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香港中文大學醫學院眼科及視覺科學學系

Eye Surgical Trainee Participant Information Sheet
眼科手術實習生參與者資料小冊子

The Effect of Virtual Reality Phacoemulsification Cataract Extraction Simulation Surgery Training on Patient Safety and Outcomes: A Randomised Controlled Trial
白內障超聲乳化手術模擬訓練對於病人安全和結果影響的隨機對照試驗研究

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Introduction 簡介

You are cordially invited to participate in a prospective, randomised controlled trial for a virtual reality phacoemulsification cataract extraction simulation surgery training programme for eye surgical trainees. The study plans to recruit 30 trainees in total.

我們誠邀您參加一項針對眼科手術實習生的前瞻性和隨機對照的虛擬現實白內障超聲乳化手術訓練計劃。這研究共招募 30 名實習生。

Please read this information sheet with care and ask any questions you may have about this study. Your questions will be answered. You may consult your family members, friends or family doctor if necessary. If you have any questions or would like to have more information, please consult investigators of this research and decide your participation afterwards. Also, you will be given a signed copy of the consent form and participant information sheet for retention.

以下內容告訴您有關此研究。請小心閱讀此資料頁及提出有關於這項研究的任何問題。您的問題將被回答。如有必要，請您和您的家人、朋友及您的家庭醫生討論。若您有任何疑問，或想知道更多的資料，請向負責這項研究的人員詢問，然後決定是否參與。此外，您將獲得已簽署的同意書副本及參與者資料小冊子作保存。

Purpose of research 研究目的

This research project will help us evaluate the impacts of virtual reality phacoemulsification cataract extraction simulation training based on patient safety and outcomes. The results of this study will become a reference for ophthalmic surgical training centers and professional institutes with statutory power to regulate specialists training credentials in all parts of the world when considering the implementation of novel virtual reality-based phacoemulsification

simulation training.

本研究將有助我們從患者安全性和效果上評估白內障超聲乳化手術模擬訓練的影響。在考慮應用虛擬現實為本的白內障超聲乳化手術訓練時，本研究的結果將會為世界各地的眼科手術訓練中心和管理專科訓練資格的法定專業機構提供參考。

Description of study design and procedures 研究設計及程序簡介

This study is led by the Department of Ophthalmology & Visual Sciences of the Chinese University of Hong Kong. Basic ophthalmic surgical trainees from 5 HA clusters in Hong Kong will be eligible to participate in the study. Prior to the phacoemulsification training and subsequent surgeries performed on participants with cataract, all trainees would have undergone wet lab training for basic ophthalmic microsurgical skills and extracapsular cataract extraction performed on pigs' eyes per usual training in Hong Kong. A computer program will randomize these 30 trainees with a ratio of 1:1 to the intervention or control group.

本研究是由香港中文大學眼科及視覺科學學系領導，在醫管局轄下 5 個醫院聯網的初級眼科手術實習生將會合乎資格參加研究。所有實習生在參與本研究及為白內障參與者進行手術前，都需按常規訓練完成基礎的顯微外科操作訓練以及在豬眼上完成白內障囊外摘除手術。電腦程式會以 1:1 比例將 30 名實習生隨機分至干預組或對照組。

Trainees in the intervention group will receive a standardized video-based introduction to the simulator. The cataract interface on the Eyesi Simulator, version 3.0, will be used for the study with a previously validated, structured training module. The control group would have received routine training instead of using the Simulator prior to surgeries. However, they have the option to receive Eyesi training after the end of the research project to ensure fairness to all participants during their training curriculum. 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 trainees in the intervention and control groups will perform 3 consecutive phacoemulsification cataract extraction surgeries on cataract participantssupervised by qualified trainers, which will be video recorded as a routine procedure for clinical audit and/or educational purposes. Trainees are only allowed to operate on uncomplicated cataract cases, defined as follows: (1) being performed under local anesthesia, (2) patient >60 years of age, (3) preoperative best-corrected visual acuity >1/60 (measured using a standard Snellen chart at 6 meters' distance). Participants with cateract will not know the group to which the trainees performing the surgeries belong. The identities of both participants with cataract and trainees will be kept anonymous.

干預組的實習生會先觀看一個標準化的模擬器影片介紹。本研究會使用 Eyesi 模擬器版本 3.0 白內障操作界面及一個已驗證且有組織的訓練課程。對照組的實習生在手術前會接受常規而非 Eyesi 模擬訓練，但為公平起見，他們在手術結束後也會獲得接受相同模擬訓練的機會。所有干預組的實習生必須完成合共 7 個指定訓練課程，並連續兩次取得

600 分或以上的合格分數（滿分 700 分）。
在合資格的訓練員監督下，每名干預組和對照組的實習生會對參與者進行三次白內障超聲乳化手術，並會被錄影。在手術室錄影是臨床審計和/或教育用途的常規程序。實習生只能對不複雜的白內障病況進行手術，條件為：(1) 在局部麻醉下進行、(2) 參與者年齡超過 60 歲、(3) 手術前最佳矯正視力低於 1/60（使用標準史奈侖視力檢查表以 6 米距離測量）。白內障參與者不會知悉哪一組的實習生會為他們進行手術，而他們和實習生均會保持匿名。

A research assistant will visit the hospital where the trainee performs the operation to ensure that the cataract cases comply with the criteria defined above. Data including the cataract participants' age and visual acuity, the surgical steps performed by trainees or supervisors, phacoemulsification time and energy, and total operation time will be collected. The video recordings will also be collected. Only the operated eye will be recorded. The recordings before and after performance of the actual procedure in addition to logos, person identifiable data, and audio will be cropped. The videos will be reviewed by 3 masked cataract surgeons (1 cataract surgery training consultant from the HA and 2 experienced cataract surgery trainers from overseas) in a random order through a secured web-based video-rating software.

一名研究助理將會到訪實習生進行手術的醫院，在手術前檢查病例是否符合上述標準；亦會收集手術資料，包括白內障參加者的年齡和視野、由實習生或訓練員所進行的手術步驟、白內障超聲乳化手術時間和能量，以及手術所需時間。研究助理將會錄影整個手術過程，當中只有進行手術的眼睛會被錄影。手術前後的錄影片段，以及標誌、個人識別數據及聲音將會被裁剪。錄影片段將會用保密網絡的評估軟件，隨機由 3 名單盲的白內障外科醫生（1 名醫管局的白內障手術訓練顧問和 2 名經驗豐富的海外白內障手術訓練員）審核。

Potential benefits 可能的益處

The ultimate goal of using the simulator is to improve patient safety and outcome, as well as the efficiency of phacoemulsification training. There are preliminary evidences on the validity and impact of Eyesi virtual reality simulation training modules. If you decide to participate in this study, you will have the chance to receive said training to enhance surgical skills.

使用模擬器的最終目標是改善患者的安全和結果，以及白內障超聲乳化手術的有效性。有初期的研究證實 Eyesi 模擬訓練對提升白內障超聲乳化手術技術有一定幫助。如果您決定參與這項研究，您將會接受虛擬實境模擬手術訓練，從而提高手術技術。

Potential risks or discomfort 潛在的風險與不適

Trainees from both the intervention or control group will not be subjected to any potential

risks or discomfort by participating in this study.

獲分配到干預組和對照組的實習生都不會受到任何潛在的風險與不適。

Costs and rewards of the study 參與研究的費用及報酬

All study related training is free of charge. No monetary reward will be received for participating this study.

所有研究相關訓練都是免費；實習生不會因參加此研究得到金錢上的回饋。

Alternatives if trainees opt out of the study 實習生不參加研究計劃的其他選項

If you do not wish to join this study, you can still receive routine surgical training according to requirements from The College of Ophthalmologists of Hong Kong. You may not receive extra vitual reality simulation training unless it is arranged.

如果您不願意參加本次研究，您仍可接受香港眼科醫學院常規的手術訓練。如果沒有安排，您就可能不會額外接受虛擬實境模擬訓練。

Expected duration of research 預期研究的持續時間

This study will last for approximately 2.5 years.

這研究會持續約兩年半。

Circumstances under which your participation in the research will be terminated 終止參與者進行此研究的情況

We reserve the right to terminate your participation in the research project. In the event that any safety concerns are raised during the study or interim results from the study show no further samples needed, your participation will no longer be required.

我們保留終止您參與本研究項目的權利。如果在本項目進行中出現任何潛在的安全問題或者數據表明本項目的研究對象已經足夠的情況下，您將不需要繼續參與研究。

Arrangements after completion of study 研究計劃完結後的安排

After study completion, your routine surgical training will continue under the arrangement of Hospital Authority.

研究結束後，您將會在醫管局安排下繼續接受常規的手術訓練。

Compensation and treatment available for study related injury
因研究所致的損害所獲之賠償和治療

If you are injured during your participation in this study, the investigator will provide medical treatment to you or refer you to other treatment.

若您因參與本研究而引致任何身體損傷，研究負責人將會為您進行治療或轉介您接受治療。

Confidentiality 保密

Electronic data will be only saved in physically-secured and password-protected computers in our research office. Information from this study will be submitted to the Department of Ophthalmology & Visual Sciences, Chinese University of Hong Kong for statistical analysis. Only the overall result will be published and your identity will remain confidential. Records and results of all study investigations can be destroyed on your request in future. By signing a written informed consent form, you are authorizing the Research Ethics Committee (REC) and the regulatory authority(ies) a direct access to your original research data for verification of clinical trial procedures and/or data, without violating your confidentiality, to the extent permitted by the applicable laws and regulations.

電子數據將只在我們安全的研究室電腦內保存，並受到密碼保護。這項研究的資料將給予香港中文大學眼科及視覺科學學系進行統計分析。您的身份將受嚴格保密，只有整體的結果將被公佈。於任何時間，您可要求銷毀所有相關的研究結果和記錄 。簽署知情同意書的同時，亦表示您允許臨床研究倫理委員會及有關法定機構在合適的條例及法例容許下及在不侵犯您的私隱情況中，直接翻查您的研究數據正本以核實臨床研究計劃之程序和/或數據。

Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Personal Data or his officer (Tel no.: 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

根據香港法律規定（特別是第 486 章《個人資料（私隱）條例》），您享有或可享有確保您的個人資料保密的權利，例如在或為本研究中有關收集、監管、保留、管理、控制、使用（包括分析或比較）、轉進或轉出香港、不披露、清除和 / 或以任何方式處理或棄

置的權利。如有任何問題，請您諮詢個人資料私隱專員或其職員（電話號碼：2827 2827），以瞭解妥善監控或監管您的個人資料保護之事宜，以確保您完整掌握和瞭解遵守規管個人資料私隱的法律之重要性。

Voluntary participation / withdrawal 自願參加 / 退出研究

Your participation in this study is entirely voluntary. You will be updated of new information that may be relevant to your willingness to continue participation in the study. You are allowed as much time as you need to consider participation in this study, or to discuss with your relatives prior to signing the informed consent form. You can call us via the contact telephone number provided on this participant information sheet when you would like to get more information. You may choose to withdraw from the study at any time without reason, without your training or evaluation in any manner being affected . After signing the informed consent form, a participants information sheet and a signed copy of the informed consent form will be given. Even after signing the informed consent form, you are free to withdraw your consent and discontinue your participation in the study at any time. Once you request to withdraw, all clinical data arising from study investigations will be deleted. The clinical data in the medical records will, however, be retained for future clinical management.

您參與這項研究是完全自願的。您將收到更新的訊息去決定是否繼續參與這項研究。您會給予足夠的時間去考慮是否參與這項研究。在簽署知情同意書前，您亦可與親戚一起討論。當您獲得更多信息時，您可以撥打我們在參與者資料小冊子提供的聯絡電話號碼去得到更多資料。您有權在任何時間退出，而無須給予理由，同時不影響培訓或評估。簽署知情同意書後，您會獲得一份參與者資料小冊子及已簽署的知情同意書副本。即使已簽署知情同意書，您可以在任何時候改變您參與這項研究的意願。一旦您要求退出，所有的臨床研究數據將被刪除。但是臨床醫療記錄將被保留作臨床治療用途。

Further information 詳細資料

For further information, you can contact us at the address and telephone below:
Contact person: Dr. Ng Siu Chun Danny
Telephone no. : 3943 5818
Address : CUHK Eye Center, 3/F, Hong Kong Eye Hospital,
147K Argyle Street, Kowloon, Hong Kong

如想得到進一步的資料，可親臨以下地址或致電下列熱線：

聯絡人 ：吳兆駿醫生

電話 ：3943 5818

地址 ：香港九龍亞皆老街 147K 號
香港眼科醫院 3 樓
眼科及視覺科學學系 香港中文大學眼科中心

If you have any questions about your rights as a subject, you may contact Research Ethics Committee (Kowloon Central / Kowloon East)
Telephone no. : 35068888
Address : Room 414, 4/F, Nurse Quarters, Queen Elizabeth Hospital,
30 Gascoigne Road, Kowloon

若對研究參與者權利有任何疑問 , 您可以聯絡九龍中及九龍東聯網臨床研究倫理委員會

電話 : 3506 8888

地址 : 九龍加士居道 30 號伊利沙伯醫院護士宿舍 4 樓 414 室

Department of Ophthalmology & Visual Sciences,

Faculty of Medicine, The Chinese University of Hong Kong

香港中文大學醫學院眼科及視覺科學學系

INFORMED CONSENT FORM 知情同意書

I _____hereby consent to participate in the research study of **"The Effect of Virtual Reality Phacoemulsification Cataract Extraction Simulation Surgery Training on Patient Safety and Outcomes: A Randomised Controlled Trial".**

本人 _____ 茲同意參與「**白內障超聲乳化手術模擬訓練對於病人安全和結果影響的隨機對照臨床試驗研究**」。

I have read the **PARTICIPANT INFORMATION SHEET** and **INFORMED CONSENT FORM**. The study has been explained to me by investigator. I understood all the benefits and the risks associated with this study. I am not giving up any of my legal rights by signing this informed consent form. I have had opportunities to ask questions to investigator and all my questions have been satisfactorily answered. I have received enough information about the study.

本人已細讀**參與者資料小冊子**及**知情同意書**。研究員已向本人詳細解釋研究的細節。本人明白所有有關本研究的好處及風險。本人沒有因簽署這知情同意書而放棄了任何法律權益。本人有機會向研究員提出疑問，而研究員亦已完滿地解答本人的疑問。對於此研究，本人已獲得足夠的資料。

If the result of my participation in this study caused any physical injury or feel uncomfortable emotionally, the investigator will treat me or refer me for treatment.

若本人因參與本研究而引致任何身體不適或情緒上的波動，研究員將會為本人進行治療或轉介本人接受治療。

By signing this informed consent form, I certify that all information provided is true and correct. I consent to participate in this study and understand that my participation is voluntary and I have the right to withdraw at any time without having to give a reason for withdrawing and the withdrawal will not affect my present and future training or evalution.

因為簽署此知情同意書，証明本人提供的所有資料均為正確無誤。本人同意參與這項研究，本人的參與是自願的，本人有權在任何時間退出，而無須給予理由，同時不影響本人現在或日後所獲得的訓練或評估。

I ☐ agree / ☐ disagree to be contacted via phone or email to see my interest in participating relevant studies in future.

本人 ☐ 同意 / ☐ 不同意 就日後諮詢參與其他相關的研究計劃的興趣，以電話或電郵

方式再進一步聯絡本人。

I understand that my identity will be kept confidential. I agree to authorize the Research Ethics Committee (REC) and the regulatory authority(ies) a direct access to my original research data for verification of clinical trial procedures and/or data, without violating my confidentiality, to the extent permitted by the applicable laws and regulations.

本人明白，本人之身份將獲得保密處理。本人亦允許臨床研究倫理委員會及有關法定機構在合適的條例及法例容許下及在不侵犯本人的私隱情況中，直接翻查本人的研究數據正本以核實臨床研究計劃之程式和/或資料。

Name of Participant (in BLOCK Letter) 參與者姓名（正楷）	Signature 簽署	Date 日期
Name of investigator (in BLOCK Letter) 研究員姓名（正楷）	Signature 簽署	Date 日期

I will be given a participant information sheet and a signed copy of this informed consent form.
本人將會獲得一份參與者資料小冊子及已簽署的知情同意書副本。