

TUNG WAH COLLEGE

Information Sheet

“Evaluation of N95 respirators on fit rate, real-time leakage, and usability among Chinese healthcare workers”

You are invited to participate in a research study conducted by Professor Simon C. Lam in the School of Nursing at Tung Wah College (TWC). Your participation is entirely voluntary. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and contact Professor Simon Lam Ching at TWC, Room 1601G, School of Nursing, Ma Kam Chan Memorial Building, Tung Wah College, 31 Wylie Road, Homantin, Kowloon, Hong Kong. Tel: 3468 6854. Email: simonlam@twc.edu.hk if you have any enquiries.

PURPOSE OF THE STUDY

This study aims to investigate and compare the fit rate, real-time leakage, and mask usability of traditional and new N95 respirators among Chinese Health Care Workers (HCWs).

PROCEDURES

The study will have two phases. In Phase 1, you will be trained on donning and doffing skills of N95 masks through video. Practice and demonstrate back to the Research Assistant to ensure the proper wearing of N95 respirators. Next, you will complete three different types of N95 respirators (1 new, 2 traditional) fit tests with both 8-step protocol and 4-step protocol. After fit tests, you are asked to fill out the usability questionnaires for the corresponding respirators. Last but not least, a trained researcher will help you to measure your facial anthropometrics. It requires about 1-1.5 hours to finish all the procedures in Phase 1.

In Phase 2, the inclusion criteria are:

1) staff with professional license or students who may obtain professional license after graduation. 2) completed phase 1 study and obtained passes of fit tests (Score 100 or above) for at least one traditional N95 respirator as well as one new respirator. However, those who have a history of chronic respiratory diseases or medical conditions (e.g., asthma, congestive heart failure, coronary heart disease etc.), or are pregnant, or have any musculoskeletal diseases that restrict the capacity of Cardiopulmonary Resuscitation (CPR) performance cannot join Phase 2 of the study.

During Phase 2, you will be randomly assigned to wear either a traditional respirator or the new respirator first. You will have 10 min to familiarize yourself with the scenario, devices, and settings. Then you are asked to wear personal protective equipment (PPE) to perform nasopharyngeal suctioning and CPR. Vital signs will be taken as baseline. Next, you will perform 15s suctioning for 2 times and 4 min one-man CPR while data of real-time leakage will be recorded at 30 s intervals. Right after the suctioning and CPR, vital signs will be

taken again followed by fit test and mask usability questionnaire. Rest for 10 min and then repeat the above procedures with another respirator. Phase 2 will last for about 1 hour.

Please be assured that you have right to decide whether to participate or not. You can also withdraw from this study at any time during the process. All your personal data will be used for research purpose and it will be kept strictly confidential and anonymity.

POTENTIAL RISKS / DISCOMFORTS AND THEIR MINIMIZATION

Wearing the N95 respirators may cause some minor discomforts like feeling hot and stuffy, tightening of face, interference on speaking, skin itchiness, mask displacement, discomfort on ear lobe, interference on working efficiency, and mist over glasses. In Phase 2 CPR session, a few people will pant or experience other minor discomforts due to vigorous movement.

To ensure your safety in both phases, our team of researchers will continuously monitor your conditions. If you have any problems at any time during the study, you can approach our researchers for help. Adequate rest time will be given between different procedures to minimize discomforts.

COMPENSATION FOR PARTICIPATION

To thank for your participation, \$100 cash coupon will be given as a token of appreciation upon the completion of phase 1. For phase 2, as greater body movement is required, \$300 cash coupon will be given upon completion.

POTENTIAL BENEFITS

Wearing a well-fitting N95 mask in handling patients with infectious respiratory diseases is a life-saving procedure. We will provide you training on proper donning and doffing of N95 masks. If fit test of designated mask is requested by your institution of work or study, you will obtain all the full reports of fit tests right after the procedures.

The collected data is of substantial value in the research field of prevention and control of infectious disease.

CONFIDENTIALITY

Strict confidentiality is promised and that the information obtained in the study will be used for research purposes only. Research data is kept in secure and safe place. You have the right to review and erase the records by anytime.

Responsible members of TWC may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

DATA RETENTION AND STORAGE

Data would be kept in a secured and accessible form in the campus of Tung Wah College for at least seven years after publication or public release of research work. Personal identifiers will be removed upon the completion of study / stored separately for long term retention of the research data.

PARTICIPATION AND WITHDRAWAL

If your institution requests the fit test result of a designated N95 respirator, your withdrawal of that fit test may affect your job or study arrangement. After the designated mask fit test, your participation is voluntary. This means that you can choose to stop at any time without negative consequences.

FUNDING SOURCE

Health and Medical Research Fund (Food and Health Bureau, the Hong Kong Government)

QUESTIONS AND CONCERNS

This study has been reviewed and approved by Research Ethics Committee (REC), TWC, to protect participants' interests.

If you have any questions or concerns about the research, please feel free to contact Professor Simon C. Lam at TWC, Room 1601G, School of Nursing, Ma Kam Chan Memorial Building, Tung Wah College, 31 Wylie Road, Homantin, Kowloon, Hong Kong. Tel: 3468 6854. Email: simonlam@twc.edu.hk if you have any enquiries.

If you have questions about your rights as a research subject, contact the Secretary, Research Ethics Committee (REC), TWC (ro@twc.edu.hk).

- Thank you for reading this information -

東華學院 資料書

“華人醫護人員使用 N95 口罩的貼合率、實時洩漏率和易用性研究”

東華學院護理學院邀請您參與由林清教授主理的研究調查。

研究目的

這是一項關於預防及控制傳染疾病的學術研究，旨在研究及比較華人醫護人員使用不同 N95 口罩的適合度、洩漏程度和易用性程度。

研究程序

該研究將分為兩大階段。第一階段，您將觀看及學習不同 N95 口罩的佩戴及除下方法。練習並向研究人員演示，以確保正確佩戴。接下來，您將進行三款不同 N95 口罩（1 個新款及 2 個傳統）的面型配合測試和其易用性評估。然後，研究人員將幫您測量三個面部量度。整個第一階段研究大約需要 1-1.5 小時。

第二階段的納入條件為：

1) 具有專業執照的工作人員或畢業後合資格獲得專業執照的學生。 2) 完成了第一階段研究並在至少一個傳統 N95 口罩和一個新款口罩的測試中合格（須取得 100 分或以上）。但是，有慢性呼吸系統疾病或其他狀況，如：哮喘、充血性心力衰竭、冠心病等，或懷孕，或有任何肌肉或骨骼疾病而限制了進行心肺復甦 (CPR) 能力的人士，將不能參與第二階段研究。

在第二階段，您將被隨機分配到首先佩戴傳統口罩或首先佩戴新型口罩的組別。您將有 10 分鐘的時間熟練場景、設備和環境設置。穿上個人防護裝備 (PPE) 後研究人員將為您量度您的基本維生指數作為基線。接下來，您將進行 2 次 15 秒的鼻咽抽痰和 4 分鐘的單人 CPR。同時每隔 30 秒將記錄一次實時洩漏數據。在抽痰和 CPR 後，將再次測量您的維生指數。然後進行面型配合測試和其易用性評估問卷。休息 10 分鐘後，佩戴另一款 N95 口罩重複上述步驟。第二階段大約需要 1 小時。

請放心，您有權決定是否參加。您也可以在此過程中隨時退出這項研究。您的所有個人資料將用於研究目的，並將嚴格保密和匿名。

風險

佩戴 N95 口罩可能會引起一些輕微不適。如：感到悶熱、面部繃緊、影響說話、皮膚敏感、口罩移位、耳垂不適、影響工作效率或眼鏡有霧氣。在第二階段的 CPR 過程中，一些人會因劇烈運動而氣喘或出現其他輕微不適。

為確保您在兩個階段的安全，我們的研究團隊將持續監察您的狀況。如果您在研究過程中遇到任何問題，請隨時向我們的研究人員尋求協助。在不同的程序之間，我們會給予您足夠的休息時間，以盡量減少不適。

費用與報酬

參與是次研究計劃費用全免。此外，為感謝您的參與，完成第一階段後您將獲贈\$100 現金禮券以示感謝。第二階段，由於需要更多的體力活動，完成後將獲得\$300 現金禮券。

研究效益

正確佩戴及除下 N95 口罩在接觸傳染性呼吸道疾病患者中，是一項能挽救自己生命的醫療程序。我們將提供教學和練習正確佩戴及除下 N95 口罩的機會給您。若然，您的工作或學習機構要求您進行指定 N95 口罩的適合性測試，完成測試後，您將即時取得所有完整報告，以滿足機構要求。除此之外，其他研究用的 N95 口罩的測試結果能為您提供額外的參考價值，知道哪型號的 N95 口罩適合或不適合您佩戴。

所有搜集的數據將對預防及控制傳染疾病研究上提供寶貴的資料。

私隱保障

所收集的資料只作研究用途，個人資料將絕對保密。研究數據將保存在安全的地方，您有權隨時查看和刪除記錄。東華學院的負責成員可能有權存取數據以監測和/或審計研究，以確保研究符合適用的法規。

保留含個人識別資料的時限

所有研究數據均以安全及便於儲取的方式在東華學院範圍內保存。於發表研究結果後，有關研究數據將會儲存最少 7 年。個人識別資料會與研究數據分開儲存。

參與性質

是次參與純屬自願性質，你可隨時終止參與是項行動，有關決定將不會引致任何不良後果。

研究經費來源

醫療衛生研究基金（香港特區政府 – 食物及衛生局）

查詢及意見

如日後你對是項研究有任何查詢，請與林清教授聯絡（電話號碼：3468 6854）。如你想知道更多有關研究參與者的權益，請聯絡東華學院研究事務操守小組委員會 (ro@twc.edu.hk)。

- 感謝閱讀此資料書 -

備註：有關每項之詳情可參考英文版本