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

Submission date
05/05/2023

Recruitment status
No longer recruiting

Registration date
09/05/2023

Overall study status
Completed

Last Edited
20/11/2024

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

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
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

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 objectives
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

Study type(s)
Prevention

Health condition(s) or problem(s) studied
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(s)
Real-time leakage is measured by two portable aerosol spectrometers by factoring the difference in small particles (0.3μm) 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.

Key secondary outcome(s))
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

Completion date
30/05/2023

Eligibility

Key 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key 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.

Date of first enrolment
01/11/2021

Date of final enrolment
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
School of Nursing
The Hong Kong Polytechnic University
Hung Hom, Kowloon
Hong Kong SAR
China
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Sponsor information

Organisation
Tung Wah College

ROR
https://ror.org/04jfz0g97

Funder(s)

Funder type
Government

Funder Name
Health and Medical Research Fund

Results and Publications

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?
Protocol article		17/11/2023	04/12/2023	Yes	No
Other publications		13/11/2024	20/11/2024	Yes	No
Participant information sheet	version 3	01/05/2021	09/05/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes