Informed Consent Form

Participant information: CPV-RCT: Cardiopulmonary Resuscitation Virtual Reality Simulation vs. Conventional Training for Cardiac Arrest after Cardiac Surgery: A Randomised Controlled Trial

General information and objectives

The cardiopulmonary resuscitation (CPR) protocol of post-cardiac surgery patients differs from the protocol for other clinical patients. A main difference is the rapid decision for re-sternotomy. Over the past years emerging virtual reality (VR) applications have quickly gained broad attention in the medical field, including cardiology and cardio-thoracic surgery, as well as medical education and communication. Combining VR technology with head mounted displays (HMD) (e.g. Oculus), enables the design of a reality-like, custom made simulation in a 3D and fully immersive environment. Such a VR simulation enables the user to train themselves repeatedly and learn the steps described within the protocol in a reality-like setting, without the need for other supplies or instructor-led training sessions. In this research we investigate the concurrent validity of the CPVR-sim Virtual Reality training. This study will be performed during the “juniorkamer NVT”.

1. What participation involves

If you participate in this study, you will first fill in a short questionnaire, about experience in cardiothoracic surgery, CPR experience after cardiac surgery, and experience with digital training methods such as e-learning and Virtual Reality.
Next, you are randomly assigned to one of the two groups:

1. Conventional ALS training for cardiac arrest after cardiac surgery
2. Virtual Reality (CPVR-sim) training

After completion of the training, you will perform a videotaped assessment. A blinded expert will review and time the performance using a checklist. After this test the study is completed. No follow up is required. There are no risks involved in participating.

2. If you don’t want to participate and/or stop participating in the study

Participation is voluntary, so you decide whether to participate or not in this study. You can decide to stop participating at any point. Your participation ends if you choose to stop or when all measurements are completed.

3. Usage and storage of data

Your personal data will be collected, used, and stored securely for this study. This concerns data such as age, experience in CTC, VR and e-learning. Additionally, a video-recording is made of the assessment. The collection, use, and storage of this data is necessary to answer the questions asked in this research and to publish the results. When data is collected, your data will be assigned a study code, and the data is anonymized. Only with a key the data is traceable, this key is safely stored in the Erasmus MC. 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 maximum of 15 years after ending the study.

Consent form for participation in scientific research

Title of the research: **CPV-RCT: Cardiopulmonary Resuscitation Virtual Reality Simulation vs. Conventional Training for Cardiac Arrest after Cardiac Surgery: A Randomised Controlled Trial**

I declare that I read the consent form. I had the opportunity to ask additional questions which are answered to my satisfaction.

- I had sufficient time to consider my participation
- I am aware that participation is voluntary and that I may decide at any time not to participate or withdraw from the study. I do not need to give a reason for this.
- I give permission for collection and use of my data to answer the research question of this study,
- I am aware that some people may have access to my data in order to verify the study. These people are listed in the information sheet. I give consent for the inspection by them.

O I **do** want to participate in this study and give consent for using my data for this study

O I **do not** want to participate in this study and give consent for using my data for this study

_____

Name of study subject: .....

Signature: ..... Date: __ / __ / __

_____

I hereby declare that I have fully informed this study subject about this study.

Name of investigator (or his/her representative): .....

Signature: ..... Date:__ / __ / __