







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

<b>Submission date</b> 05/05/2023	<b>Recruitment status</b> No longer recruiting	 Retrospectively registered
<b>Registration date</b> 09/05/2023	<b>Overall study status</b> Completed	 Protocol added
<b>Last Edited</b> 04/12/2023	<b>Condition category</b> Not Applicable	 SAP not yet added
		 Results not yet added and study completed for 1-2 years
		 Raw data not yet added
		 Study completed

## Plain English Summary

### Background and study aims

Worldwide outbreaks of different infectious diseases have caused an increased awareness of occupational protection among healthcare workers (HCWs). Therefore, the use of N95 respirators as an effective nonpharmaceutical measure to limit the spread of diseases in hospitals is vital. N95 respirators are used to limit the transmission of respiratory viruses in clinical settings. There are two to three major types of N95 for all healthcare workers in Hong Kong. However, after the coronavirus outbreak and the consequent shortage of many commonly used respirators, several new N95 respirators were adopted temporarily in clinical settings without evaluation. Prior literature indicates that traditional N95 respirators used in hospitals in Hong Kong are not fit for Chinese people and have fit rates ranging from 50% to 60%. This study aims to investigate and compare the fit rate, real-time leakage, and mask usability of traditional and new N95 respirators among Chinese healthcare workers.

### Who can participate?

Healthcare workers aged 18 years and above who are students or staff with a licence who provide direct care to patients, certified and able to perform standard cardiopulmonary resuscitation for delivery of basic life support or advanced cardiovascular support, those who have completed an accredited institutional training program, and those who perform cardiopulmonary resuscitation in the clinical field; and obtained a pass of fit tests for one of traditional N95 respirators (best-fit one) as well as new respirators in the phase 1 study.

### What does the study involve?

Data will be collected from healthcare workers in non-governmental organisations, and students studying in healthcare disciplines at universities/colleges. Participants will be screened with reference to the inclusion criteria, and eligible participants will be invited to join the study by signing a written consent with an explanation. Once consent has been obtained, participants will

be introduced to the standard scenarios and sufficient time will be provided to participants to familiarise themselves with the device and settings. Participants will be required to don all necessary personal protective equipment in the designated simulation environment. Data of real-time leakage will be recorded during nasopharyngeal suctioning and cardiopulmonary resuscitation. A research nurse will be present to monitor the procedure.

What are the possible benefits and risks of participating?

Participants who complete the trial will be provided with an incentive of HK\$300 as time compensation. There are no risks to participating in the study.

Where is the study from?

School of Nursing, Tung Wah College, Hong Kong SAR, China

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

January 2019 to May 2023

Who is funding the study?

Health and Medical Research Fund (HMRF) Hong Kong SAR, ref: 20190322

Who is the main contact?

Prof. Simon Ching Lam  
simlc@alumni.cuhk.net

## Contact information

### Type(s)

Principal Investigator

### Contact name

Prof Simon Ching Lam

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## Additional identifiers

### EudraCT/CTIS number

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Protocol/serial number**

20190322

## Study information

**Scientific Title**

Comparison of real-time leakage using traditional and new N95 respirators among Chinese healthcare workers: A phase two randomised cross over trial

**Study hypothesis**

This study is a randomised controlled trial (specifically a cross over experimental design) to compare real-time leakage by using traditional and new N95 respirators when donned by Chinese healthcare workers during two clinical procedures, that is, nasopharyngeal suctioning and cardiopulmonary resuscitation.

Hypothesis: The researchers hypothesise that there is no significant group difference in real-time leakage between the use of traditional and new N95 respirators among Chinese healthcare workers during designated clinical procedures.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

1. Approved 03/06/2021, Departmental Research Committee, The Hong Kong Polytechnic University (Hung Hom, Kowloon, Hong Kong SAR, China; +852 3400 3214; thomasks.choi@polyu.edu.hk), ref: HSEARS20210406001
2. Approved 19/01/2022, Research Ethics Committee, Tung Wah College (31 Wylie Road, Homantin Kowloon, Hong Kong SAR, China; +852 3190 6678; ro@twc.edu.hk), ref: REC2021115

**Study design**

Randomized cross over trial

**Primary study design**

Interventional

**Secondary study design**

Randomised cross over trial

**Study setting(s)**

Training facility/simulation, University/medical school/dental school

**Study type(s)**

Prevention

**Participant information sheet**

See additional files

## Condition

Prevention to limit the spread of infectious respiratory pathogens to healthcare workers in hospitals during clinical procedures.

## Interventions

Traditional respirators refer to the commonly used 3M head-loop respirators in hospitals in Hong Kong, namely the 3M cup-shaped 1860S and the three-panel-designed 1870+.

New respirators refer to the NASK M0011 respirators made of nanomaterial and ear-loop with clip design.

Participants are randomized at a ratio of 1:1 using computer-generated randomization to one of the two groups (traditional or new respirator group). Participants will don the assigned respirator, gown, and face shield for nasopharyngeal suctioning and cardiopulmonary resuscitation. Data of real-time leakage will be recorded at 30 s intervals during the standard nasopharyngeal suctioning and cardiopulmonary resuscitation. After a 2 min suctioning and a 4 min cardiopulmonary resuscitation, the participants donned with the tested respirator will perform the fit testing and respond to mask usability, which is recorded post-procedure. With a 10 min rest, participants will don another respirator and repeat the measurement of real-time leakage, that is the crossover experiment to compare leakage of traditional best-fit respirators and new respirators.

Control: Participants don traditional respirators, namely the 3M cup-shaped 1860S and the three-panel-designed 1870+

Intervention: Participants don a new respirator, the NASK M0011 ear-loop with clip design

## Intervention Type

Device

## Phase

Not Applicable

## Drug/device/biological/vaccine name(s)

Portable aerosol spectrometers (Grimm Model 1.109-006 and 007; Grimm Technologies, Ainring, Germany), PortaCount respirator fit-tester system (model Pro+ 8038/8040; TSI Limited), Traditional respirators: 3M cup-shaped 1860S and the three-panel-designed 1870+, New respirator: NASK M0011 nanomaterial ear-loop with clip design

## Primary outcome measure

Real-time leakage is measured by two portable aerosol spectrometers by factoring the difference in small particles (0.3 $\mu$ m) between ambient and inside respirators at an average of 30 s intervals while performing cardiopulmonary resuscitation. A total of eight sets within a 4 min procedure.

## Secondary outcome measures

1. Fit rate, which is the proportion of fit factor >100 among total samples with a given respirator measured by a PortaCount respirator fit-tester system (model Pro+ 8038/8040; TSI limited)
2. Mask usability measured using an 11-item Mask Usability Scale to measure wearers' personal feedback on a donned respirator measured at a single time point

**Overall study start date**

04/01/2019

**Overall study end date**

30/05/2023

## Eligibility

**Participant inclusion criteria**

1. Healthcare workers who are students or staff (with licence) who provide direct care to patients
2. Aged 18 years or above
3. Certified and able to perform standard cardiopulmonary resuscitation for delivery of basic life support or advanced cardiovascular support, those who have completed an accredited institutional training program, and those who perform cardiopulmonary resuscitation in the clinical field.
4. Healthcare workers who obtained a pass of fit tests for one of the traditional N95 respirators (best-fit one) as well as new respirators in the phase1 study

**Participant type(s)**

Health professional

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

200

**Participant exclusion criteria**

Healthcare workers who have a history of chronic respiratory diseases or medical conditions or medical conditions (e.g., asthma, congestive heart, coronary heart diseases), are pregnant, and have any musculoskeletal diseases that restrict the capacity of cardiopulmonary resuscitation performance.

**Recruitment start date**

01/11/2021

**Recruitment end date**

30/05/2023

## Locations

**Countries of recruitment**

China

Hong Kong

**Study participating centre**

**Integrative Health Centre, Tung Wah College**

Room 1401 Mong Kok Campus  
Cheung Chin Lan Hong Building  
98 Shantung Street  
Mongkok, Kowloon  
Hong Kong SAR  
China

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**Study participating centre**

**Squina International Center for Infection Control**

Room FJ502  
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## **Sponsor information**

**Organisation**

Tung Wah College

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<http://www.twc.edu.hk/>

**ROR**

## Funder(s)

### Funder type

Government

### Funder Name

Health and Medical Research Fund

## Results and Publications

### Publication and dissemination plan

The research findings will be disseminated to the Infection Control Branch of the Hospital Authority, Center of Health Protection of the Hong Kong SAR Government for their information and reference. The study results will also be presented at local and international conferences and published in refereed journals related to infection control and occupational health.

### Intention to publish date

31/10/2023

### Individual participant data (IPD) sharing plan

The datasets generated during and analyzed during the current study will be available upon request from Simon Ching Lam (simlc@alumni.cuhk.net)

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version 3	01/05/2021	09/05/2023	No	Yes
<a href="#">Protocol article</a>		17/11/2023	04/12/2023	Yes	No