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The effect of virtual reality cataract extraction simulation surgery training on patient safety and outcomes

Submission date
08/12/2020

Recruitment status
No longer recruiting

Registration date
15/12/2020

Overall study status
Completed

Last Edited
04/01/2024

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Simulation medical education has been long recognized for its advantage in allowing trainees to experience the consequences of their decisions and actions as they learn new skills without putting patients at risk. For decades, eye surgeons in Hong Kong have first practiced surgery in pigs' eyes as a simulation, but this only produced limited benefit due to the differences in tissue consistency and anatomy to human eyes.

With the advent of 3-dimensional computer-generated virtual reality operating environments, the simulated phacoemulsification (a method used for cataract surgical treatment) surgical experience has become more authentic. Given the wide adoption of simulator-based training by universities and tertiary ophthalmic centers in many parts of the world, there is an imminent need for a robust clinical trial to justify the efficacy of implementing virtual reality simulator training modules in structured phacoemulsification surgery training programmes.

The aim of this study is to determine the effect of Eyesi virtual reality training on phacoemulsification performed on actual patients by eye doctor trainees. The study expects that trainees who receive simulation training on Eyesi will have a better overall technical performance on phacoemulsification cataract surgery on actual patients and a reduced operation time required than trainees who have no prior Eyesi training.

Who can participate?
Basic ophthalmic surgical trainees who sign informed consent before participation in the study will be eligible. Trainees will be recruited from Hong Kong Hospital Authority (HA) clusters (Eight hospitals: Pamela Youde Nethersole Eastern Hospital, Tung Wah Eastern Hospital, Hong Kong Eye Hospital, Tseung Kwan O Hospital, United Christian Hospital, Prince of Wales Hospital, Alice Ho Miu Ling Nethersole Hospital and Tuen Mun Eye Centre.) in Hong Kong are eligible to participate in the study. All trainees should have no ophthalmic microsurgical simulation training or phacoemulsification experience in the operating theater prior to enrolment.

What does the study involve?
Trainees will be randomly allocated into two equal-sized groups to receive either Eyesi and wet laboratory training versus wet laboratory training only.

Trainees must attend and complete a module before proceeding to the next. All trainees receive the first two modules. The first module consists of basic microsurgical training workshop and extracapsular cataract extraction course under supervision. The second module is phacoemulsification wet laboratory training with phacoemulsification system using model eyes under supervision.

After the second module, the trainees assigned to receive Eyesi and wet lab training proceed to the third module, followed by an operating room video-recorded assessment of phacoemulsification surgery in patients. The trainees assigned to receive wet lab training only proceed directly to operating room video assessment. This second group also receives the same simulator training after the study surgical assessments have been completed to ensure fairness to all participants during their training curriculum.

The first 3 consecutive phacoemulsification surgeries performed by trainees in actual patients supervised by qualified trainers are video recorded and assessed by 2 independent graders.

What are the possible benefits and risks of participating?
Participants receive virtual reality cataract extraction simulation surgery training and wet laboratory training free of charge. Upon completion of the training, they may have better performance on phacoemulsification cataract surgery on actual patients.

The results of this study will become a reference for ophthalmic surgical training centers and professional institutes with statutory power to regulate specialist training credentials in all parts of the world when considering the implementation of novel virtual reality-based simulation phacoemulsification training.

Where is the study run from?
The study is being run by the Department of Ophthalmology and Visual Sciences, the Chinese University of Hong Kong and involves eight hospitals in Hong Kong.

When is the study starting and how long is it expected to run for?
From April 2018 to March 2021.

Who is funding the study?
The Hong Kong Health and Medical Research Fund (Hong Kong)

Who is the main contact?
Dr Danny Ng
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HMRF Ref. No. 05162446

Study information

Scientific Title
The effect of Virtual Reality PHACOemulsification cataract extraction SIMulation surgery training on patient safety and outcomes: a randomised controlled trial (VRPhaco Sim Study)

Acronym
VRPhaco Sim Study

Study objectives
Trainees who receive virtual reality cataract extraction simulation training on Eyesi will have better overall technical performance on phacoemulsification cataract surgery on actual patients based on the validated, objective, and task-specific assessment tool (ICO-OSCAR) and reduced operation time required than trainees who have no prior Eyesi training.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 12/08/2019, New Territories West Cluster Research Ethics Committee, Hong Kong Hospital Authority (Rm821, 8/F, Block A, Nursing Quarters, Tuen Mun Hospital, Hong Kong; +852 3767 7866; ntwcrec@ha.org.hk), ref: NTWC/REC/19070
2. Approved 29/11/2017, Kowloon Central Cluster Research Ethics Committee/ Kowloon East Cluster Research Ethics Committee, Hong Kong Hospital Authority (Rm808, Block S, Queen Elizabeth Hospital, Hong Kong; +852 3506 6307/+852 3506 8642; kckecrec@ha.org.hk), ref: KCC /KEC-2017-0175
3. Approved 02/02/2018, New Territories East Cluster Research Ethics Committee, Hong Kong Hospital Authority (8/F, Lui Che Woo Clinical Sciences Building, Prince of Wales Hospital, Shatin, Hong Kong; +852 3505 3935/+852 3505 4275 / 2144 5926; crec@cuhk.edu.hk), ref: 2017.675
4. Approved 25/02/2018, Hong Kong East Cluster Research Ethics Committee, Hong Kong Hospital Authority (Rm145, 2/F, Main Block, Pamela Youde Nethersole Eastern Hospital, 3 Lok Man Road, Chai Wan, Hong Kong; +852 2595 5561/+852 2595 5563/+852 2595 5567; hkececsec@ha.org.hk), ref: HKECREC-2018-006

Primary study design
Interventional

Study design
Multicenter interventional single-blinded randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cataract surgery, phacoemulsification cataract extraction simulation surgery training

Interventions
Invitation letters will be sent out to the Chief of Services at participating hospitals and distributed to all eligible trainees. Trainees would have no ophthalmic microsurgical simulation training or phacoemulsification experience in the operating theater prior to enrolment. To ensure that the trainees' baseline characteristics were similar within and between each group, their surgical logbooks will be inspected just before the trainees attain their qualification to become higher surgical trainees by the College of Ophthalmologists of Hong Kong.

Trainees will go through a maximum of three modules of training. Trainees must attend and complete a module before proceeding to the next.

The first module consists of basic microsurgical training workshop and extracapsular cataract extraction course in the wet laboratory under supervision by a fellowship-trained instructor (at least 2-year post-fellowship). The second module will be phacoemulsification wet laboratory training with phacoemulsification system using model eyes (Kitaro WetLab, Frontier Vision Co., Ltd., Hyogo, Japan) under supervision.

After the second module, the statistician will use a computer program to perform block randomization to allocate the trainees to intervention or control groups in a 1:1 ratio. Trainees will receive their training assignment through Whatsapp text message. Group A (Eyesi + Wet lab) will proceed to the third module, followed by operating room video-recorded assessment of phacoemulsification surgeries in patients. Group B (Wet lab) will proceed to operating room video assessment without receiving the third module.

Trainees in Group A will be given a introduction tutorial to the simulator. The cataract interface on the Eyesi simulator, version 3.0, will be used for the study. A previously validated, structured training module will be used. In brief, the participants in the intervention group will complete all 7 specified training modules on Eyesi, until they achieved a predefined pass/fail score of 600 points (of a maximum of 700 points) in 2 consecutive sessions.

All video recordings of assessments were collected and sent to masked expert graders for technical performance assessment. The rating scale consists of task-specific items and global indices, which are rated from 0 points ("inadequately performed") to 5 points ("well performed"). Draping (item 1) and global indices will not be included in the final assessment score because all of the trainees have not been independent surgeons. The expert graders will evaluate all videos independently. Before the initiation of the study, raters will be trained to

ensure a standardized assessment and to avoid rater errors. Specifically, for the surgical steps remarked as performed by the supervisor, they will be adjusted to the lowest score ("inadequately performed") post hoc by the statistician.

Intervention Type
Behavioural

Primary outcome(s)
1. Technical performance measured by 2 masked expert graders using the ICO-OSCAR rating scale while reviewing video-recorded operations collected and assessed in June 2020

Key secondary outcome(s)
1. Total operation time measured from study video records at the end of each cataract surgery
2. Phacoemulsification time obtained from phacoemulsification machine at the end of each cataract surgery
3. Phacoemulsification power obtained from phacoemulsification machine at the end of each cataract surgery
4. Number of run-away capsulorrhexis measured from cataract surgery videos after all cataract surgery videos have been graded
5. Number of posterior capsule rupture measured from cataract surgery videos after all cataract surgery videos have been graded
6. Number of vitreous loss requiring anterior vitrectomy measured from cataract surgery videos after all cataract surgery videos have been graded

Completion date
31/03/2021

Eligibility

Key inclusion criteria
1. Basic ophthalmic surgical trainees from five HA clusters (eight hospitals) in Hong Kong
2. No ophthalmic microsurgical simulation training or phacoemulsification experience in the operating theater prior to enrolment
3. Signed informed consent
4. Deemed eligible by the College of Ophthalmologists of Hong Kong following review of surgical logbooks

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment
01/04/2018

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
Hong Kong

Study participating centre
Tuen Mun Eye Centre
No. 4 Tuen Lee Street
Tuen Mun
Hong Kong
-

Study participating centre
Pamela Youde Nethersole Eastern Hospital
3 Lok Man Road
Chai Wan
Hong Kong
-

Study participating centre
Prince of Wales Hospital
30-32 Ngan Shing Street
Shatin
Hong Kong
-

Study participating centre
Hong Kong Eye Hospital
147K Argyle Street
Kowloon
Hong Kong
-

Study participating centre
Alice Ho Miu Ling Nethersole Hospital
11 Chuen On Road
Tai Po
Hong Kong
-

Study participating centre
Tseung Kwan O Hospital
No. 2 Po Ning Lane
Hang Hau
Tseung Kwan O
Hong Kong
-

Study participating centre
United Christian Hospital
130 Hip Wo Street
Kwun Tong
Kowloon
Hong Kong
-

Study participating centre
Tung Wah Eastern Hospital
19 Eastern Hospital Road
Causeway Bay
Hong Kong
-

Sponsor information

Organisation
Chinese University of Hong Kong

ROR
https://ror.org/00t33hh48

Funder(s)

Funder type
Government

Funder Name
Health and Medical Research Fund

Alternative Name(s)
, HMRF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Hong Kong

Results and Publications

Individual participant data (IPD) sharing plan
Participant-level data will be available on request. Individual participant data the underlies the results reported in this article, after deidentification (texts, tables, figures, and appendices), will be shared. Study protocol will also be available. Data will be shared with investigators whose proposed use of the data, for individual participant data meta-analysis, has been approved by an independent review committee identified for this purpose. Data will be available beginning 9 months and ending 36 months following article publication. Data sharing proposals should be directed to dannyng@cuhk.edu.hk. To gain access, requestors will need to sign a data access agreement.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/10/2023	04/01/2024	Yes	No
Participant information sheet	version v2.0	15/04/2019	04/01/2021	No	Yes
Protocol file	version v1.2	23/01/2018	04/01/2021	No	No