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Gamification of a virtual-reality simulation curriculum in endoscopy: impact on clinical performance

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

This is a consent form regarding the above mentioned research study. Before you give your consent to voluntarily participate in this study, it is important that you read the following information and ask the study personnel as many questions as necessary to be sure you understand what you will be asked to do.

Investigators

Principal Investigator:

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Background and Purpose of the Study

Colonoscopies are medical procedures that gastroenterology physicians and general surgeons learn during their residency training. Traditionally, these procedures are learned for the first time on patients in the clinical setting under the supervision of a fully-trained attending physician. Virtual reality (VR) has since been used to create devices, called endoscopic simulators that can emulate the look and feel of performing colonoscopies, and have been validated in research studies to confer basic skills to trainees. The optimal method to use virtual reality simulators for teaching trainees that have yet to begin procedures in colonoscopy has yet to be determined, and was identified by the American Society for Gastrointestinal Endoscopy as a need for further training.

The primary objective of this project is to evaluate the impact of a simulation-based training curriculum using gamification on clinical performance in colonoscopy.

Eligibility

You are asked to consider taking part in this study if you are a resident in General Surgery, Adult Gastroenterology or Pediatric Gastroenterology at the University of Toronto.

In order to be eligible for this study, you must be a post-graduate trainee in the above programs, must have completed less than 25 colonoscopic procedures, and must have completed less than 25 simulated colonoscopy procedures to date.

Description of the Study

We aim to recruit 36 postgraduate novice endoscopists from the Adult Gastroenterology, Pediatric Gastroenterology and General Surgery training programs at the University of Toronto. **Note:** this study takes place concurrently alongside the Annual Endoscopic Simulation Training Course. The study, as described below, is a randomized control trial that is investigating the effectiveness of a new simulation-based curriculum. The Annual Endoscopic Simulation Training Course is an educational program through the University of Toronto, which aims to teach novices how to perform colonoscopies. Participation in the study component is optional; if you chose to opt-out of the study, it will not impact your participation in the course.

You will be asked to take a written questionnaire at the start of the study to collect demographic and background information including: age, sex, level of training, previous endoscopy experience and nature of experience, and video game experience, which may correlate with baseline endoscopic skill.

Following this you will take part in a pre-test consisting of the following:

1. **Knowledge Test:** A 30 minute (17 questions) multiple-choice question test designed to assess participants' theoretical knowledge of colonoscopy, including indications, sedation, safety, findings, pathology and follow-up.

2. VR Simulation Test: This test will assess baseline endoscopic technical proficiency through the completion of a colonoscopy procedure on the VR simulator (EndoVR® Colonoscopy Module 3). This scenario simulates a screening colonoscopy, without the need for any type of intervention (such as biopsy). The time limit of the procedure will be 30 minutes. An expert rater will be present to assess performance, but will not provide assistance. You will be videotaped in order to obtain performance measures, such that your faces are not captured (to ensure anonymity). Prior to starting the procedure, you will complete a questionnaire to measure self-efficacy.

3. VR Simulation Based "Integrated Scenario" Test: Following the simulator-only test, participants will complete an Integrated Scenario format test to assess their baseline endoscopic non-technical proficiency. This simulated procedure will mimic the setup of an endoscopic suite, as the VR simulator will be positioned next to a patient bed. A standardized patient, who will receive instructions regarding their medical role, will act out a scenario on colon cancer screening. You will be expected to explain the colonoscopy procedure, its benefits and risks, and to obtain procedural consent. You will then carry out the procedure on the VR simulator (EndoVR® Polypectomy Module #3) while responding to the patient and interacting with the standardized nurse (SN) as appropriate. The Standardized Patient (SP) will act out cues from the VR simulator if the simulator signals that the procedure has exceeded its threshold for discomfort. Your performance will be videotaped (in a manner that their faces are not captured to ensure anonymity) in order to obtain performance measures. You will be given a maximum of 45 minutes to complete the procedure.

You will then be randomized, using an online randomization algorithm, to one of two groups:

1. Control Group: This group will receive 4 hours of interactive small-group didactic and hands-on sessions. During these sessions, participants will focus on learning about the theory of colonoscopy, including related concepts of pathology, anatomy, and therapeutic technique. The last session will focus on non-technical skills (NTS) relevant to endoscopy (situation awareness, decision making, communication, teamwork, and leadership) and how they relate to clinical performance. During this session, participants will also watch a video that demonstrates an ideal endoscopic procedure in terms of NTS, as well as learn about the "E-NTS Checklist", which will be provided for them to later use during the integrated scenario training. This checklist has been developed according to evidence-based recommendations and targets non-technical skills. After each didactic session, a short MCQ based on the topics covered in that session will be administered, in keeping with suggestions from the literature regarding "test-enhanced learning". In addition to didactic training, the control group will be given six hours of expert-assisted instruction on both the low-fidelity simulator (1 hour) and on the high-fidelity VR simulator (5 hours). Six modules of increasing difficulty in colonoscopy and colonoscopic polypectomy will be taught using one-on-one feedback from an expert academic endoscopist. The endoscopy instructor will demonstrate techniques, answer

questions and provide individualized performance feedback on global performance, with a focus on non-technical skills. During training on the high-fidelity simulator, the last two hours will take the form of the integrated scenario, which will feature a standardized patient (SP) and standardized nurse (SN). Terminal feedback will be given after each integrated scenario by the instructor. Finally, the "E-NTS Checklist" will be accessible during training in the integrated scenario, as participants can view the checklist prior to each case and review it after the case.

2. Intervention Group: This group will receive the same 4 hours of didactic teaching, and hands-on sessions. The intervention group will also receive the same teaching on both the low-fidelity and high-fidelity simulators. Within the context of the didactic sessions and simulator training, the GIC group will engaged in "gamified practice" in two ways. First, leaderboards will also be used to track and rank participants' performances. Prior to training, participants in the GIC group will watch a tutorial video on the functionality of the leaderboards and subsequently receive an anonymized ID tag that can be used to identify only their position on the leaderboard. Participants will also be informed that awards will be given to the individual who achieves first place. An "introductory" leaderboard, based on technical skills performance during the low-fidelity simulator practice, will be used to familiarize participants with the function of the leaderboard. After practice on the low-fidelity simulator is completed, participants will be introduced to the leaderboard for performance on the VR simulator and didactic sessions. Specifically, this leaderboard will include 4 components: a non-technical skills score, a technical skills score, a cognitive skills score,and an overall ranking, which will be determined through an algorithm that accounts for non-technical, technical and cognitive scores. Scoring of the non-technical and technical skills will be based on assessed performances during practice sessions on the VR simulator using the M-OSANTS and JAG-DOPS, respectively, while the scoring of the cognitive skills will be based on percentage scores of the MCQ from the didactic sessions. Scores will be aggregated only from participants training on the same days. The leaderboard will be displayed on a central laptop and/or TV screen and will be accessible at any time throughout the day. Finally, participants in the GIC group will have the opportunity to be rewarded for their performances. One method of reinforcing good performance will be through achievement badges. These badges will be awarded after each scenario on the high-fidelity simulator and will be based on completion, proper technique, and/ or correct identification of pathology. Additionally, the participant who has accumulated the most badges will be awarded a prize.

A post-test will be administered after completion of the training period to compare learning between the two groups, consisting of:

1. Knowledge Test

Knowledge acquisition will be evaluated using a 30 minute (17 questions) multiple-choice question test designed to assess theoretical knowledge of colonoscopy.

2. Simulation-based Assessment

You will be assessed through the completion of a colonoscopy procedure on the VR simulator. As with the pre-test, the post-test will include an "integrated scenario" which links a standardized patient with the VR colonoscopy simulator. You will once again be required to explain the procedure, its benefits and risks, and obtain informed consent. You will then carry out the procedure on the simulator while responding to the patient as appropriate. Once again, the performance of all participants will be videotaped, such that their faces are not captured to ensure anonymity, in order to obtain performance measures.

3. Patient-based transfer test

You will then be contacted to undertake two colonoscopies on real patients. These procedures will be videotaped in a manner that anonymizes you and the patient. The videotapes will be assessed by two independent blinded expert endoscopists.

Potential Harms (Injury/Discomfort/Inconvenience)

There are no known harms associated with participation in this study.

Potential Benefits

You will not receive credit in performing colonoscopies by participating in this study. You may receive no direct benefits from being in this study. Results from this study will be used to adjust the structure and format of the current University of Toronto virtual-reality colonoscopy training curriculum for novice endoscopic trainees.

Confidentiality and Privacy

All the persons associated with this study, including the study investigators and delegates (study team) are committed to respecting your privacy. No information that discloses your identity will be published or released to any other persons without your consent unless required by law.

Video-recordings of your face are considered to be identifying personal information and will not be shown when videotaping these procedures. During the video-recordings, you are requested not to state your name or the names of anyone else or any institutions. However if this does happen, you should know that the audio track from the video will be removed so identifying information is removed.

Any records, documentation, or information related to you will be coded by study numbers to ensure that persons outside of the study will not be able to identify you. All study data forms will be identified by study code number and not by name. No identifying information about you will be allowed off site. All information that identifies you and study data will be securely stored at St. Michael's Hospital. The video recordings will be securely destroyed after data collection. Other identifying information will be securely destroyed after all the colonoscopy procedures have been completed. The study

data will be securely destroyed when the study results have been published, within five years after completion of the study.

It is important to understand that despite these protections being in place, experience in similar studies indicates that there is the risk of unintentional release of information. The principal investigator and study personnel will protect your records and keep all the information in your study file confidential to the greatest extent possible. The chance that this information will accidentally be given to someone else is minimal.

Data collected during this study will not form any part of your evaluation for the rotation and will not be forwarded to your program director or any other individual involved in your evaluation in residency. The study investigators will have access to the coded study data, but will not have access to your identifying information, including the video-recordings. The St. Michael's Hospital Research Ethics Board may have access to your identifying information and study data collected, for the purpose of study monitoring.

In no way does signing this consent form waive your legal rights nor release the investigators or involved institution from their legal and professional responsibilities.

Voluntary Participation and Withdrawal

Participation in this study is voluntary. You are free to decline participation in this study and to withdraw from the study at any time if you so desire. Whether you participate in this study or not, it will not have any effect on your clinical evaluations, or standing in your academic program at the University of Toronto, nor will it in any way affect your admission to (or current status in) a residency/fellowship program, nor your current or future employment at St. Michael's Hospital. If you withdraw or are withdrawn from the study, information gathered from you up to that point will be kept and used in the study, unless you request that it not be used, and we are able to remove it.

Study Results

We may present this study at a scientific conference and we intend to write an article about this study for a scientific journal. No identifying information about you will be revealed in any presentation or publication about the study. Study results will be communicated to you by request following completion of the study. You can ask for a copy of the published article by contacting Michael Scaffidi, Research Assistant, at (416) 864-5628 or by e-mail at scaffidim@smh.ca.

Potential Costs of Participant and Reimbursement to the Participant

Participating in this study will not result in any costs charged to you, and as such, no reimbursements or compensation will be provided.

Sponsor

This study is funded by a grant from the University of Toronto.

Compensation for Injury

If you suffer a physical injury from (the procedure(s) or participation) in this study, medical care will be provided to you in the same manner as you would ordinarily obtain any other medical treatment. In no way does signing this form waive your legal rights nor release the study doctor(s), sponsors or involved institutions from their legal and professional responsibilities.

Participation and Withdrawal

Participation in this study is voluntary. You are free to decline participation in this study and to withdraw from the study at any time if you so desire. Whether you participate in this study or not, it will not have any effect on your participation in the Annual Endoscopic Simulation Course, clinical evaluations, or standing in your academic program at the University of Toronto, nor will it in any way affect your admission to (or current status in) a residency/fellowship program, nor your current or future employment at St. Michael's Hospital. If you withdraw from the study, information gathered from you up to that point will be kept and used in the study, unless you request that it not be used, and we are able to remove it.

Can Participation in this Study End Early?

You can choose to end your participation in this study at any time. If you withdraw voluntarily from the study, you are encouraged to contact the Research Coordinator, Michael Scaffidi, Division of Gastroenterology (416-864-5628) immediately.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

The study investigators have the right to stop your participation in the study if it is not in your best interest to continue or if you do not follow study directions

Research Ethics Board Contact

If you have any questions regarding your rights as a research participant, you may contact the Chair of the Research Ethics Board, St. Michael's Hospital at 416-864-6060 ext. 2557 during regular business hours.

The study protocol and consent form have been reviewed by a committee called the Research Ethics Board at St. Michael's Hospital. The Research Ethics Board is a group of scientists, medical staff, individuals from other backgrounds (including law and ethics) and members of the community. The committee is established by the hospital to review studies for their scientific and ethical merit. The Board pays special attention to the potential harms and benefits involved in participation to the research participant as well as the benefit to society. The committee is also required to do periodic reviews of ongoing research studies. As part of this review, someone may contact you form the Research Ethics Board to discuss your experience in the research study.

Study Contacts

If you require further information, or have any questions concerning this study, please contact the principal investigator:

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E-mail: grovers@smh.ca

Collect calls will be accepted.

You may also contact the research assistant, Michael Scaffidi, at (416)-864-5628 or by e-mail at scaffidim@smh.ca.

You will be given a copy of this consent form to keep for your own records.

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Declaration of Consent

The research study has been explained to me, and any questions that I have asked about the study have been answered to my satisfaction. A member of the study team, who has no influence on my academic program, will be obtaining my consent form. I have the right not to participate and the right to withdraw from this study without affecting my participation in the Annual Endoscopic Simulation Course, evaluation or standing on my academic program at the University of Toronto, or any admission to (or current status in) a residency/fellowship program. I have also been informed that my choice will not affect my current or future employment at St. Michael's Hospital. As well, the potential harms and benefits (if any) of participating in this research study have been explained to me. I have been told that I have not waived my legal rights nor released the investigators or involved institution from their legal and professional responsibilities. I know that I may ask now, or in the future, any questions I have about the study. I have been told that records relating to me in this study will be kept confidential and that no information will be released or printed that would disclose my personal identity without my permission unless required by law. I have been given sufficient time to read the above information. I consent to participate in this study. I will be given a signed copy of this consent form.

Name of Participant (print)	Signature	Date

I have explained the study to the above-named participant and discussed the potential risks and benefits (if any) associated with participation in this research study. I have answered all questions asked with respect to this research study.

Name and Position of Person Conducting Consent Discussion (print)	Signature of Person Consent Discussion	Date