ISRCTN15612510 https://doi.org/10.1186/ISRCTN15612510

Evaluation of new and conventional N95 fit testing protocols on equivalence and reproducibility

Submission date
27/05/2025

Recruitment status
No longer recruiting

Registration date
28/05/2025

Overall study status
Ongoing

Last Edited
28/05/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims

Global outbreaks of contagious respiratory illnesses have heightened awareness of occupational safety among healthcare workers (HCWs). An N95 filtering tight-fitting half-facepiece respirator (hereafter, N95 respirator) is a specialised mask designed to securely fit the face and efficiently filter airborne particles. For an ill-fitting respirator, the average infiltration of an ambient aerosol was determined to be 33%, vs only 4% for well-fitting respirators. Leakage (i.e., penetration) can occur when there is a gap between the respirator and the wearer's face. This gap (i.e., face-seal leakage) may enable the infiltration of airborne contaminants into the wearer's respiratory area, compromising the effectiveness of protection. To ensure sustainable occupational safety, reputable authorities such as the National Institute for Occupational Safety and Health (NIOSH), the World Health Organization (WHO), the Center for Disease Control and Prevention (CDC), and the Hospital Authority in Hong Kong require HCWs to undergo N95 fit testing before using an N95 respirator, particularly if they are performing aerosol-generating procedures. N95 fit testing facilitates both the selection of a suitable respirator and the training of its user.

In 2019, OSHA introduced a shortened N95 fit testing protocol with four steps. This new protocol involves the performance of only four pre-determined exercises and has drastically decreased the time required for fit testing. Nevertheless, there has been a lack of empirical evidence to support this notion of equivalence. Additionally, no prior research has explored the stability (or reproducibility) of fit testing results, even in relation to the conventional protocol. Uncertainty regarding stability has led to uncertainty regarding the reproducibility of previous fit testing results for a given respirator. This study aims to investigate the equivalence (i.e., pass or fail) and evaluate the reproducibility of fit testing results, specifically the fit factor, of three different designed respirators among Chinese healthcare workers using the new and conventional protocols.

Who can participate?

Students pursuing healthcare disciplines or healthcare workers who are licensed staff members providing direct patient care, aged 18 years and above.

What does the study involve?
The data collection process will have four distinct phases: room and system preparation, registration, a training session, and a fit testing session. The participants' demographic information, including their sex, age, and body weight, along with the results of the user seal check and fit testing conducted using both the new and conventional protocols, will be documented in a data sheet. To regulate environmental variables that might impact the outcome of fit testing, all data will be collected in a designated air-conditioned room with an area of 10 m2. During registration, all participants will be obligated to provide signed consent and present themselves in a manner consistent with clinical duty. During the training session, a licensed nurse who has received specialised training will introduce a 30-minute training session covering the proper techniques for donning a standardised N95 respirator and conducting a user seal check. The session will include a video demonstration and opportunities for participants to practice the techniques. The trained nurses will evaluate the donning procedure and user seal check method of each participant through redemonstration before proceeding to the next session. In addition to the time spent on registration and the training session, which will vary among participants, an additional 60 minutes will be required to collect the remaining data. This process will include user seal check and fit testing of three types of N95 respirators according to the new and conventional protocols.

What are the possible benefits and risks of participating?
Participants will be provided with an incentive of HK$200 as time compensation upon completing six N95 fit tests (3 respirators x 2 protocols). 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?
November 2024 to November 2026

Who is funding the study?
Health and Medical Research Fund (HMRF), Hong Kong SAR; ref: 24230052

Who is the main contact?
Prof. Simon Ching LAM
simonlam@twc.edu.hk; simlc@alumni.cuhk.net

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Simon Ching Lam

ORCID ID
https://orcid.org/0000-0002-2982-9192

Contact details
Room 1601G, 16/F
King's Park Campus, Ma Kam Chan Memorial Building

31 Wylie Road, Homantin
Hong Kong SAR
China
-
+852-3468-6854
simlc@alumni.cuhk.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
24230052

Study information

Scientific Title
Comparison of new and conventional N95 fit testing protocols for three respirators with different designs: Evaluation of equivalence and reproducibility

Study objectives
This study is a cross-sectional observational study to investigate the equivalence (i.e., pass or fail) and evaluate the reproducibility of fit testing results, specifically the fit factor, of three different designed respirators among Chinese healthcare workers using the new and conventional protocols.

The researchers hypothesise that there is no equivalence in the fit testing results between new and conventional fit testing protocols among Chinese healthcare workers donned with three different designed respirators. Besides, it is also hypothesised that the fit testing results of new and conventional fit testing protocols are not reproducible.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/11/2024, Research Ethics Committee,Tung Wah College (31 Wylie Road, Homantin Kowloon, Hong Kong SAR, -, China; +852-3190-6678; ro@twc.edu.hk), ref: REC2024221

Study design
Multicenter cross-sectional observational study

Primary study design
Observational

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Fit testing protocols for three respirators

Interventions
This proposed methodological study will have a cross-sectional observational design with repeated measures, according to the Guidelines for Reporting Reliability and Agreement Studies (GRRAS) (https://www.equator-network.org/)

The proposed cross-sectional observational study will evaluate the equivalence (also known as agreement) and reproducibility of the fit testing results of three different designed respirators tested among Chinese HCWs using the new and conventional fit testing protocols. A cross-sectional design is appropriate for testing the reliability of a protocol (including agreement and reproducibility) and is commonly used in instrument validation. Figure 1 in the appendix presents a flow diagram of the proposed study.

The fit testing device will be used in accordance with the manufacturer's instructions and the protocol established by OSHA. After following the manufacturer's instructions to don the respirator, the wearer will perform pre-defined exercises as instructed by the system. For the conventional eight-step protocol, OSHA 29CFR 1910.134, the participant will perform eight exercises: normal breathing, deep breathing, side-to-side head movement, up-and-down head movement, talking (a standard set of passages will be provided for reading aloud), grimacing, bending over, and normal breathing. The grimace is an intentional attempt to disrupt the face seal and observe the respirator's ability to subsequently reset itself. For the new four-step protocol, OSHA Fast-filtering Face, the participants will be required to perform only four exercises: side-to-side head movement, up-and-down head movement, talking, and bending over. Every exercise except the grimace task will be assigned a specific individual fit factor ranging from 0 to 200. Each fit factor (FF) will be determined as the ratio of the concentration of a challenge agent outside the respirator to the concentration of the same agent inside the respirator via leakage (Cout/Cin). The overall FF (range = 0–200) will be determined using a respective equation specified in the conventional and new protocol. An overall FF greater than 100 will indicate a 'pass', indicating that the tested respirator fits the wearer properly.
The sequence in which each respirator and protocol is tested will be randomly assigned to the participants in a sealed envelope.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
PortaCount respirator fit-tester system (model Pro+ 8048)

Primary outcome(s)
Fit factor (range 0-200) and the pass rate of fit testing (pass or fail). A validated system will be used to measure these variables.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/04/2026

Eligibility

Key inclusion criteria
1. Students pursuing healthcare disciplines or healthcare workers who are licensed staff members providing direct patient care.
2. Aged 18 years or above.

Participant type(s)
Health professional, Learner/student, Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Healthcare workers with a documented medical history of chronic respiratory diseases or conditions such as asthma, congestive heart failure, or coronary heart disease.
2. Those who are currently pregnant.

Date of first enrolment
01/03/2025

Date of final enrolment
28/02/2026

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
Mong Kok, Kowloon

Hong Kong SAR
China
-

Sponsor information

Organisation
Tung Wah College

ROR
https://ror.org/04jfz0g97

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
The data set generated and analysed during the current study will be available upon request from Simon Ching Lam (simonlam@twc.edu.hk; simlc@alumni.cuhk.net)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			28/05/2025	No	Yes