Participant Information Sheet: Investigating the feasibility of augmented reality and simulation training for urgent laryngectomy care

Name of principal investigator/researcher: Ms Freya Sparks and Ms Louise Occomore-Kent
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We would like to invite you to take part in a research study. Before you decide whether you would like to take part it is important that you understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. You can download a copy of this information sheet to keep. If you have any questions or you would like more information before making your decision you can contact Freya Sparks on freya.sparks@city.ac.uk

What is the purpose of the study?

The purpose of this study is:

- To evaluate the feasibility of augmented reality and simulation-based training for urgent laryngectomy care
- To increase the knowledge of key healthcare professionals in managing urgent laryngectomy care needs
- To gain preliminary efficacy data on training outcomes and wider metrics such as impact on A&E attendances and service user experience

People who have undergone a laryngectomy (removal of the voice box, usually due to throat cancer) have key differences in their anatomy. These differences affect how they breathe, communicate and swallow. For example, people with laryngectomy breathe through a stoma (opening) at the front of the neck instead of via the nose and mouth. Some people with laryngectomy also have a small silicone prosthetic device placed between the trachea and the oesophagus to help them communicate.

Speech and Language Therapists play a central role in the care and rehabilitation of people with laryngectomy. However If a person with laryngectomy requires urgent care, for example at A&E, in an ambulance, a ward or community setting; this may occur outside of SLTs' normal working hours. Therefore they require the support of another healthcare professional (HCP). Due to the differences in anatomy and function, it is essential that other HCPs understand how to support people with laryngectomy in an emergency. This could involve a blockage of the airway or a dislodgement of the prosthesis for example.

With increasing evidence for simulation and augmented reality-based healthcare education, this study aims to establish if these approaches combined are an effective method of educating HCPs about urgent laryngectomy care needs.

Why have I been invited to take part?

We are seeking healthcare professionals who are likely to encounter people with laryngectomy, with urgent care needs. For example, A&E clinicians, on-call Physiotherapists, ENT doctors, head and neck cancer-specialising Speech and Language Therapists, paramedics or therapeutic Radiographers.

Do I have to take part?

No. Participation in this study is voluntary and you can choose not to participate at all in this project. Please take your time to consider whether you wish to participate, it is up to you to decide whether or not to take part. If you do decide to take part, you will be asked to complete a written consent form. You can choose to leave the study without completing it at any time, however any data recorded up to that point may be retained for analysis.

What will happen if I take part?

Taking part means you will attend a one-day training course at City, University of London. The course is free to attend.

What does the training day involve?

The training day will be held at City, University of London. The university is approximately a 15-minute walk from Farringdon or Angel stations. You will be required to attend the whole training day, which it is anticipated will run between 9:00 to 17:00 with mid-morning, lunch and afternoon breaks.

The training is run by Speech and Language Therapists, who specialise in laryngectomy care and rehabilitation; and an expert patient with laryngectomy. It takes place within a medical simulation centre and a classroom environment.

During the morning session you will be given information on the changes to anatomy and function that occur after a laryngectomy surgery. We will explain how this affects breathing, communication and swallowing. Participants will then be supported to take part in immersive simulation scenarios and post-scenario group debriefing. The afternoon session will be a skills-based workshop where we will discuss equipment and daily care needs. This session will use augmented reality to support skill acquisition. The afternoon will also include time with an expert patient with laryngectomy.

You will be asked to complete a short self-assessment and evaluation questionnaire before and after the training day.

What are the possible disadvantages and risks of taking part?

We do not anticipate any risks or disadvantages in taking part. We acknowledge that some participants may feel nervous about taking part in a simulation-based scenario, or apprehensive about discussing laryngectomy-related learning needs within a group. The SLT facilitators aim to create a friendly, safe space for learning with emphasis on exploring and sharing knowledge together. Participants will be able to access support during simulation scenarios and each scenario will be debriefed immediately afterwards by an SLT trained in debriefing and human factors appropriate to simulation-based education.

What are the possible benefits of taking part?

By taking part you will receive training on urgent laryngectomy care needs and education on laryngectomy daily care needs. This will be of benefit to your clinical practice and may also benefit people with laryngectomy requiring urgent care.

How is the project being funded?

This project is by the British Association of Head and Neck Oncology 2024 research grant.

Conflicts of interests

There are no known conflicts of interest held by the research team or funding organisation.

What should I do if I want to take part?

If you wish to take part you can contact Freya Sparks, via freya.sparks@city.ac.uk . We will check if you are eligible to participate and ask the following questions to understand more about your work:

- Which healthcare profession do you work in?
- How many years have you worked post-qualification?
- What area do you work in e.g. A&E, inpatients, community?
- Have you worked with laryngectomy previously?

Data privacy statement

City, University of London is the sponsor and the data controller of this study based in the United Kingdom. This means that we are responsible for looking after your information and using it properly. The legal basis under which your data will be processed is City's public task.

Your right to access, change or move your information are limited, as we need to manage your information in a specific way in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personal-identifiable information possible (for further information please see https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/public-task/).

Participants can opt to obtain an update on the study outcomes by informing the research team and providing their email address or address for postal updates. If you choose to provide your email and/or postal address for updates, this identifiable information will be held for up to one year after the close of the study, so that results can be shared with you. Only the researchers (Freya Sparks and Louise Occomore-Kent) will have access to this information.

City, University of London considers the lawful basis for processing of special category data relating to health to fall under Article (9) (2) of GDPR (Explicit Consent) as the research participants given their explicit consent for the processing of health information by volunteering to take part in the research and the completion of the consent form. The research participants are able to withdraw from the research project at any time.

You can find out more about how City handles data by visiting https://www.city.ac.uk/about/governance/legal. If you are concerned about how we have processed your personal data, you can contact the Information Commissioner's Office (IOC) https://ico.org.uk/.

What will happen to the results?

Data from the study will be analysed and the outcomes will be submitted for publication in peer-reviewed journals, professional publications (e.g. RCSLT Bulletin), disseminated at conference and stakeholder events. Results may include quotations taken from free-text responses if you have given consent for this. Any such quotations will be de-identified and not identifiable to you.

Who has reviewed the study?

This study has been approved by City, University of London School of Health Sciences Research Ethics Committee.

What if there is a problem?

If you have any problems, concerns or questions about this study, you should ask to speak to a member of the research team. If you remain unhappy and wish to complain formally, you can do this through City's complaints procedure. To complain about the study, you need to phone 020 7040 3040. You can then ask to speak to the Secretary to Senate Research Ethics Committee and inform them that the name of the project is **Investigating the feasibility of augmented reality and simulation training for urgent laryngectomy care.**

You can also write to the Secretary at:

John Montgomery
Head of Strategy and Compliance (Research and Enterprise)
City, University of London, Northampton Square
London, EC1V 0HB
Email: senateREC@city.ac.uk

Further information and contact details

You can contact Freya Sparks freya.sparks@city.ac.uk or Louise Occomore-Kent louise.occomore-kent@city.ac.uk If you have any enquiries about the research.

Thank you for taking the time to read this information sheet.

Consent Form

Thank you for agreeing to take part in this study.

	I confirm that I have read and understood the participant information dated 20/06/24 v1.0 for the above study. I have had the opportunity to consider the information and ask questions which have been answered satisfactorily.
	I understand that my participation is voluntary and that I am free to withdraw without giving a reason without being penalised or disadvantaged.
	I understand that once I have completed the training I will not be able to withdraw my data and that, if I leave part-way through the training I will not be able to withdraw any data recorded up to that point
	I understand that de-identified quotations may be taken from my responses and included in publications, conference and stakeholder presentations.
	I understand that de-identified data from this study will be held in City University's data repository and may be used for future secondary analysis in studies that have been given ethical approval.
	I agree to City recording and processing this information about me. I understand that this information will be used only for the purpose(s) explained in the participant information and my consent is conditional on City complying with its duties and obligations under the General Data Protection Regulation (GDPR).
	By participating in this research I consent to the processing of information regarding my profession and the type of location I work in. I understand that I am able to withdraw from the research project at any time.
	I would like to be informed of the results of this study and understand that I can choose for my email or postal address to be collected and retained separately for this purpose.
	I give consent to take part in the study.

Signed (Participant) Name: Date:

Signed (Research Team) Name: Date