PARTICIPANT INFORMATION SHEET

Title of Study: Remote Education Strategies Training Oncology Residents for End-of-Life Discussions (The RESTORED study)

Locally Responsible Investigator and Principal Investigator: Dr. Oren Levine, Department of Oncology, McMaster University

Co-Investigator(s):
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You are being invited to participate in a research study conducted by Dr. Oren Levine because you are currently either enrolled in a medical or radiation oncology residency training program or a health care provider that is a member of Hospice Palliative Care Ontario (HPCO). A novel educational program is being piloted at your institution/organization along with others in Ontario.

In order to decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate. Please take your time to make your decision.

The investigators on this study have no conflicts of interest.

WHY IS THIS RESEARCH BEING DONE?

Difficult conversations are common in oncology practice and patient-centered communication is essential to care for individuals with cancer. High quality communication benefits patients, families and clinicians. Oncology residency training is a time to build strong communication skills. Proficiency in a variety of communication tasks is now a requirement within competency-based medical education (CBME) in Canada. Within oncology training programs, communication training is mostly unstructured observation and feedback in the clinic and many learners receive inadequate training. Currently, educational resources are limited, and residents and clinicians have indicated a desire for more education on end-of-life communication skills. A formal communication curriculum could fill a gap and help to standardize teaching and evaluation.

Virtual care has been quickly adopted within oncology practice in the context of the COVID19 pandemic. This limits opportunities for direct observation of learners, making assessment of communication skills more difficult. How best to teach communication skills in the context of virtual care is unclear. To mitigate current challenges, we have adapted two recognized educational tools, electronic learning modules (ELMs) and standardized patients (SPs), to create a novel virtual training strategy. We want to determine the impact of each training experience for oncology residents and clinicians.

WHAT IS THE PURPOSE OF THIS STUDY?

The overall goal of this study is to establish an effective communication skills curriculum for oncology residents and clinicians that can be delivered remotely and that addresses difficult conversations with cancer patients. Through this preliminary study, we will explore the feasibility of a randomized controlled trial comparing different training experiences to understand how best to help oncology residents and clinicians develop strong end-of-life communication skills.

WHAT WILL MY RESPONSIBILITIES BE IF I TAKE PART IN THE STUDY?

If you volunteer to participate in this study, we will ask you to do the following things:

You will be randomly assigned (like a flip of a coin) to one of two groups. Neither you, the study staff nor the investigators can influence which group you enter. Regardless of your group assignment, you will be asked to complete a series of online ELMs. There are six modules in this course, each should take 30-40 minutes to complete. There will be content to read and example videos to watch. A link to each module will be sent to your email. You will have 2 weeks to complete a module on your own time.

You will be asked to complete an electronic questionnaire before and after the ELM curriculum. Questionnaires will ask about your confidence in end-of-life communicating and your satisfaction with the teaching format. Your responses to questionnaires will be collected according to a unique coded identifier

and stored in a secured database. No personal or identifying information will be collected, nor will IP addresses be collected. LimeSurvey software will be used to store data in an encrypted format housed on Canadian servers. Responses are anonymous and risk of privacy breach is minimal. Some questions have open text response options and information you choose to share may be identifiable, so please bear this in mind. We ask you to avoid identifiable information (e.g., name), if possible. If identifiable information is shared, we will remove it when analyzing data. You may choose not to answer any question. Once survey responses are submitted, they cannot be withdrawn.

You will be asked to sign up for one simulated patient encounter before starting the ELM curriculum. You will also be asked to sign up for one simulated patient encounter after completing the curriculum. Each session will be a maximum of 30 minutes long and will be conducted virtually through a Zoom link. You will be able to sign up at times of convenience for you. Only you and a standardized patient will participate in the encounters. These 2 simulated encounters will be video- and audio-recorded for evaluation at a later date. Recordings will be housed securely within the McMaster server and only study personnel and trained evaluators will be able to view the files. Volunteer faculty will serve as evaluators. They will not be faculty from your own program, or institution. Your communication skills will be scored, but these scores will be stored in a secure and anonymized database with unique study identifiers. No personal or identifying information will be stored. Your program directors will not have access to the recordings or study-related assessments. Recordings and any identifiable data will be destroyed as soon as data collection is complete. De-identified data will be stored for 10 years and then destroyed.

Participants in one group will also be asked to sign up for a series of 3 simulated patient encounters with virtual SPs. These will be hosted through the Zoom platform and each simulation will last up to 30 minutes. They will be scheduled at a time that is convenient for you. Simulations will be staggered between the self-learning modules and relate to the content of the modules. In each simulation, an actor will play a cancer patient. You will be observed by an experienced faculty member who will provide feedback and coaching. It is possible that a preceptor from your own program will be an observer.

You will have a 1 in 2 chance of being in the group that receives only the ELMs and a 1 in 2 chance of being in the group that receives the ELMs and the virtual SP simulations with feedback and coaching.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There are no medical risks to you from participating in this study. Taking part in this study may make you feel uncomfortable. You may become uncomfortable in the simulated patient encounters when discussing topics related to end-of-life. You may stop the discussion at any time. You may refuse to answer questions on the questionnaires that make you feel uncomfortable. The assessment involved with this study will not impact on your formal evaluation. Your program director will not have access to your results, but preceptors from your program may be involved with providing coaching feedback during SP simulations.

If you choose to take part in this study, you will be told about any new information which might affect your willingness to continue to participate in this research.

HOW MANY PEOPLE WILL BE IN THIS STUDY?

It is expected that a minimum 40 people will enter this study across Ontario.

WHAT ARE THE POSSIBLE BENEFITS FOR ME AND/OR FOR SOCIETY?

We cannot promise any personal benefits to you from your participation in this study. However, possible benefits include improving your confidence and communication skills for end-of-life communication and other difficult conversations with patients with cancer. You may find this experience useful for your overall training goals in residency and/or practice. Your participation may help other oncology residents and clinicians by validating novel educational resources for future use.

IF I DO NOT WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

It is important for you to know that you can choose not to take part in the study. Medical residents will have access to any other communication skills training experiences that are provided in the residency program. Choosing not to participate in this study will in no way affect your education or evaluations.

WHAT INFORMATION WILL BE KEPT PRIVATE?

Your identifiable data will not be shared with anyone except with your consent or as required by law. All personal information such as your name will be removed from the data and will be replaced with a number. A list linking the number with your name will be kept in a secure place, separate from your file. The data, with identifying information removed, will be securely stored in a locked office in the Juravinski Hospital and Cancer Centre.

For the purposes of ensuring the proper monitoring of the research study, it is possible that a member of any institutional regulatory body may consult your research data. However, no records which identify you by name or initials will be allowed to leave the hospital. By signing this consent form, you authorize such access.

If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your specific consent to the disclosure.

CAN PARTICIPATION IN THE STUDY END EARLY?

If you volunteer to be in this study, you may withdraw at any time and this will in no way affect your residency training or HPCO membership, as applicable. You have the option of removing your data from the study *OR* information provided up to the point where you withdraw will be kept unless you request that it be removed. You may also refuse to answer any questions you don't want to answer on the surveys and still remain in the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so.

WILL I BE PAID TO PARTICIPATE IN THIS STUDY?

You will receive a $75 gift card for participation in this study, i.e., completion of the training intervention, standardized patient encounters, and study survey(s).

WILL THERE BE ANY COSTS?

Your participation in this research project will not involve any additional costs to you.

WHAT HAPPENS IF I HAVE A RESEARCH-RELATED INJURY?

There is no expected risk of research-related injury. However, if you sign this consent form it does not mean that you waive any legal rights you may have under the law, nor does it mean that you are releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

IF I HAVE ANY QUESTIONS OR PROBLEMS, WHOM CAN I CALL?

If you have any questions about the research now or later, please contact Dr. Oren Levine (905-387-9495x63123; levineo@hhsc.ca).

CONSENT STATEMENT

Participant:

I have read the preceding information thoroughly. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I agree to participate in this study. I understand that I will receive a signed copy of this form.

Name	Signature	Date

Person obtaining consent:

I have discussed this study in detail with the participant. I believe the participant understands what is involved in this study.

Name, Role in Study	Signature	Date

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HIREB). The HIREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call the Office of the Chair, Hamilton Integrated Research Ethics Board at 905.521.2100 x 42013.