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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TEMPLATE RESEARCH PROTOCOL

for non-WMO-applicable research

Template 19-01-2023, versie 2

Full title of protocol	Training Healthcare Staff to Use an Extracorporeal Membrane Oxygenator Circuit in Virtual Reality; a Randomised Controlled Trial
Short title or Acronym	HEALTH-ECMO-VR-RCT
Protocol ID / Panama number	11261
Version	V1.0
Date	12/10/2023
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Student Investigator	Priscilla Westbroek – Klinisch Perfusionist in opleiding p.westbroek@erasmusmc.nl
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Sponsor[4] (in Dutch: verrichter/opdrachtgever)	Erasmus MC
Subsidizing party[5]	Erasmus+ Grant 2022-1-NL01-KA220-HED-000087770 LUMC Fellowship Grant 2023

Name	**Signature**	**Date**
Head of Department: Prof. Dr. J (Jolanda) Kluin MD PhD Head of Department (Head of Cardiothoracic Surgery Department)		
Project Leader: Drs. S. A. Max – Physician / PhD Candidate **Principal Investigator:** Dr. E. A. F. Mahtab – Cardiothoracic Surgeon		

1. *Coordinating investigator: Investigator who bears the responsibility for the coordination of investigators operating in the various centers participating in multicenter research. Not all multicenter research will have a coordinating investigator. There is no requirement to appoint one. A project leader has the responsibility to develop a research protocol and to complete the study within the predefined goals.*
2. *Principal investigator: Investigator who has the overall responsibility to comply and to complete the study within the predefined goals.*
3. *Multicenter research: as an alternative you can also state that these are specified in the list with participating centers including principal investigator. This separate document with version date must be uploaded under category I1.*

4. *Sponsor: The party that commissions the organization or performance of the research, for example a pharmaceutical company, academic hospital, scientific organization or the investigator's employee. A party that provides funding for a study but does not commission it is not regarded as the sponsor, but referred to as a subsidizing party.*
5. *Subsidizing party: A party that provides funding for a study but does not commission it*

Table of Contents

Please note that it is not allowed to remove paragraphs from this template protocol. If a paragraph is not applicable, please mention this in the specific paragraph, preferably with a short motivation.

List of abbreviations and relevant definitions*

CTA	Clinical Trial Agreement
De novo biobank	A new data, human material or imaging collection
DMP	Data Management Plan
DPIA	Data Protection Impact Assessment
DTA	Data Transfer Agreement
Exception consent	Form Care for data Template, in Dutch: Formulier uitzondering toestemming
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation in Dutch: Algemene Verordening Gegevensbescherming
IC	Informed Consent
IFU	Instruction For Use
MTA	Material Transfer Agreement
NWTC	Non-WMO Review Committee; in Dutch: Niet WMO Toetsingscommissie
UAVG	Dutch Act on Implementation of the General Data Protection Regulation; in Dutch: Uitvoeringswet Algemene Verordening Gegevensbescherming
WMO	Medical Research Involving Human Subjects Act, in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen

**Please add any new definitions that are used in the research protocol*

Summary

The summary should give a brief description of the central question that the research is intended to answer and its justification. It should specify the hypothesis (if applicable) and the research objectives. In addition, the synopsis should briefly describe the design, population, methods and procedures of the study. Finally, if applicable, the nature and extent of the burden and risks should be indicated.

Rationale
For intensive care staff in training, learning the steps in monitoring the function of an extracorporeal membrane oxygenator (ECMO) machine are fundamental concepts that form the basis on which their future practice will be built. The modality of this training is often practical in the form of an apprenticeship, shadowing experienced intensivists or perfusionists in order to learn their craft. We propose that if this initial training required more active participation in the form of a simulation, that trainees would learn these procedures more quickly and more reliably.

Over the past few years, emerging virtual reality (VR) applications have quickly gained broad attention within the medical field, including in cardiology and cardiothoracic surgery, as well as medical education more generally. Combining VR technology with head mounted displays (HMD), enables the design of a realistic, custom-built simulation in a 3 dimensional fully immersive environment [1]. Our group has developed a Virtual Reality (VR) simulation of the process of monitoring and performing a full circuit check for an ECMO patient. This Virtual Reality Extracorporeal Membrane Oxygenator Simulator (VR-ECMO sim) promises to update how we approach education of perfusionists and intensive care staff for their critical role.

In a related study on the VR-Extracorporeal Simulator (entitled “Virtual Reality Simulation as a Training Tool for Perfusionists in Extra Corporeal Circulation; Establishing Face and Content Validity” currently under peer-review), we showed that experts and novices alike found the simulator to be useful & realistic, and therefore valid for face and content validity. Due to the demonstration of feasibility in a closely related simulator, we aim to demonstrate face and content validity alongside concurrent validity in a single study for the VR-ECMO sim. We hypothesise that VR will enable participants to better learn and retain information through interactive engagement with a virtual reality simulator.

Objective(s)
Primary outcomes

The accuracy with which the predefined sequence of steps is performed by the participant, defined as number of mistakes made and time taken, and amount of prompts/assistance required from the expert perfusionist.

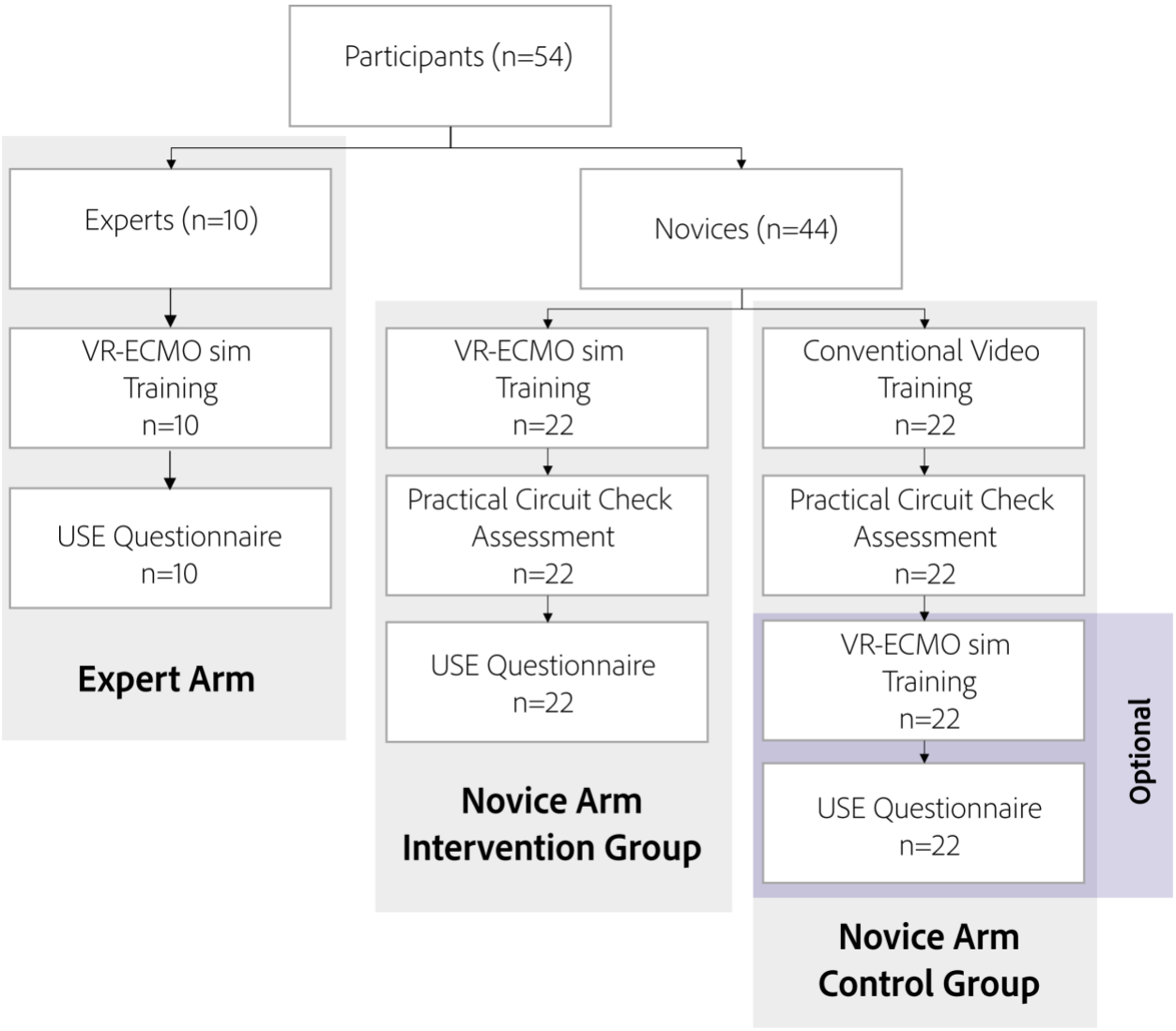
Secondary outcomes

Additional data include participants views on the advantages and disadvantages of virtual reality training in the context of ECMO.

Additional study parameters

Data will be collected on the participants age, gender, experience with ECMO, and experience with VR usage.

Study type
This will be a hybrid study, with an expert & novice face & content study, and contained within the novice group, a single blinded randomised controlled trial.



Study population
Our study will recruit from two populations for the expert and novice arms of this study. For the former, 10 experts who are experienced perfusionists/intensivists with more than 6 years of experience with ECMO will be included. For the novice arm, the population will include intensive care nurses & cardiothoracic surgery nurses who work at one of the academic hospitals in the Netherlands, with no prior experience with ECMO.

Methods
The study is broadly divided into two arms: expert (experienced perfusionists / intensive care staff) and novices (Intensive care staff who have no experience with ECMO) and is summarised in Figure 1.

Novice Arm (Randomised Controlled Trial)

Novice participants will be allocated a study ID from 1-50 at the point of recruitment and randomised by an online research randomiser (https://www.randomizer.org/) between the instructional video (control) group and VR-ECMO sim (intervention) group. The control group will watch a video in which a perfusionist explains how to perform a circuit check for an ECMO patient on VA ECMO. The participants are then individually assessed using a real ECMO machine and ECMO doll, whereby they are asked to repeat the steps that they have been trained in. This assessment is recorded on video to be assessed later by an expert assessor, and an expert perfusionist & assessor will be present during the assessment

to provide prompts when a student is unsure how to perform a certain step. After completion of the assessment, the VR group will be asked to fill out an objective questionnaire (Appendix 2) based on the standardised USE questionnaire [2] to assess baseline characteristics such as prior experience/training and the usefulness, satisfaction, and ease of use of the VR training modality. Participants from the control group will be given the option to also perform the VR training, and subsequently fill a USE questionnaire about their experience with VR.

Expert Arm

Expert participants will not be randomised, and will all perform the VR-ECMO sim before completing the USE questionnaire. Their data will be used for the face and content validity portion of this study.

Randomisation

Participants in the novice arm will be randomly assigned to either interventional or control group, using https://www.randomizer.org/ as stated above to generate a group allocation for the participant according to their study ID number.

Blinding

Participants will not be blinded as the differences in the differing nature of the intervention versus control group do not allow for this. Selected study personnel, including those physically facilitating both groups during the intervention phase will not be blinded, as again the study design does not allow for this. Study personnel who facilitate the physical assessment for the novice arm, perform data collection & analysis, including the expert assessor for the video recording, will be blinded.

Burden and risks
We do not foresee any risks or burdens incurred with participation, aside from mild nausea which may occasionally occur during a virtual reality experience. This typically subsides quickly once the head mounted display is removed.

Recruitment and consent
Our study will recruit from two populations for the expert and novice arms of this study. For the former, 10 experts who are experienced perfusionists/intensivists with more than 6 years of experience with ECMO will be included. For the novice arm, the population will include intensive care nurses & cardiothoracic surgery nurses who work at one of the academic hospitals in the Netherlands, with no prior experience with ECMO. We calculated a required sample size of 44 novice participants (22 per group) in order to likely achieve statistically significant results.

The recruitment process will be performed by a combination of poster advertisements featuring a QR could where participants can sign up. These posters will be hung in areas where eligible staff are likely to gather e.g. break rooms. On the sign-up page, the participants will be asked to enter name and contact details, and then will be presented with the participant information form as attached as an appendix to this application. Once they have read this sheet, and agreed to it in the form by selecting ‘I wish to participate’ from multiple choice question, they will be taken to a further webpage where the option will be given to select a date on which to participate

1. Introduction and rationale

For intensive care staff in training, learning the steps in monitoring the function of an extracorporeal membrane oxygenator (ECMO) machine are fundamental concepts that form the basis on which their future practice will be built. The modality of this training is often practical in the form of an apprenticeship, shadowing experienced intensivists or perfusionists in order to learn their craft. We propose that if this initial training required more active participation in the form of a simulation, that trainees would learn these procedures more quickly and more reliably.

Over the past few years, emerging virtual reality (VR) applications have quickly gained broad attention within the medical field, including in cardiology and cardiothoracic surgery, as well as medical education more generally. Combining VR technology with head mounted displays (HMD), enables the design of a realistic, custom-built simulation in a 3 dimensional fully immersive environment [1]. Our group has developed a Virtual Reality (VR) simulation of the process of monitoring and performing a full circuit check for an ECMO patient. This Virtual Reality Extracorporeal Membrane Oxygenator Simulator (VR-ECMO sim) promises to update how we approach education of perfusionists and intensive care staff for their critical role.

In a related study on the VR-Extracorporeal Simulator (entitled “Virtual Reality Simulation as a Training Tool for Perfusionists in Extra Corporeal Circulation; Establishing Face and Content Validity” currently under peer-review), we showed that experts and novices alike found the simulator to be useful & realistic, and therefore valid for face and content validity. Due to the demonstration of feasibility in a closely related simulator, we aim to demonstrate face and content validity alongside concurrent validity in a single study for the VR-ECMO sim. We hypothesise that VR will enable participants to better learn and retain information through interactive engagement with a virtual reality ECMO simulator versus conventional training.

2. Objective(s)

In this study, the goal is to assess the face, content, and concurrent validity of the VR-ECMO sim by comparing the questionnaire ratings of novices and experts after completing the VR-ECMO sim, and comparing the novice intervention group who completed the VR-ECMO sim versus the control arm (video training) in terms of how well they are able to perform an ECMO circuit check, as rated by an expert.

3. Study type

3.1. **Study type**

☐ Retrospective
☒ Prospective
☐ Combination Retrospective/Prospective

3.2. **Single center / Multicenter**

☐ Single center
☒ Multicenter

3.3 **Check all the applicable boxes**

☐ Medical records (re-use of data from healthcare, including AI)

☐ Case report

☐ Re-use data from research

☐ Evaluations of quality of healthcare (retrospective

☐ Research with additional use of residual material from regular healthcare

☐ Research with re-use of human material from research or existing biobank

☐ De novo biobank

☐ Phase IV research

☐ Healthcare evaluation research (prospective)

☐ Research with medical devices

☐ Research with In Vitro Diagnostic Tests

☒ Other research, describe

Research with medical professionals comparing a new educational simulator with an educational video

4. Study population

4.1. Study population

☒ Adults (16 years and older)

☐ Minors (younger than 16 years)

☐ Incapacitated adults (16 years and older)

☐ Incapacitated minors (younger than 16 years)

4.2. Population (base)

As above; Our study will recruit from two populations for the expert and novice arms of this study. For the former, 10 experts who are experienced perfusionists/intensivists with more than 6 years of experience with ECMO will be included. For the novice arm, the population will include intensive care nurses & cardiothoracic surgery nurses who work at one of the academic hospitals in the Netherlands, with no prior experience with ECMO.

4.3. Inclusion criteria

Novices Inclusion Criteria

In order to be eligible as participant in this study in the **Novice Arm**, a subject must meet the following criteria:

1. Currently working as a nurse in one of the academic hospitals in the Netherlands
2. Provide informed consent

Experts Inclusion Criteria

In order to be eligible as participant in this study for the **Expert Arm**, a subject must meet the following criteria:

1. Currently working as an intensivist or perfusionist in one of the academic hospitals in the Netherlands
2. Provide informed consent

4.4 Exclusion Criteria

Novices Exclusion criteria

1. Failure to provide informed consent
2. Previous experience with ECMO equipment
3. Any reason that participants may not be able to perform the physical assessment

Experts Exclusion criteria

1. Failure to provide informed consent
2. Less than 6 years' experience with ECMO

4.5 Sample size calculation

We calculated a required sample size of 32 novice participants (16 per group) in order to likely achieve statistically significant results in the Novice RCT arm. This is based on an alpha of 0.05, beta of 85, and a mean difference of 1. The expert group requires 10 participants in order to reasonably assess the face & content validity.

5. Methods

5.1. Research methods

Data will be extracted using online questionnaires. These questionnaires will be built in Microsoft Forms, the results from which are sorted in Microsoft Sharepoint. In this way, results are automatically added when a form is completed, and assigned to the correct row using the participant's study ID, assigned to them once they are recruited. Video footage of the physical assessments will be filmed with a camera, before the footage is locally stored on the V drive, and also a backup of the footage is made in Sharepoint.

Once the study is complete, an archive of the study data will be created, and stored for 10 years using the facilities afforded to us by the Erasmus MC.

5.2. Standard clinical care versus extra for research

N/A

5.3. Burden and risks

Aside from mild nausea which may occasionally occur during a virtual reality experience,wWe do not foresee any risks or burdens incurred with participation. Any nausea typically subsides quickly once the head mounted display is removed.

5.4. Medical device(s) / In vitro diagnostic tests

N/A

6. Incidental findings

6.1. Chance of incidental findings

Is there a chance of incidental findings?

☐ Yes

☒ No

6.2. Procedures

If yes, describe who will be notified and how the subjects and other parties will be notified in case of incidental findings from the study that may be in the interest for the participant's health.

7. Statistical analysis

Describe how data will be analyzed

7.1 Main study parameters/endpoints

The accuracy with which the predetermined sequence of steps involved in an ECMO circuit check is performed by the participant. This is defined as number of mistakes made, and amount of prompts/assistance required from the expert perfusionist present at the assessment. Additionally, time to

accurately perform the predetermined endpoints/steps in the protocol of performing a circuit check as defined in Appendix 3.

7.2 Secondary study parameters/endpoints

USE questionnaire (Appendix 2) to include participant ratings on the perceived usefulness, satisfaction, ease of use, and level of immersion of the VR-ECMO sim. Additional data include participants views on the advantages and disadvantages of virtual reality training in the context of ECMO.

7.3 Other study parameters

Data will be collected on the participants age, gender, experience with ECMO, and experience with VR usage.

7.4 Analysis

Please describe how the analysis will be done for the outcome parameters.

R version 4.2.2 will be used for analysis. Continuous data will be assessed for normal distribution using a Q-Q plot and Shapiro Wilk test. The data will be described as median (IQR) or means (SD) and compared using either an unpaired t-test or the Mann-Whitney U test (whichever is appropriate according to the distribution) will be used to determine significance. Categorical variables will be reported as numbers (%) and compared using a chi-squared test or fishers exact test (whichever is appropriate according to the distribution). All baseline characteristics and outcome data will be compared using abovementioned tests. In case of confounding variables, we will correct for these using Analysis of Covariance (ANCOVA). A P-value of <.05 will be considered statistically significant.

8. Ethical considerations

8 Regulation statement

The study will be conducted according to the principles of the Declaration of Helsinki (64th WMA General Assembly, Fortaleza, Brazil, October 2013), Gedragscode Gezondheidsonderzoek 2022 and in accordance with ISO 27799:2016(en) standards, regulations and Acts.

8.1 Informed consent

Will the subjects be asked for informed consent?

☒ Yes *(Upload Participant Information Letter and Informed Consent)*

☐ No, consent already given in previous study *(Upload Participant Information Letter and Informed Consent previous study)*

☐ No, this research will be performed under the exception consent *(Upload form Care for data Template, in Dutch: Formulier uitzondering toestemming)*

☐ Other (e.g. partly, indirectly) *Please describe the situation.*

8.2 Recruitment and informed consent procedures

If yes, please give a description of the recruitment and informed consent procedures. How and by whom (investigator, supervising doctor, other person) participants will be informed about the

study and asked for their consent, how much time will they be given to consider the decision. The patient information letter with informed consent form should be attached as a separate document.

The recruitment process will be performed by a combination of poster advertisements featuring a QR code where participants can sign up. These posters will be hung in areas where eligible staff are likely to gather e.g. break rooms. On the sign-up page, the participants will be asked to enter name and contact details, and then will be presented with the participant information form as attached as an appendix to this application. Once they have read this sheet, and agreed to it in the form by selecting 'I wish to participate' from multiple choice question, they will be taken to a further webpage where the option will be given to select a date on which to participate

8.3 **Exception consent**
N/A

9. Handling and storage of data / images / sound recordings / photos / film recordings

Data / images / sound recordings / photos / film recordings
Please describe which data / images / sound recordings / photos / film recordings is/are used, are they obtained for regular healthcare purposes or in the context a research project, or a combination.

In line with Erasmus MC guidelines, all video footage recordings will be kept 10 years after it is collected. The videos of the assessments will be stored on Microsoft Sharepoint, with filenames labelled only with the participants' study ID. Only the PI, research coordinator, and the expert who will assess the videos will be granted access to them.

9.1 **Privacy protection**
Describe how subject's privacy is protected. Describe how, when and by whom data is coded (unique code without initials or date of birth) and how the key table is safeguarded, mention the General Data Protection Regulation.

The handling of data will comply with the EU General Data Protection Regulation and the Dutch Act on Implementation of the General Data Protection Regulation (in Dutch: Algemene Verordening Gegevensbescherming en Uitvoeringswet Algemene Verordening Gegevensbescherming. A key table is produced and stored on Microsoft Sharepoint with only the PI and Research Coordinator who will be granted access to it. The rest of the data is stored in a separate table containing no identifiable personal information. The latter database includes all of the data from the questionnaires and the results from the assessments. The final data include the videos of the assessment, which stored on sharepoint, labelled only with the participants study ID. Only the PI, research coordinator, and the expert who will assess the videos will be granted access to them.

9.2 **Handling and storage of data**
Describe how data is handled and stored (i.e., which data management system/data capture system), anonymous / pseudonymized / coded / identifiable, who has access to the coded source data, how long data will be kept, which steps are taken to ensure data security, what happens with the data after the research has been completed.

Each pseudonymised participant data set will be assigned a study number known by the investigator. Using these coded study numbers, offline data will be stored using SPSS. Data will be stored on an Erasmus MC local network drive with automatic overnight back-up. Stored data regarding anonymous data sets and personnel included in this study can only be accessed by the investigators, the Erasmus MC ethics committee, Erasmus MC auditors and Erasmus MC monitors and any person or

agency required by law like the “Inspectie voor de Gezondheidszorg”. All data will be treated according to the “Wet Bescherming Persoonsgegevens” and the Erasmus MC privacy regulations. Any information from this study, if published in scientific journals or presented at scientific meetings, will not reveal participant identity. Data will be stored for a minimum of 10 years according to Erasmus MC guidelines, and a maximum of 15 years after ending the study. Collected data will be secured against unauthorised access and will be stored and secured by the department of Cardiothoracic Surgery.

9.3 **Handling and storage of images / sound recordings / photos / film recordings**
Describe how images / sound recordings / photos / film recordings are handled and stored, how the subject’s privacy is protected, anonymous / pseudonymized / coded / identifiable, what happens with images after the research has been completed.

As above, the videos of the assessment will be stored on Microsoft Sharepoint, labelled only with the participants study ID. Only the PI, research coordinator, and the expert who will assess the videos will be granted access to them. After the completion of the study, in line with Erasmus MC guidelines, all video footage recordings will be kept 10 years after they are collected, and will be destroyed after 10 years.

9.4 **Approval of access to data / images / sound recordings / photos / film recordings**
Describe how the access is approved. Is access granted by the Data Board, Department, Principal investigator of the collection or other?

Access is determined by the primary research team (PI + Project Coordinator), and only members of the research team and any authorized audit bodies may access the video recordings.

10. Handling and storage of human material

10.1 **Human material**
N/A

10.2 **Check all the boxes which are applicable to the human material origin:**

☐ Residual material from regular healthcare

☐ Research (material acquired from a previous study).
Add the reference of the study i.e., MEC-number Erasmus MC.

☐ Re-use of human material from existing biobank
Describe whether the human material originates from research into the same disease.

☐ Other, *please specify*

10.3 **Handling and storage of human material**

☐ Anonymous, i.e. the material can never be traced back to an individual subject

☐ Pseudonymized/Coded

☐ Identifiable

Describe how human material is handled and stored (i.e. which data management system / data capture system), anonymous / pseudonymized / coded / identifiable, who has access to the human material, how long the human material will be kept, what happens with the data after the research has been completed.

In line with Erasmus MC guidelines, human material will be kept 10 years after it is collected.

10.4 **Biobank**
In case of new human material collection (biobank), describe how the human material is coded and stored (which registration system, Central Biobank or other location), who has access to the registration system and human material, by whom the key to the code is safeguarded, how long and where human material will be kept, what happens to the human material when the storage period is expired.

10.5 **Approval of access to human material**
Describe how the access is approved. Is access granted by the Department, Principal investigator of the collection or other?.

11. Exchange, sharing or transfer of data and/or human material and/or images

Describe with which organization the data and/or human material and/or images are shared, are they profit or non-profit organizations, whether these organizations are in the EU or outside the EU, how the privacy of subjects is protected outside the Erasmus MC and describe the procedures regarding the exchange(s), whether a Data Transfer Agreement/Material Transfer Agreement is available (if yes, please upload the DTA/MTA).

N/A

12. Amendments

Any amendments of alterations to the study in terms of overall study design, intervention, or analysis will be submitted to the METC for approval, and participants notified where necessary. Substantial amendments must be approved by the Niet WMO Toetsingscommissie before they can be implemented.

13. End of study report

Within one year after the end of the study a final study report will be submitted with the results of the study, including any publications/abstracts of the study.

This will be completed one year after the conclusion of the study.

14. Publication

Do you have the intention to submit the study results in a manuscript for publication in a journal:

☒ Yes

☐ No, *please motivate*

Describe when the final study report with the results of the study will be submitted.

We aim to have the results analyzed and published by March 2024

15. References

Include a list of all key references published in peer review journals that are relevant for the study and are discussed in the protocol

1. Sadeghi A, Peek J, Max S, Smit L, Martina B, Rosalia R, Bakhuis W, Bogers A, Mahtab E. Virtual Reality Simulation Training for Cardiopulmonary Resuscitation After Cardiac Surgery: Face and Content Validity Study JMIR Serious Games 2022;10(1):e30456 URL: https://games.jmir.org/2022/1/e30456 DOI: 10.2196/30456

2. Lund A. Measuring Usability with the USE Questionnaire. Usability and User Experience Newsletter of the STC Usability SIG. 2001;8.

3. Dankbaar MEW, Richters O, Kalkman CJ, Prins G, ten Cate OTJ, van Merrienboer JJG, et al. Comparative effectiveness of a serious game and an e-module to support patient safety knowledge and awareness. BMC Medical Education. 2017;17(1):30.

4. Dankbaar M, Roozeboom M, Oprins E, Rutten F, Saase J, Van Merrienboer JJG, et al. Gaming as a training tool to train cognitive skills in Emergency Care: how effective is it? 2014. p. 13-4.

Currently under review:

Babar ZUD, Max SA, Martina BG, Rosalia RA, Peek JJ, van Dijk A, Sadeghi H, Mahtab EAF. Virtual Reality Simulation as a Training Tool for Perfusionists in Extracorporeal Circulation: Establishing Face and Content Validity (2023)

16. Attachments

☒ Participant information letter and Informed consent document

☐ Care for data Template – Formulier uitzondering toestemming

☒ Questionnaires

☐ Data Management Plan

☐ Data Transfer Agreement

☐ Material Transfer Agreement

☐ Clinical Trial (Site) Agreement

☐ Other, *please describe*

Appendix 1

Baseline Participant Data Questionnaire

1. Gender:_____
2. Age: _____
3. Job title: _____

4. How many years of work experience do you have?
    - <1 year
    - 1-5 years
    - 5-10 years
    - More than 10 years

5. How many years of experience do you have working with ECMO machines?
    - I have never worked with ECMO machines
    - 0-5 years
    - 5-10 years
    - More than 10 years

6. Do you have experience with gaming consoles (e.g. computer gaming, xbox, playstation)?
    - I have never used a gaming console
    - I have used a gaming console a few times before
    - I am gaming on a regular basis (at least once a month)

7. How often do you use VR hardware/software (e.g. VR gaming, simulations, consoles, entertainment etc.)?
    - I have never had a VR experience until today
    - I have used VR a few times before
    - I am experienced and use VR on a regular basis (at least once a month)
    - I am an VR expert (have a VR console and applications myself)

8. Do you have experience with physical simulation trainings ()?
    - I have never had simulation training before
    - I have had simulation trainings multiple times before
    - I am a certified simulation trainer

9. Do you have experience with digital training (e.g. e-learning or serious games)?
    - I have never had such training before
    - I have had a digital training a few times before
    - I have had digital trainings multiple times before

10. Do you have experience with simulation training in VR?
    - Yes
    - No

Appendix 2 - User Experience USE Questionnaire

		1. Fully disagree	2. Disagree	3. Neutral	4. Agree	5. Fully agree	N/A
	Usefulness						
1	I learned a lot from this simulation about how to perform an ECMO circuit check						
2	The training helped me being more confident in managing ECMO patients						
3	The training helped me remember the steps an ECMO circuit check						
4	After the training, I have enough knowledge to take the lead in an ECMO circuit check						
	Satisfaction						
6	I enjoyed participating in this ECMO simulation						
7	I was satisfied with the quality of this simulation						
8	I would recommend using this simulation to other colleagues						
9	I would prefer VR training additionally to conventional training (shadowing an expert)						
10	I would prefer VR training instead of conventional training (shadowing an expert)						
	Ease of use						

11	The software is easy to use						
12	I learned to use it quickly						
13	The interaction with the software felt intuitive						
14	I can use the software without written instructions						
	Immersiveness						
15	I was <u>not</u> distracted during the training						
16	The simulator was realistic						
17	I felt like I was in a real ICU box						
18	I was interested in the progress of the events within the simulation						
19	I felt actively involved in the patient scenario of the training						

Please list and rank, in order of importance from most (1) to least (3), the advantages and disadvantages of training to use an ECMO machine in VR:

<u>Advantages:</u>

1.

2.

3.

<u>Disadvantages:</u>

1.

2.

3.

Do you have any additional suggestions or recommendations for enhancing or adding new features to the simulation?

_____

_____

_____

_____

Thank you for participating

Appendix 3

Skill Assessment Form

Step	Completed Correctly Yes	No	Time to action (min:s)	Comments
1. Checking RPM, flow, and pressures				
2. Checking alarm limits for flow, and venous & arterial pressures				
3. Checking for presence of tubing clamps				
4. Checking for colour difference between venous & arterial lines with flashlight				
5. Check cannulation site, and confirm the canula has not moved				
6. Check lines for blood clots, and confirm they are free from kinks or obstructions				
7. Check the oxygenator for fibrinogen strands or blood clots using the flashlight				
8. Check arterial line outflow at the oxygenator for clots				
9. Check FiO2 and gas flow settings				
10. Check that the heparin line is attached to the oxygenator, and confirm the dose on the pump				
11. Check that the backup RPM meter on the ECMO system is functional, and check hand crank is present and operational.				
12. Check the heater cooler temperature settings and check for circulation				

13. Check lab results in the patients electronic health record				

Additional Comments: