawa GRS and ACLS checklist score over time will be analyzed using a repeated measures analysis of variance (ANOVA), adjusting for the correlation among observations from the same participant. This analysis will be followed by specific pairwise comparisons: 1- pre-test (scenario 1) compared to immediate post-test (scenario 2), and 2- immediate post-test (scenario 2) compared to retention post-test (scenario 3).

Sample Size Estimate:

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Our primary analysis looks at the relationship between age and CRM skills. A sample of 60 will provide 80% power at alpha of 0.05 to detect a correlation of 0.72 or greater (a high correlation) compared to a null hypothesis value of 0.5 (a moderate correlation). The sample size calculation was carried out using PASS Version 12 (Hintze, J. (2014). NCSS, LLC. Kaysville, Utah).

Ethics and Dissemination

This study will explore the relationship between ageing with CRM performance and learning in a simulated clinical setting. As such, the results will be a critical first step in informing continuing professional development practices and be the foundation for future studies investigating this medical population. Furthermore, no matter the outcome, the results of this study will be part of the discussion in helping shape not only national policy regarding practice assessment, but also help guide continuing professional development for ageing physicians.

This study aims to investigate whether ageing is correlated with baseline CRM skills in ACPs and determine whether ageing influences the acquisition and retention of CRM skills from theatre-based simulation and debriefing. If ageing does have an impact on CRM skills in physicians, then methods can be implemented aimed at assessing and intervening through continuing professional development earlier in a physician's career. Hopefully, this can prevent potential negative patient outcomes. One such method could be through the use of simulation, but this study will first delineate whether this method of instruction needs to be modified for older more experienced clinicians. If they do not learn the same way as residents, and we are delivering instruction based on research conducted with junior learners, then this may be ineffective for older physicians. This study will help clarify this uncertainty.

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The main challenge of this study is recruiting and scheduling physicians. Financial compensation has been identified as a barrier for staff participation in simulation sessions.[28] To mitigate this, we include continuing professional development section 3 credits for all participants in order to facilitate recruitment, allowing participants to track and document their skills, knowledge and experience that is gained formally and informally as it is mandatory for all practicing physicians complete a required number of credits to maintain their status with the Royal College of Physicians and Surgeons of Canada. There also is potential for an unintentional recruitment bias since ageing physicians likely did not train with mannequin-based simulation. To account for this, investigators will present at grand rounds with each acute care department to emphasize the implications of this study. Another challenge might be the concept of biological age vs. chronological age. This study will be using both chronological and biological age to mitigate this potential confounder.

Findings will be presented at local and national meetings (e.g., Canadian Anesthesiologists' Society Annual Meeting) and we plan to publish our study in a peer-reviewed journal as an open access article. Lastly, we intend to discuss findings at national specialty societies, interested provincial Colleges of Medicine and the Royal College of Physicians and Surgeons, with the goal of developing and implementing appropriate continuing education strategies for ACPs.

In conclusion, the results from this study will fill in the gap in the literature on whether physicians' age influences baseline CRM performance and also learning from simulation. The results will be a critical first step in helping shape and develop continuing education tailored to physicians' age.

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List of Abbreviations

ACLS= Advance Cardiac Life Support

ACPs= acute care physicians

CRM = crisis resource management

GRS= Global Rating Scale

PEA= pulseless electrical activity

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Author's contributions

FA and SB contributed to secure research funding and conceived and designed all aspects of the study protocol. AB, VL, JT, DP, CF, NK-G, YG, AK, PC, SA and SL contributed to the study design. FA, SB, and SA drafted and finalized the manuscript. All authors have approved the final manuscript. This study has been endorsed by the Perioperative Anesthesia Clinical Trials Group.

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Competing Interests

The authors have no conflicts of interest to declare.

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Table 1: Study visits

	Visit -1	Visit 0	Visit 1	Visit 2	Visit 3
ENROLMENT:					
Eligibility screen	**X**				
Informed consent	**X**				
Allocation		**X**			
INTERVENTIONS:					
Demographic questionnaire			**X**		
Life expectancy questionnaire			**X**		
Orientation and non-crisis scenario			**X**		
Pre-test			**X**		
Debrief *			**X**	**X**	
Immediate post-test			**X**		
Retention post-test				**X**	
ASSESSMENTS:					
Ottawa global rating scale **					**X**
Advance cardiac life support checklist **					**X**

* to be performed by experienced debriefers **to be performed by two independent raters

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Figure 1: Study flow chart for participants consented and randomized to this study.

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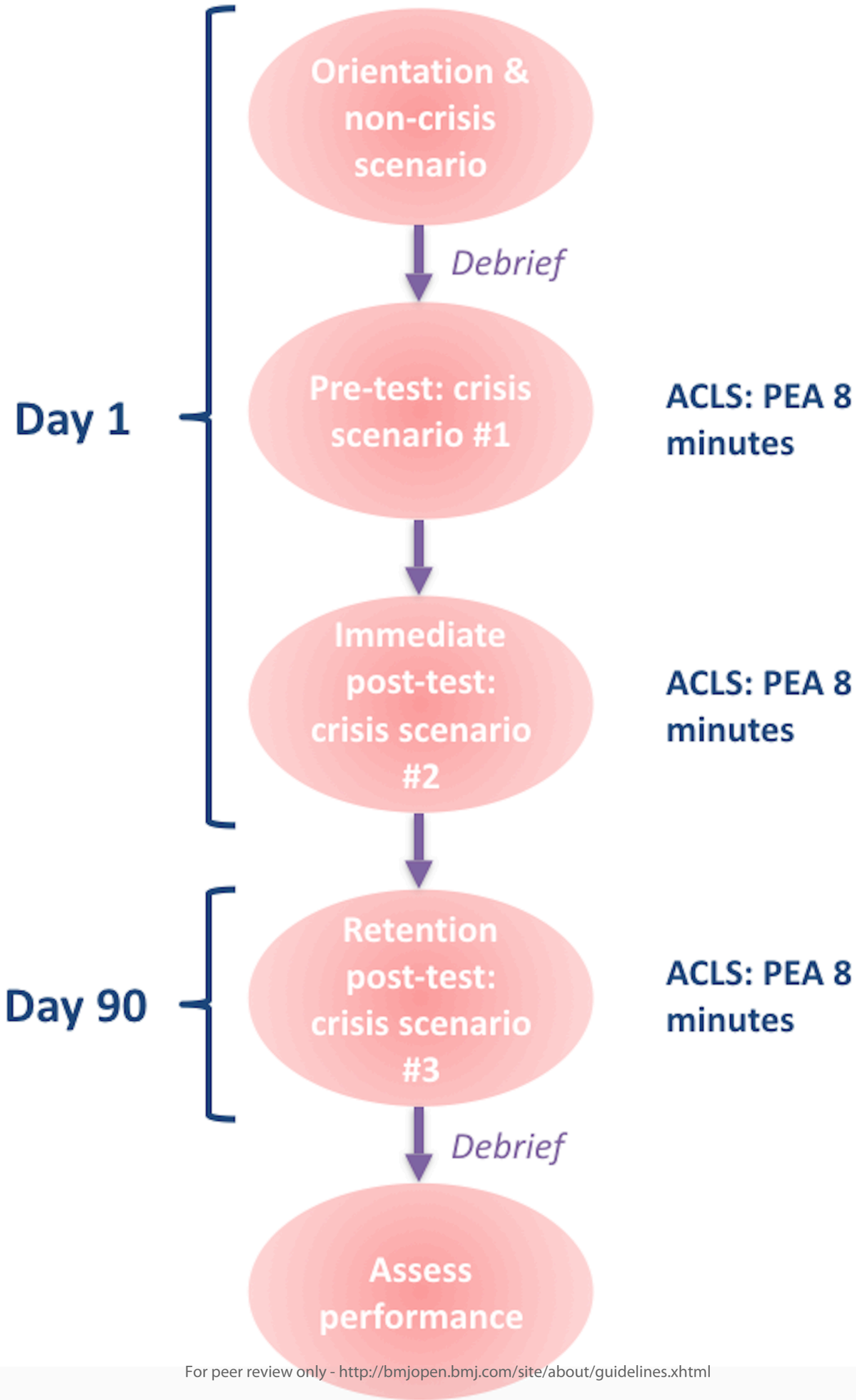
Orientation & non-crisis scenario
Debrief
Pre-test: crisis scenario #1
ACLS: PEA 8 minutes
Day 1
Immediate post-test: crisis scenario #2
ACLS: PEA 8 minutes
Retention post-test: crisis scenario #3
ACLS: PEA 8 minutes
Day 90
Debrief
Assess performance

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	_____1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	_____3_ _____
	2b	All items from the World Health Organization Trial Registration Data Set	See trial registration
Protocol version	3	Date and version identifier	See trial registration_____
Funding	4	Sources and types of financial, material, and other support	_____15_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_____1 and 15__
	5b	Name and contact information for the trial sponsor	_____N/A_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	_____15_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	____7-10_____

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Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	___4-6_____
	6b	Explanation for choice of comparators	___5_____
Objectives	7	Specific objectives or hypotheses	___5_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	___6_____

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	____7_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	____8_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	____8-10_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	____N/A_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_____N/A_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	_____N/A_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	_____10_____
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	_____19_____

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Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	11
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	8
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A

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Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9-11
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	10-11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	10-11
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	10
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	7-8
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	7-8

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Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7-8
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	8-9
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	14
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	12-13
	31b	Authorship eligibility guidelines and any intended use of professional writers	15
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	21-31
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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BMJ Open

Does the age of acute care physician's impact their 1) crisis management performance and 2) learning after simulation-based education? A protocol for a multicentre prospective cohort study in Toronto and Ottawa, Canada.

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Title

Does the age of acute care physician's impact their 1) crisis management performance and 2) learning after simulation-based education? A protocol for a multicentre prospective cohort study in Toronto and Ottawa, Canada.

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Abstract

Introduction: The proportion of older acute care physicians (ACPs) has been steadily increasing. Ageing is associated with physiological changes and prospective research investigating how such age-related physiological changes affect clinical performance, including crisis resource management (CRM) skills, is lacking. There is a gap in the literature on whether physician's age influences baseline CRM performance and also learning from simulation. We aim to investigate whether ageing is associated with baseline CRM skills of ACPs (emergency, critical care, anesthesia) using simulated crisis scenarios and to assess whether ageing influences learning from simulation-based education.

Methods and Analysis: This is a prospective cohort multicenter study recruiting ACPs from the Universities of Toronto and Ottawa, Canada. Each participant will manage an Advanced Cardiovascular Life Support (ACLS) crisis simulated scenario (pre-test) and then be debriefed on their CRM skills. They will then manage another simulated crisis scenario (immediate post-test). Three months after, participants will return to manage a third simulated crisis scenario (retention post-test). The relationship between biological age and chronological age will be assessed by measuring the participants CRM skills and their ability to learn from high-fidelity simulation.

Ethics and Dissemination: This protocol was approved by Sunnybrook Health Sciences Centre Research Ethics Board (REB Number 140-2015) and the Ottawa Health Science Network Research Ethics Board (#20150173-01H). The results will be disseminated in a peer reviewed journal, and at scientific meetings.

Trial Registration: NCT02683447; Pre-results

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Strengths and Limitations of the Study:

- Acute care physicians are recruited from various institutions across Ontario from three specialties
- Participants are immediately debriefed by experts on their crisis resource management performance
- Simulation environment for each scenario is tailored to the participant's specialty
- Ageing physicians likely did not train with mannequin-based simulation compared to physicians who recently completed their certification

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Introduction

The proportion of older acute care physicians (ACPs) has been steadily increasing.[1] Within Canada, approximately 32% - 40% of anesthesiologists, emergency and critical care physicians are over the age of 55. A survey of members of the American Society of Anesthesiologists in 2013 revealed that a greater percentage of members are older (>55) in 2013 compared to 2007.[2] The shift in workforce demographics may be explained by several factors such as the recent economic crisis, which has forced some physicians to choose to delay retirement. Furthermore, the reduction in the number of residency positions in the early 1990s led to a smaller proportion of middle aged ACPs.[3-4] Thus, with an overall shortage of healthcare providers, this has led to a greater proportion of older ACPs delaying retirement in order to meet the demands of the healthcare system.

Acute care specialties such as critical care, emergency medicine and anesthesiology, require providers to excel at both technical and non-technical skills (e.g. teamwork, communication and leadership) and function at a high cognitive level in a fast-paced environment that requires quick decision-making and problem solving. Ageing is associated with physiological changes, which in turn can influence both a physician's clinical and decision-making abilities. The time required for processing information is prolonged and decision-making can be compromised in physicians as they age.[5-8] Physiological stress impacts the ageing physician to a great extent (compared to their younger cohort) with potential consequences on performance. The prevalence of stress, illness, fatigue, and dementia increases as one ages.[3, 5-7, 9] Manual dexterity can also be affected with the onset of arthritis and alterations in visual acuity.[3, 10] Siu and colleagues found that anesthesiologist's age and years from residency were associated with decreased simulated cricothyroidotomy proficiency.[5, 11]

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Research investigating how such ageing-related physiological changes affect clinical performance and patient safety is limited.[10, 12] The common idea that ageing physicians compensate through experience and pattern recognition from previous similar clinical situations[8, 11] has been called into question. First, physiological studies have shown that neural compensation mechanisms to ageing are limited and cannot prevent a certain amount of cognitive decline in the long-term.[13] Secondly, Duclos *et al*. found that older surgeons had an increased rate of patient complications after thyroid surgery.[14] In addition, 10 years of litigation data shows that anesthesiologists in British Columbia, Ontario, and Quebec who are older than 65 have 1.5 times the risk of being involved in litigation compared with those aged less than 51, with the settlements being generally larger.[10-11] For all specialties, disciplinary incidents involving physicians are likely to occur later in practice, increasing with each 10-year interval since first getting a license.[8, 12, 15] Moreover, the degree of injury identified in the claims of physicians 65 years of age or older was of greater severity.[8] Lastly, studies have shown that long term medical knowledge retention can be negatively impacted with increasing age as well [16]. Overall, human physiology, previous investigations, litigation, disciplinary and critical event data strongly suggests that ageing effects among physicians are not compensated by greater experience as previously thought.

Crisis Resource Management (CRM) skills are essential clinical skills within acute care specialties, and are vital for patient safety. CRM encompasses technical skills (e.g. defibrillation, drug preparation, intubation), as well as a rapid and structured approach to non-technical, cognitive skills such as decision-making, task management, situational awareness and team management. CRM skills are crucial during life threatening crises and are precisely the

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type of processing and decision-making skills that may decline as one ages, thus contributing to patient safety concerns described above.

Evidence shows that high-fidelity simulation-based education is effective for learning CRM, transferring skills to the clinical setting, and improving patient outcomes.[17] However, the effectiveness of simulation-based education for teaching CRM has mainly focused on undergraduate and post-graduate learners, whereas limited data is available for the ageing physician population.[18] Despite the limited evidence to support claims that simulation for continuing professional development actually improves learning,[19] simulation-based education has been recommended as a tool to train and assess ACPs.[10, 20] Thus, there is a need to investigate if physicians' age influences baseline CRM performance or learning from simulation-based education.

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Methods and Analysis

Aim:

Our research aims are to investigate whether ageing impacts CRM skills in acute care physicians and to determine whether ageing influences CRM skill learning from high fidelity simulation and debriefing.

We hypothesize that ACPs' baseline CRM performance as assessed using high-fidelity, simulation-based scenarios decline as physician age increase. Our secondary hypothesis is that although ACPs' CRM performance will increase immediately following simulation-based practice scenarios with feedback, increasing physician age will negatively impact the retention of CRM skills.

Design:

This study is a prospective cohort multicenter interventional study. This study has been registered on **ClinicalTrials.gov (**NCT02683447) and this manuscript follows the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) reporting guidelines.[21]

Ethics:

This study will recruit from two large university-affiliated tertiary centres in Toronto and Ottawa, Canada. Ethical approval was received from the Ottawa Health Science Network Research Ethics Board (#20150173-01H) (Ottawa, ON) and the Sunnybrook Health Sciences Centre, Research Ethics and Human Research Protections Program (#140-2015) (Toronto, ON). Written informed consent and a confidentiality agreement will be obtained from all participants by a trained research assistant or a study investigator. ACPs from the academic affiliated sites of

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both universities will be approached for recruitment, with data collection being conducted locally in each center. Throughout the study and upon completion of the study, all data will be stored on secure servers at each sites institution. Data will be transferred using secure, encrypted, protected file transfer software.

Participant Characteristics:

All practicing emergency, critical care and anesthesia staff with a minimum of 5 years of clinical practice post-certification will be approached for participation. Participants will not be scheduled for a study session on a post-call day. Participants will receive email advertisements for voluntary participation in the study and all eligible physicians will be recruited from both academic and community sites. In Toronto, a formal simulation training curriculum for faculty does not exist. In Ottawa, a curriculum is in development and is in its infancy when it comes to implementation.

Simulation Scenario Development:

The core concepts pertaining to CRM skills and subsequent management of pulseless electrical activity (PEA) arrest will be consolidated into one document by the principal investigators (FA and SB) and then sent out to three faculty acute care physicians (one from each specialty involved) from Universities not involved in the recruitment, who are trained advanced cardiovascular life support (ACLS) instructors, for review and revisions. Once core concepts are agreed upon, the three simulation scenarios will be developed. The simulation environment for each scenario will be tailored to their respective specialty (i.e. Intensive Care Unit, Operating Room, and Emergency Room). Each scenario will be adapted in terms of environment

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(layout/equipment) and appropriate background noise (overhead announcements, monitor noise) for the participant's specialty to ensure psychological and environmental/technical fidelity. Each scenario will then be piloted before recruitment to ensure an equal degree of difficulty and appropriate fidelity.

Data Collection:

Research personnel at Sunnybrook Health Sciences Centre will generate computer-based randomization of scenarios for all participants. Study participants will be blinded to their randomization assignment and un-blinding will not occur. The simulation environment for each scenario will be tailored to their respective specialty (i.e. Intensive Care Unit, Operating Room, and Emergency Room). Scenarios will be designed by an interdisciplinary group and will be piloted before recruitment to ensure an equal degree of difficulty. It will consist of a unique inciting event and will result in PEA arrests.

An overview of the study visits for all participants are shown in Figure 1, and detailed assessments for each visit are listed in Table 1. On day one, participants will complete a demographic questionnaire to *quantify potential confounding factors,* such as previous simulation, ACLS and crisis management experience and a life expectancy questionnaire online to determine subject's biological versus chronological age (www.projectbiglife.ca). Depending on certain lifestyle factors, a person might have a 'younger or older' biological age when compared to their stated chronological age.[22] Next, a standardized structured orientation session will be held for each participant, including a non-crisis simulated scenario for familiarization with the simulation environment/equipment in which the study scenarios will take

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place. The scenario will be an induction of general anesthesia using rapid sequence induction (a common technique performed by all three acute care specialties in this study).

Participants will manage three distinct scenarios for this study. All three scenarios will be matched for difficulty. The first will be a PEA arrest scenario (pre-test), followed by a 20 minute facilitator-led debrief on their CRM performance. They will then manage another PEA crisis scenario (immediate post-test). Three months later, participants will return and manage a third PEA arrest scenario (retention post-test) in addition to a questionnaire to assess whether they have recently completed ACLS training. The retention post-test can be completed starting at 3 months (up to 6 months) following the initial pre-test. These scenarios will all be video-recorded and all data will be stored on encrypted devices in compliance with local privacy policies, at each institution. Following a pre-written standard script, confederates (trained actors with healthcare backgrounds) will serve as a respiratory technician and nurse to be directed by the participant, but they will not provide tips or guidance in terms of how to manage the crisis. Two raters who have not worked with the participants, blinded to the study hypotheses and test phase will evaluate the participant's performance using validated assessment tools stated below.

Debrief

All facilitators will be experienced in debrief and CRM training. Despite this, the facilitators will be trained on the outcome measures and will have the opportunity to debrief the participants in the pilot scenarios prior to the recruitment of study participants. Debrief will be led using the standardised ACLS algorithms and non-technical skills measured by the outcome assessment tools.

Performance Measures:

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The Ottawa Global Rating Scale (GRS) is a tool that has shown validity and reliability evidence for measuring non-technical CRM skills.[23] It assesses each of the following categories on a 7-point anchored scale: situational awareness, leadership, problem solving, communication, resource utilization and overall performance.

A simple checklist that has been shown to be a reliable tool for PEA arrest published by the Heart and Stroke Foundation will be used to assess for adherence to ACLS algorithm (technical skills) in addition to the quality of cardiopulmonary resuscitation.[24] Within each category, the participant gets a dichotomous option ("yes" or 'no") for each item required and the final score will be determined by tallying up the "yes" scores.

Outcome measures:

We will assess the relationship of biological and chronological age with:

- CRM skills (Primary Outcome), as measured by the total Ottawa GRS[23] score and the Heart and Stroke ACLS checklist for PEA.[24]
- Learning from high-fidelity simulation education (Secondary Outcome), measured by change in performance *from pre-test, immediate post-test,* and *retention post-test* using the Ottawa GRS scale[23] and the ACLS checklist for PEA.[24]

Statistical Analysis:

Descriptive statistics will be calculated for all variables of interest. Continuous measures such as age will be summarized using means and standard deviations whereas categorical measures will be summarized using counts and percentages.

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To test the first hypothesis, the association between CRM skills and age measured using the Ottawa GRS and ACLS checklist, we will use a Pearson correlation (or Spearman correlation for non-normal data). We will then conduct a multivariable linear regression model analysis including demographic variables of interest (i.e. past simulation experience, previous ACLS management) and time of retention test (i.e., between 3-6 months following initial post-test) as predictor variables. This model will also adjust for the correlation among observations taken from the same site.

The secondary outcome of change in the Ottawa GRS and ACLS checklist score over time will be analyzed using a repeated measures analysis of variance (ANOVA), adjusting for the correlation among observations from the same participant. This analysis will be followed by specific pairwise comparisons: 1- pre-test (scenario 1) compared to immediate post-test (scenario 2), and 2- immediate post-test (scenario 2) compared to retention post-test (scenario 3).

Sample Size Estimate:

Our primary analysis looks at the relationship between age and CRM skills. A sample of 60 will provide 80% power at alpha of 0.05 to detect a correlation of 0.72 or greater (a high correlation) compared to a null hypothesis value of 0.5 (a moderate correlation). The sample size calculation was carried out using PASS Version 12 (Hintze, J. (2014). NCSS, LLC. Kaysville, Utah).

Patient Involvement:

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Patients were not involved in the development of the research question and outcome measures. Study participants are physician, therefore patients were not approached for participation.

Ethics and Dissemination

This study will explore the relationship between ageing with CRM performance and learning in a simulated clinical setting. As such, the results will be a critical first step in informing continuing professional development practices and be the foundation for future studies investigating this medical population. Furthermore, no matter the outcome, the results of this study will be part of the discussion in helping shape not only national policy regarding practice assessment, but also help guide continuing professional development for ageing physicians.

This study aims to investigate whether ageing is correlated with baseline CRM skills in ACPs and determine whether ageing influences the acquisition and retention of CRM skills from theatre-based simulation and debriefing. If ageing does have an impact on CRM skills in physicians, then methods can be implemented aimed at assessing and intervening through continuing professional development earlier in a physician's career. Hopefully, this can prevent potential negative patient outcomes. One such method could be through the use of simulation, but this study will first delineate whether this method of instruction needs to be modified for older more experienced clinicians. If they do not learn the same way as residents, and we are delivering instruction based on research conducted with junior learners, then this may be ineffective for older physicians. This study will help clarify this uncertainty.

The main challenge of this study is recruiting and scheduling physicians. Financial compensation has been identified as a barrier for staff participation in simulation sessions.[25]

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To mitigate this, we include continuing professional development section 3 credits for all participants in order to facilitate recruitment, allowing participants to track and document their skills, knowledge and experience that is gained formally and informally as it is mandatory for all practicing physicians complete a required number of credits to maintain their status with the Royal College of Physicians and Surgeons of Canada. There also is potential for an unintentional recruitment bias since ageing physicians likely did not train with mannequin-based simulation. To account for this, investigators will present at grand rounds with each acute care department to emphasize the implications of this study. Another challenge might be the concept of biological age vs. chronological age. This study will be using both chronological and biological age to mitigate this potential confounder.

Findings will be presented at local and national meetings (e.g., Canadian Anesthesiologists' Society Annual Meeting) and we plan to publish our study in a peer-reviewed journal as an open access article. Lastly, we intend to discuss findings at national specialty societies, interested provincial Colleges of Medicine and the Royal College of Physicians and Surgeons, with the goal of developing and implementing appropriate continuing education strategies for ACPs.

In conclusion, the results from this study will fill in the gap in the literature on whether physicians' age influences baseline CRM performance and also learning from simulation. The results will be a critical first step in helping shape and develop continuing education tailored to physicians' age.

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List of Abbreviations

ACLS= Advance Cardiac Life Support

ACPs= acute care physicians

CRM = crisis resource management

GRS= Global Rating Scale

PEA= pulseless electrical activity

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Author's contributions

FA and SB contributed to secure research funding and conceived and designed all aspects of the study protocol. AB, VL, JT, DP, CF, NK-G, YG, AK, PC, SA and SL contributed to the study design. FA, SB, and SA drafted and finalized the manuscript. All authors have approved the final manuscript. This study has been endorsed by the Perioperative Anesthesia Clinical Trials Group.

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Competing Interests

The authors have no conflicts of interest to declare.

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Table 1: Study visits

	Visit -1	Visit 0	Visit 1	Visit 2	Visit 3
ENROLMENT:					
Eligibility screen	**X**				
Informed consent	**X**				
Allocation		**X**			
INTERVENTIONS:					
Demographic questionnaire			**X**		
Life expectancy questionnaire			**X**		
Orientation and non-crisis scenario			**X**		
Pre-test			**X**		
Debrief *			**X**	**X**	
Immediate post-test			**X**		
Retention post-test				**X**	
ASSESSMENTS:					
Ottawa global rating scale **					**X**
Advance cardiac life support checklist **					**X**

* to be performed by experienced debriefers **to be performed by two independent raters

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Figure 1: An overview of study visits for participants consented and randomized to this study.

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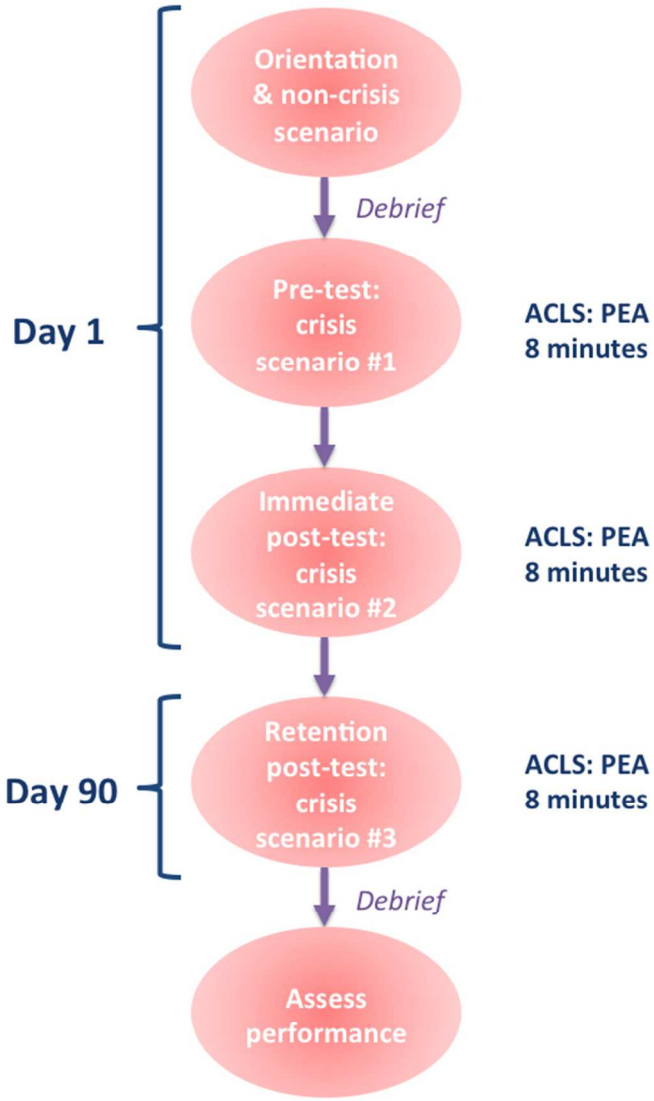

An overview of study visits for participants consented and randomized to this study.

60x81mm (300 x 300 DPI)

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	_____1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	_____3_ _____
	2b	All items from the World Health Organization Trial Registration Data Set	See trial registration
Protocol version	3	Date and version identifier	See trial registration_____
Funding	4	Sources and types of financial, material, and other support	_____15_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_____1 and 15__
	5b	Name and contact information for the trial sponsor	_____N/A_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	_____15_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	____7-10_____

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Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	___4-6_____
	6b	Explanation for choice of comparators	___5_____
Objectives	7	Specific objectives or hypotheses	___5_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	___6_____

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	____7_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	____8_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	____8-10_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	____N/A_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_____N/A_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	_____N/A_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	_____10_____
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	_____19_____

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Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	11
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	8
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A

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Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9-11
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	10-11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	10-11
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	10
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	7-8
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	7-8

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Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7-8
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	8-9
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	14
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	12-13
	31b	Authorship eligibility guidelines and any intended use of professional writers	15
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	21-31
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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