ISRCTN10064213 https://doi.org/10.1186/ISRCTN10064213

Randomised control trial comparing two methods of learning: the Cambridge Medical Robot virtual reality headset, and computer-based e-learning modules, for training the set up of the Cambridge Medical Robot in an operating theatre

Submission date	Recruitment status	[_] Prospectively registered
23/06/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/08/2023	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/09/2024	Surgery	

Plain English summary of protocol

Background and study aims
This study aims to test the usability and effectiveness of a virtual reality headset which takes students through setting up a robotic machine in the operating theatre compared to an online learning programme currently used as part of the learning process.

Who can participate?
Medical students with no prior robotic exposure

What does the study involve?
Students will be randomly allocated into two groups: one will have the online e-learning resources, and the other will be issued a virtual reality headset which includes different tasks that 'immerse' them into an operating room environment where they can watch and practice the steps through virtual reality. They will be asked to complete either allocated resource within 2 weeks and attend the assessment thereafter.

What are the possible benefits and risks of participating?
The benefits of taking part include access to a new technology. Minor risks involve that of immersing into a virtual environment: a small risk of eye strain from using a VR headset for prolonged periods of time and will be cautioned against in the participant information sheet. It will be suggested participants use the headset in a space free of any wires/objects so as to not trip or collide with these in a virtual environment.

Where is the study run from?
Cardiff and Vale University Health Board (UK)

When is the study starting and how long is it expected to run for?
December 2022 to July 2023

Who is funding the study?
Cardiff and Vale University Health Board (UK)

Who is the main contact?
Catherine Eley, catherine.eley@wales.nhs.uk

Contact information

Type(s)
Principal investigator

Contact name
Miss Catherine Eley

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
VROBOT: Virtual Reality Or e-learning Better for robot Operating Theatre set up

Acronym
VROBOT

Study objectives
Virtual reality training improves practical operating room set-up when compared to existing e-learning module training

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/01/2023, Cardiff University School of Medicine Research Ethics Committee (Cardiff University, Heath Park, Cardiff, CF144XN, United Kingdom; +44 (0)2920687689; hcareethics@cardiff.ac.uk), ref: SMREC23/01

Study design
Single-centre interventional single-blinded randomized control trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Improvement of the set-up of the CMR Versius robot in an operating theatre

Interventions
Participants were randomised using an electronic randomiser into one of two groups. CMR (Cambridge Medical Robot) Virtual reality headsets were issued to the virtual reality training group and CMR e-learning credentials issued to the e-learning group. The assessors were blinded to the training intervention. The training method was issued and participants were given 2 weeks to complete either method.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
CMR (Cambridge Medical Robot) virtual reality headset

Primary outcome(s)
Improvement in operation theatre CMR versius robot set-up is measured using a modified CMR assessment sheet following the completion of either intervention. The overall score will be measured using the sum of 38 tasks using a Likert scale of 1-5 per task: Timepoint 0 hours; Total score /190

Key secondary outcome(s))
Robot set-up self-assessed confidence:
1. Individual task scores will be measured using a Likert scale of 1-5 at 0 hours post-assessment: Timepoint 0
2. Time will be measured in minutes from the beginning to the end of the assessment: Timepoint 0
3. Self-assessed confidence scores will be assessed using a Likert scale of 1-5 at 0 hours post assessment

Completion date
01/07/2023

Eligibility

Key inclusion criteria
1. Medical students with no prior robotic experience
2. Access to a laptop and internet connection at home
3. Visually able to use the VR headset

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Those with prior education in setting up the CMR Versius robot
2. Those unable to use the VR headset

Date of first enrolment
08/02/2023

Date of final enrolment
01/05/2023

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Sponsor information

Organisation
Cardiff and Vale University Health Board

ROR
https://ror.org/0489f6q08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Cardiff and Vale University Health Board

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request from Catherine Eley (catherine.eley@wales.nhs.uk).
The type of data that will be shared: SPSS spreadsheet of anonymised data.
Whether consent from participants was required and obtained: Consent was obtained via returned electronic consent form.
Comments on data anonymization: Participants were assigned a participant ID and all data saved was done so anonymously using this study ID number.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/03/2024	11/09/2024	Yes	No
Participant information sheet	version 2		26/06/2023	No	Yes