Study Title: Training Healthcare Professionals in an Artificial Intelligence Based Virtual Reality Extracorporeal Membrane Oxygenation Simulator Versus Conventional Video Training; a Multicentre Feasibility Study and Randomised Controlled Trial

Protocol ID: MEC-2023-0666

NCT Number: not yet allocated.

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Validation of a Virtual Reality Extracorporeal Membrane Oxygenator (ECMO) for face, content and concurrent validity; a randomised controlled trial.

Information for research participation

Validation of a Virtual Reality Extracorporeal Membrane Oxygenator (ECMO) in terms of usability, realism and effectiveness compared to the gold standard; a randomised controlled trial

1. Introduction

Dear Participant,

We are excited to invite you to be a part of an (medical) scientific research study. Your participation is entirely voluntary.

This letter provides detailed information about the study, including its purpose and what participation entails. We encourage you to read it thoroughly to understand the study better.

If you are interested, please take your time to read this information letter. Should you have any queries or need further clarification, feel free to ask the research team.

If you decide to participate:

- Please fill out and sign the consent form provided in Appendix B. We appreciate your consideration and hope to have you on board.

2. General Information

The study was set up by Erasmus MC University Medical Centre.
The research is conducted by doctors, clinical perfusionists, and data scientists at the department of thoracic surgery at Erasmus MC.

The Erasmus+ fund (as part of the European Commission) reimburses (part of) the costs of the study.

The non-WMO Toetsingscommissie Erasmus MC has assessed whether or not this research falls within the scope of the Medical Research Involving Human Subjects Act (WMO) and has assessed the research content.

3. What is the aim of this study?

In this study, the aim is to assess the face, content and concurrent validity of the VR-ECMO sim by 1) examining experts' opinions on this simulation with regard to how realistic and useful the VR-ECMO sim is as an ECMO training modality and 2) comparing the performance of novices in performing an ECMO circuit check trained in the VR-ECMO sim with those who underwent conventional training from an expert perfusionist introducing and preparing an ECMO in a randomised controlled trial.

4. How will the study take place and what does it mean for you?

As an expert intensivist/perfusionist, you will be invited to participate in this study. You wil start by first reading this text and asking any questions you may have. You will then complete the attached form in Appendix B. After this, you will receive VR goggles from someone from the research team, who will instruct you how to perform the VR-ECMO simulation. You go through the simulation once and then

fill out two more forms about your experience with the simulator, including a USE questionnaire. The USE questionnaire concerns the usefulness, satisfaction, ease of use and realism of the scenario, which you rate on a scale from strongly disagree (1) to strongly agree (5). The other questionnaire concerns your experience with perfusion, virtual reality, and digital eLearning.

No follow-up is required after this study is completed.

5. What are the advantages and disadvantages of taking part in the study?

You yourself will have no (direct) benefit from participating in this study. Your participation will contribute to the evidence of VR ECMO education, and will help train ICU nurses and other healthcare personnel in the future.

The disadvantages of participating are that it will take 1 hour of your time.

6. If you do not want to participate or want to leave the study

Participation in the study is entirely voluntary. Only if you wish to participate will you sign the consent form (Appendix B).

You can stop the study at any time. Please inform the researcher as soon as possible. You do not have to say why you are stopping. The data collected up to that point will still be used for the study.

7. What data do we collect?

Your name, role, questionnaire scores and feedback will be collected and stored during the course of this study.

8. What will we do with your data?

Why do we collect, use and store your data?
We collect, use and store your data to answer the questions of this research.

We want to publish the results of the research.

How do we protect your privacy?
To protect your privacy, we give your data a code. We associate this code on all your data, and remove any identifiable information from your data.

The data that refers directly to you will then no longer be used. We keep the key to the code in a secure location in our digital research environment at Erasmus MC. Only the researcher and members of the research team know which code you have. When we process or share your data, we always use only that code. In reports and publications about the research, no one can recall that it was about you.

How long do we keep your data?
We will store your data during the research in a secure digital environment at Erasmus MC. They will be kept for 10 years so that they can be used for this research (or similar research in the future). As soon as this is no longer necessary, we will destroy your research data.

Can you withdraw your consent to the use of your data?

You can withdraw your consent to the use of your data at any time. This applies to the use in this study and to the use in other research. If you withdraw your consent, the researchers may still use the data already collected.

Would you like to know more about your privacy?
Would you like to know more about your rights when processing personal data? Then look up https://www.autoriteitpersoonsgegevens.nl/nl/over-privacy/personal data.
If you have any questions or complaints about your privacy, we recommend that you first discuss these with the research team. You can also go to the Data Protection Officer of Erasmus MC. Or you can file a complaint with the Dutch Data Protection Authority.

9. Do you receive compensation for participating?

You will not receive any compensation for participating in this study.

10. Do you have any questions?

This research has been assessed by the Non WMO Assessment Committee Erasmus MC. According to this committee, this research does not fall under the Medical Research Involving Human Subjects Act.

If you have any questions about this research, please contact Drs. Samuel Max, on behalf of the ECMO VR sim team.

The contact details can be found in Appendix A.

Yours sincerely,

The VR ECMO Research Team

Appendix A: Contact information

Lead researcher:
Dr. Edris Mahtab MD PhD
e.mahtab@erasmusmc.nl

Project coordinator:
Drs. Samuel Max Bm Bch (Oxon)
s.max@erasmusmc.nl

Complaints:
The Erasmus MC Complaints Committee
Digital complaints form is available at: www.erasmusmc.nl/nl-nl/patientenzorg/klachtenopvang-enklachtenbemiddeling

Data Protection Officer of the institution:
The Data Protection Officer of Erasmus MC can be reached via the secretariat of the Legal Affairs department. E-mail: redactie.gegevensbescherming@erasmusmc.nl Tel: 010-703 4986

For more information about your rights:
For more information or if you have questions about your rights, please contact the Data Protection Officer or the Dutch Data Protection Authority.

Appendix B: Participant consent form

Title of the study: Validation of a Virtual Reality Extracorporeal Membrane Oxygenator (ECMO) for face, content, and concurrent validity; a randomised controlled trial.

- I have read the information letter. I had the opportunity to ask questions. My questions were answered. I had enough time to decide whether to participate.
- I know that participation is voluntary. I also know that I can decide at any time not to participate or to stop the study. I don't have to give a reason for that.
- I consent to the collection and use of my data in the manner and for the purposes stated in the information letter.
- I give permission to keep my data within Erasmus MC for another 10 years after this research.

I want to participate in this study.

Name (participant):
Signature: Date : __ / __ / __

I declare that I have fully informed this participant about the aforementioned study.

If information becomes known during the research that could influence the participant's consent, I will inform them in a timely manner.

Name of researcher:

Signature: Datum: __ / __ / __
