

Is Virtual Reality Training a Viable Alternative for an In-Person Tracheostomy Course

Participant Information Sheet (PIS) V 1.1 | 20 Dec 2022 | IRAS ID 327032

You are being invited to take part in a research study which aims to whether virtual reality (VR) technology has the potential to replace face-face tracheostomy skills training.

This study will form part of a PhD research degree. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

➤ **Who will conduct the research?**

Mr Jonathan Abbas; Faculty of Biology, Medicine and Human Health, The University of Manchester.

Prof Brendan McGrath; Intensive Care Medicine, Wythenshawe Hospital, Manchester University NHS Foundation Trust.

➤ **What is the purpose of the research?**

Immersive technology is frequently predicted to play an important role in medical education in the coming years. Whilst there is a rapidly progressing hardware ecosystem it has not been applied to tracheostomy skills courses.

This project aims to answer the following questions

1. Can VR technology be used to deliver learning outcomes related to tracheostomy care traditionally taught during face-face courses?
2. What do trainers feel about this method of education deliver?
3. Do participants enjoy and feel they can learn from a VR course?

Why have I been chosen?

You have been contacted as you are a member of the healthcare team who may be involved in the care of patients living with a tracheostomy. We are looking to recruit a minimum of 60 people to this study. We will recruit candidates who participate in the courses as learners and also the faculty who teach.

➤ **Am I suitable to take part?**

To be included in this study you must be:

1. Healthcare staff or students based in Manchester University Foundation Trust
2. Have the potential to be responsible for the care of patients with a tracheostomy

➤ **Will the outcomes of the research be published?**

The outcomes will be reported at scientific conferences and in peer-reviewed journals, but you won't be identifiable in any of these.

➤ **Who has reviewed the research project?**

The project has been reviewed by the University of Manchester Proportionate Research Ethics Committee.

➤ **Who is funding the research project?**

This research project is being funded by the following institutions:

1. Innovate UK
2. The National Tracheostomy Safety Project

What would my involvement be?

➤ **What would I be asked to do if I took part?**

If you agree to take part, your involvement will be in two stages.

Stage 1 – Course attendance

Following agreement and consent, we will allocate you a unique study-ID identity code number. We will ask you to keep this safe but we can remind you about it if you forget. We use this study-ID to keep your records anonymous.

We will ask you to fill out a survey asking you basic demographic information, healthcare experience and current role, and prior experience with VR technologies.

You will be randomly allocated to one of the three types of education delivery:

1. **F2F.** Traditional half-day face-to-face tracheostomy course (with manikin-based simulation scenarios and teaching)
2. **VR-F2F-Support.** Half-day VR course with face-to-face technical support
3. **VR-Remote-Support** Half-day VR course with remote technical support

There are potential risks from VR headset use which are uncommonly experienced by VR users. These include nausea, disorientation, skin rashes, headaches and dizziness. We will ask you about your experiences after the course with a series of questionnaires:

- Cyber sickness (3 mins)
- System usability (2 mins)
- Course evaluation (5 mins) (One survey for candidates and one for faculty)

Before and immediately after the course you will be asked to fill out a survey asking you about your **knowledge** of tracheostomy care. **Please don't look the answers up.** We are trying to find out if knowledge improves as a result of participation in our course. We estimate that these knowledge questionnaires will take about 10 minutes to complete. We will provide a link to an on-line platform called Qualtrics (hosted by the University of Manchester).

We will also collect some **performance data** about how participants perform during the course. The sort of things we will collect include:

- Correct answers given during standardised questions asked during the course itself.
- Timings to undertake key steps of the emergency scenario. For example:
 - Time to call for help
 - Time to apply oxygen
 - Time to identify and fix the underlying problem

Importantly, these performance data are designed to assess the performance of course and not about the individual participants. We will not be making assessments or judgements about you. We want to study whether these different course formats result in similar performance from participants.

Stage 2 - Knowledge retention test

Around one month following the course we will invite you a further 5-minute knowledge test to check if information learnt on the day of the course has been retained. A link will be emailed to you and the survey completed online via Qualtrics again.

➤ **Will I be compensated for taking part?**

There is no compensation for taking part.

➤ **What happens if I do not want to take part or if I change my mind?**

It is up to you to decide whether or not to take part. If you decide not to take part, you do not need to do anything further. If you do decide to take part, you will be given this information sheet to keep and will be asked to agree to the study online. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights.

Data Protection and Confidentiality

➤ **What information will you collect about me?**

In order to participate in this research project we will need to collect information that could identify you, called “personal identifiable information.” Specifically we will need to collect:

- Age
- Gender
- Current role
- Current professional email address
- Prior experience with VR
- Record of consent

➤ **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes.”

➤ **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our [Privacy Notice for Research](#).

➤ **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way described below.

The study team at The University of Manchester will have access to the personal information that you tell us when you sign up for the study. The study team will anonymise your records as soon as possible. All of the data analysis will take place with anonymised records. We are not collecting any identifiable information such as your name or staff/student ID numbers, but we will ask for your email address so that we can send you information about the courses and the follow up questionnaires.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as

planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

What if I have a complaint?

➤ **Contact details for complaints**

If you have a complaint that you wish to direct to members of the research team, please contact:

Prof Brendan McGrath; Intensive Care Medicine, Wythenshawe Hospital, Manchester University NHS Foundation Trust.

brendan.mcgrath@manchester.ac.uk

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner's Office about complaints relating to your personal identifiable information](#) Tel 0303 123 1113

Contact Details

If you have any queries about the study or if you are interested in taking part, then please contact the researcher(s):

Name: Jonathan Abbas

Email address: Jonathan.abbas@postgrad.manchester.ac.uk

Telephone number: +44 (0)161 701 3543

What Do I Do Now?

If you wish to take part, please navigate to the following link:

www.qualtrics.manchester.ac.uk/jfe/form/SV_6XL9w2FsDkDBQsC