Participant Information and Consent Form

Study Title: Outcome of a lecture before vs after simulation-based education on pediatric resuscitation: A randomized controlled trial

2. Study Personnel:

Principal Investigator:

Dr. Melissa Chan, MD, M.ED
Pediatric Emergency Medicine Physician
BC Children's Hospital

Study Contact Number:

Dr. John Ramsay, MD
Pediatric Emergency Medicine Fellow
BC Children's Hospital
Contact Number: 613-223-4513
Email: ramsay.s.john@gmail.com

3. Invitation:

You are being invited to take part in this research study because you are a second-year medical student at the University of British Columbia.

4. Your participation is voluntary:

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to your medical education.

Please review the consent document carefully when deciding whether you wish to be part of the research and sign this consent only if you accept being a research participant.

5. Who is conducting this study?

This study is not receiving funds from an external agency or sponsor.

6. Background

Simulation provides an opportunity to practice rare and life-threatening situations in a safe and controlled environment. It has been a recent and increasing tool in medical education over the past 10 years however the best way to support simulation with other teaching is not clear and the best way to preserve what participants learn is also unknown.

7. What is the purpose of this study?

The purpose of the study is to determine if the order of teaching combined with simulation for medical education affects the participants learning. The project is being completed to continue to improve medical simulation and teaching.

8. Who can participate in this study?

All second-year medical students attending the University of British Columbia can participate in this study.

9. Who should not participate in this study?

There are no exclusion criteria for this study.

10. What does this study involve?

If you agree to take part in this study, the following data will be collected and stored de-identified: age, previous simulation experience, background in ED nursing or EMS. Your names and contact information will be stored for logistical organization but will not be linked to survey or simulation results.

During the process of simulation, you will be asked to participate in simulations on separate days. The first day will involve and initial pre-knowledge test and basic demographics as above. You will then either complete a simulation followed by a lecture or lecture followed by a simulation. Lastly on the first day a post-intervention knowledge test will be completed. In total the time commitments of each day are outlined below. There may be up to a hour of waiting time between the simulation and the lecture if you are the first group to go.

On the second day you will complete a short simulation and knowledge test with time commitments outlined below.

The simulations will be recorded to allow analysis to be completed. The analysis will be stored de-identified and will only be reviewed by the staff simulation experts who are analysis the simulation data.

There will be no secondary release of data for other studies.

Interaction	Day:	Location	Time Commitment
• Didactic Lecture • Simulation 1 • Pre and Post Knowledge test	1	BC Children's Simulation Lab	• 60-minute didactic lecture • 10 min simulation+ 15 min debrief • ~20 min knowledge test • Up to 60 mins of waiting between simulation and lecture

• Simulation 2 • Post Knowledge test	2	BC Children's Simulation Lab	• 10 min simulation • ~20 min knowledge test

11. What are the possible harms and discomforts?

You may experience some stress participating in the simulation and interacting in the teaching session. The simulations will be recorded, and this will be stored for 5 years after the publication date.

12. What are the potential benefits to participating?

You will benefit from completing two simulation teaching sessions with a pediatric emergency medicine physician and additional focused lecture on pediatric resuscitation. By the end of the study, you will have increased comfort in managing a specific pediatric scenario.

13. After the study finishes?

You will be able to request your knowledge and simulation scores and clarify and additional management questions around pediatric resuscitation.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

14. What happens if I decide to withdraw my consent?

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, you have the right to request the withdrawal of your information. This request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn for example where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please let the principal investigator of the study know.

15. How will my taking part in this study be kept confidential?

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives and Children's and Women's Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity

will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. You also have the legal right of access to the information about you and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to the study team.

Federal and provincial privacy laws give safeguards for privacy, security, and authorized access to information. We will not give information that identifies you to anyone without your permission, except as required by law.

Disclosure of age:
Studies involving humans now routinely collect information on characteristics of individuals because these characteristics may influence how people respond to different interventions. You should be aware that providing this information is not mandatory.

Access to Video Recording:
The video recordings will be stored on an encrypted hard drive kept in a locked office of the Principal Investigator. They will be stored for 5 years after publication in line UBC research protocol after which time they will be destroyed. Only the two staff physicians (Dr. Jonathan Duff (Stollery Children's Hospital – PICU Intensivist) and Dr. Jasmine Allaire (BC Children's PEM Physician) who are analysing the video, The principal investigator, Dr. Melissa Chan, and Dr. John Ramsay will have access to the videos. No other members of the research team or other individuals will watch or have access to the videos. There will be no secondary analysis of the video recordings.

Transfer of Data:
One of the video reviewers is located in Alberta and they will be priority mailed requiring a signature a copy of the encrypted hard drive with the videos to best ensure security during data transfer.

16. What happens if something goes wrong?

By signing this form, you do not give up any of your legal rights and you do not release the principal investigator, participating institutions, or anyone else from their legal and professional duties.

17. What will the study cost me?

All research-related procedures that you will receive during your participation in this study will be provided at no cost to you.

Reimbursement

Participants will not be compensated for travel expenses.

Remuneration

Participants will not be paid for their participation in the research study.

18. If I have questions about the study procedures during my participation, who should I speak to?

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact ***John Ramsay*** at ***613-223 - 4513*** *or by email at ramsay.s.john@gmail.com*.

19. Who do I contact if I have any questions or concerns about my rights as a participant?

If you have any concerns or complaints about your rights as a research participant, privacy related complaints and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598.)

Please reference the study number (H22-03760) when contacting the Complaint Line so the staff can better assist you.

20. Signatures

Comparing the effect of teaching before and after simulation on knowledge and resuscitation performance retention for second year medical students' management of pediatric status epilepticus: a randomized control trial

Participant Consent

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me.

I will receive a signed and dated copy of this consent form for my own records.
I consent to participate in this study.

Participant's Signature	Printed Name	Date

Signature of Person Obtaining Consent	Printed Name	Study Role	Date

Future Contact

Are you interested in learning about other studies conducted by John Ramsay in the future?

☐ Yes ☐ No Initials_____

Note that for any future studies, a separate consent form will be provided to review.