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Comparing virtual reality simulation training for resuscitation after cardiac surgery with traditional classroom training

Submission date
12/10/2022

Recruitment status
No longer recruiting

Registration date
08/11/2022

Overall study status
Completed

Last Edited
29/12/2023

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims

The cardiopulmonary resuscitation (CPR) protocol for patients who undergo open heart surgery through an incision (cut) in the middle of their chest differs from the conventional advanced life support protocol for other patients. These differences have led to the development of the Society of Thoracic Surgeons (STS) Cardiac surgery Advanced Life Support (CALS) protocol that has been widely adopted by cardio-thoracic surgical centres around the world. Adherence and prompt progression through these guidelines has shown to significantly improve outcomes in patients who experience cardiac arrest after cardiac surgery. Learning how to effectively manage such an arrest is difficult, principally because these events occur relatively infrequently, the time critical nature of the event, and the high cognitive load associated with this stressful situation, which impairs short-term memory performance and learning. Currently, the gold standard for CPR education is certified Advanced Life Support (ALS) training based on guidelines by the European Resuscitation Council (ERC). ALS training includes a plenary presentation on ALS and some exceptional ALS cases including for patients after cardiac surgery and several patient scenarios which are executed using a mannequin doll, and are evaluated based on the accuracy of the protocol by certified CPR trainers after which participants will receive a certificate.

Over the past few years, emerging virtual reality (VR) applications have quickly gained broad attention within the medical field, including in cardiology and cardio-thoracic 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 3D fully immersive environment. Such a VR simulation (cardiopulmonary virtual reality simulator or CPVR-sim) was developed to train physicians and members of the multidisciplinary team for several CPR scenarios post-cardiac surgery. CPVR-sim enables the user to train themselves repeatedly and learn the steps described within the protocol in a realistic setting, without the need for other supplies or instructor-led training sessions. At present, only one study on the CPVR-sim has been conducted, to assess the face and content validity, which found that experts and their junior colleagues alike found this training method useful, easy to use, and would be suitable as an adjunct to additional training.

In order to assess the concurrent validity and effectiveness of this simulation, the aim is to

perform the first randomized controlled trial (RCT) to show the value of CPVR-sim, compared with the gold standard of CPR training. It aims to impart the key differences between the standard ALS guidelines versus the ALS guidelines post-cardiac surgery, the components of the STS protocol, and other clinical insights regarding the management of post-cardiac surgery arrests.
The aim is to show that participants who undergo VR training will be able to progress through the algorithm accurately and as quickly as participants who only undertake the traditional training, thereby demonstrating the utility of the CPVR-sim. This trial will therefore compare the scores and timing of predefined clinical endpoints and technical steps, based on the international guidelines between the control group (gold standard training) and the intervention group (CPVR-sim).

Who can participate?
Trainee heart surgeons in the Netherlands who have more than 1 year of experience

What does the study involve?
Participants will be divided into two groups, where one group will undergo VR training and the other will undergo conventional classroom teaching followed by a practical teaching session using a resuscitation doll. The researchers will then compare the performance of these two groups using the aforementioned doll in a physical test scenario. They will time the participants and see how long it takes to reach specific points in the cardiac surgery resuscitation algorithm. They will also monitor if they make any mistakes or do any steps in the wrong order.

What are the possible benefits and risks of participating?
It is expected that participants will gain a better knowledge of the cardiac surgery resuscitation protocol and thereby deliver better patient care. There is a small risk of physical injury when performing the physical assessment due to overexertion, or inappropriate handling of sharp instruments, which will be left sheathed for the purposes of the assessment.

Where is the study run from?
The study is run from the Erasmus Medical Centre, but the training day will be held at QTTime in Houten, The Netherlands, where they have the appropriate resuscitation simulation equipment.

When is the study starting and how long is it expected to run for?
January 2022 to November 2022

Who is funding the study?
1. Erasmus MC (Netherlands)
2. The junior association of cardiothoracic surgeons in the Netherlands
3. Gettinge group (Sweden)

Who is the main contact?
Dr Edris Mahtab, e.mahtab@erasmusmc.nl

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
MEC-2022-0227, date 24-03-2022

Study information

Scientific Title
Virtual reality simulator versus conventional advanced life support training for cardiopulmonary resuscitation post-cardiac surgery: a randomized controlled trial

Acronym
CPVR-RCT

Study objectives
A Virtual Reality Simulator for Advanced Life Support after Cardiac Surgery performs comparably to the gold standard of classroom and moulage Advanced Life Support Training in preparing residents for cardiac arrest situations after cardiac surgery requiring resternotomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/03/2022, Medical Ethics Review Committee Erasmus MC (Dr. Molewaterplein 40 3015 CD Rotterdam, The Netherlands; +31 (0)10 7033625; metc@erasmusmc.nl), ref: MEC-2022-0227

Study design
Single-centre interventional single-blinded randomized trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Patients who experience cardiac arrest after cardiac surgery

Interventions
Participants will be randomized using the Castor software package (Civit B.V., Amsterdam, The Netherlands). The randomisation strategy is block randomisation, using blocks of 4, based on the level of experience of each participant, defined as junior (<4 years), and senior (>4 years), such that the distribution of experience in both groups is roughly equal.

Participants in the control group will receive standard ALS training specifically for patients with cardiac arrest after cardiac surgery, from a certified ALS instructor. This training included a presentation of the protocol (±15 minutes) and simulation training (±45 minutes) with a resternotomy manikin (CSU-ALS 4th generation manikin, CALS, UK).

Participants in the VR group first will receive a short (± 5 min) introductory briefing on how the VR headset and controllers work. Next, they will undergo CPVR-sim simulation training including three different (ventricular fibrillation/pulseless electrical activity/asystole) patient cases. This CPVR-sim will take an estimated ±30-45 minutes to complete per participant, depending on their skills and experience with VR/gaming and their knowledge of the CPR protocol.

Intervention Type
Other

Primary outcome(s)
1. Successfully delivered three shocks within a given moment (1 minute) during the training
2. Successfully performed resternotomy within a given moment (5 minutes) during the training

Key secondary outcome(s))
1. Protocol deviations, defined as incorrect order of actions, missed steps, or incorrect execution of an action during the training
2. The time to specific actions that should be performed as part of the CALS algorithm stated in the international guidelines

Completion date
01/11/2022

Eligibility

Key inclusion criteria
1. CTS residents in the Netherlands
2. Have at least 1 year of experience in cardiothoracic surgery. This data will be taken from a baseline questionnaire about their work experience in the field of CTS, cardiac arrest in patients after cardiac surgery, and (emergency) resternotomies
3. Participants must provide informed consent in order to be eligible to participate in this study
4. There are no age criteria

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group

Adult

Sex
All

Total final enrolment
31

Key exclusion criteria
1. Not able to partake in the conventional or VR training
2. Not able to perform the physical assessment
3. Fail to provide informed consent

Date of first enrolment
01/05/2022

Date of final enrolment
17/05/2022

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus MC, Erasmus University Medical Centre Rotterdam
Dr. Molewaterplein 40
Rotterdam
Netherlands
3015GD

Sponsor information

Organisation
Erasmus MC

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medisch Centrum

Alternative Name(s)
Erasmus Medical Center, Erasmus MC, Erasmus Universitair Medisch Centrum, Erasmus University Medical Center, Universitair Medisch Centrum Rotterdam, Erasmus Universitair Medisch Centrum Rotterdam, EMC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Funder Name
Juniorkamer Nederlandse Vereniging van Thoraxchirurgie

Funder Name
Getinge Group

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request for participants only, and they will only be able to access data pertaining directly to themselves, in accordance with GDPR. Anonymised data will be available for audit by relevant public bodies, and/or research integrity organisations, solely for the purposes of auditing the study.

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The data will available for audit for a maximum period of 15 years after the conclusion of the study.
Informed consent will be gained from each participant prior to participation in any trial-related activity. Participant data will be anonymised, with a key available to de-anonymise should this be required for audit purposes.
There are no other relevant legal or ethical restrictions regarding our participant data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/02/2023	29/12/2023	Yes	No
Participant information sheet	version 1	24/03/2022	13/10/2022	No	Yes