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Research paper

A prospective clinical evaluation of a patient isolation hood during the COVID-19 pandemic

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ABSTRACT

Background: Healthcare workers (HCWs) have frequently become infected with severe acute respiratory syndrome coronavirus 2 whilst treating patients with coronavirus disease 2019 (COVID-19). A variety of novel devices have been proposed to reduce COVID-19 cross-contamination.
Objectives: The aim of the study was (i) to test whether patients and HCWs thought that a novel patient isolation hood was safe and comfortable and (ii) to obtain COVID-19 infection data of hospital HCWs.
Methods: This is a prospective cohort study of 20 patients, entailing HCW/patient questionnaires and safety aspects of prototype isolation hoods. COVID-19 data of HCWs were prospectively collected. Assessment of the hood's safety and practicality and adverse event reporting was carried out.
Outcome measures: The outcome measures are as follows: questionnaire responses, adverse event reporting, rates of infections in HCWs during the study period (20/6/2020 to 21/7/2020), and COVID-19 infections in HCWs reported until the last recorded diagnosis of COVID-19 in HCWs (20/6/2020 to 27/9/2020).
Results: Of the 64 eligible individual HCW surveys, 60 surveys were overall favourable (>75% questions answered in favour of the isolation hood). HCWs were unanimous in perceiving the hood as safe (60/60), preferring its use (56/56), and understanding its potential COVID-19 cross-contamination minimisation (60/60). All eight patients who completed the questionnaire thought the isolation hood helped prevent COVID-19 cross infection and was safe and comfortable. There were no reported patient safety adverse events. The COVID-19 attack rate from 20/6/2020 to 27/9/2020 among registered nurses was as follows: intensive care units (ICUs), 2.2% (3/138); geriatric wards, 13.2% (26/197); and COVID-19 wards, 18.3% (32/175). The COVID-19 attack rate among medical staff was as follows: junior staff, 2.1% (24/932); senior staff, 0.7% (4/607); aged care/rehabilitation, 6.7% (2/30); and all ICU medical staff, 8.6% (3/35).
Conclusions: The isolation hood was preferred to standard care by HCWs and well tolerated by patients, and after the study, isolation hoods became part of standard ICU therapy. There was an association between being an ICU nurse and a low COVID-19 infection rate (no causality implied). ICU HCWs feel safer when treating patients with COVID-19 using an isolation hood.

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1. Introduction

Since December 2019,[1] severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has led to the coronavirus disease 2019 (COVID-19) pandemic.[2] The World Health Organisation indicates that approximately 14% of people with COVID-19 require hospitalisation (with O_2 support) and 5% require intensive care unit (ICU) admission.[2] Controversy surrounds the degree to which SARS-CoV-2 is spread more via localised droplets versus distantly spread aerosols.[3,4] There is ongoing concern about SARS-CoV-2 infectious spread to healthcare workers (HCWs) and particularly from aerosol-generating procedures such as intubation/extubation, nebuliser therapies, high-flow O_2, and noninvasive ventilation.[5,6]

During the COVID-19 pandemic, focus has been on use of personal protective equipment (PPE) to prevent cross infections in HCWs.[7] Controlling ventilation to avoid spread from infected patients with respiratory diseases is arguably at least as important as use of appropriate PPE.[8] Negative-pressure isolation rooms (Class N) can provide greater ventilation control than open-plan rooms but are a limited resource.[9] Negative-pressure rooms (NPRs) in hospitals provide high flows (12 air changes/hour) and negative pressure to prevent the spread of pathogens beyond the room's confines,[9] however, infectious spread to personnel *within* the room remains problematic. Personal ventilation devices to protect HCWs and other patients from respiratory infections have been explored during prior and current infectious disease outbreaks, such as SARS (2003),[1] and COVID-19.[10,11] Such personal ventilation devices could be particularly useful for settings when the patient is in an open ICU or other healthcare settings.

We conducted a prospective cohort study to evaluate the safety and comfort of prototype personal ventilation hoods (the McMonty isolation hood, see Fig. 1, https://medihood.com.au/) in a clinical setting. We also prospectively observed the number of HCWs with COVID-19 infections in the ICU and other areas of the health service. In particular, we prospectively obtained data on COVID-19 infections in HCWs in hospital areas, who treated large numbers of patients with COVID-19 (the ICU and emergency department [ED], designated COVID-19 wards, and geriatric wards). The isolation hoods were used only in the ICU and ED; we sought any potential association between use of the isolation hoods in the ED/ICU versus other hospital wards and COVID-19 infection rates in HCWs.

2. Methods

We undertook a prospective, interventional study of 20 patients whose management included the use of a personal isolation hood. This hospital ethics–approved study for a Therapeutic Goods Administration (TGA)–listed isolation hood device was conducted from 20/6/2020 to 21/7/2020 in two general ICUs and EDs at a metropolitan healthcare service in Melbourne, Australia. Feedback from participants and HCWs was obtained via a structured questionnaire. Two independent data safety monitors provided stewardship of trial conduct and adverse event reporting. Further details about the personal isolation *McMonty* hood[12] and the TGA-adapted[13] Hospital Ethics Committee Adverse Events Reporting forms are provided in Supplementary Appendix 1. We prospectively monitored routine de-identified COVID-19 data of our institution's HCWs. A confirmed COVID-19 infection was defined as a positive SARS-CoV-2 test (see Supplementary Appendix 1 for SARS-CoV-2 tests used).

Eligible participants for this trial were adult patients (≥18 y), being cared for in the ED or ICU, with suspected/confirmed COVID-19, or any respiratory infection warranting droplet or airborne precautions. Patients were excluded if they were aged <18 y, were pregnant, were delirious, had a history of dementia, had claustrophobia, and were at risk of injuring themselves or others.

Patient participants or their medical treatment decision-maker provided consent for use of the personal isolation hood (Supplementary Appendix 3). The patient participants were invited to complete a feedback questionnaire, and survey consent was implied if this was attempted (Supplementary Appendix 4). HCWs who cared for patients using the isolation hood were invited to complete a single anonymous HCW questionnaire (Supplementary Appendix 4). Consent from HCWs was implied if the questionnaire was attempted.

Participants were free to open the hood cover or discontinue in the trial at any time. HCWs could also cease use of the hood at any time. Use of the hood ceased when a patient (i) had been declared negative for COVID-19 or another respiratory infectious disease, (ii) had completed at least 7 d of treatment and was deemed clinically appropriate by HCWs to cease use, (iii) had been discharged from the ICU or hospital, or (iv) withdrew from the study.

2.1. Survey design and data analysis

The HCW questionnaire comprised 18 closed and two open questions. Four of the closed questions were Likert scale questions (a 10-point Likert scale, numbered 1–10), and 14 were yes/no questions. The questions assessed the HCWs' perception of the device's ability to prevent cross-contamination, its safety (construction, mobility), and its practicality (patient access, communication). The *patient* questionnaire comprised seven closed questions (five Likert scale and two yes/no questions) and two open questions. The questions assessed the patient's perception of the isolation hood's comfort, safety, and ability to reduce infectious spread to HCWs. Free-text areas were available for all questions to allow further patient/HCW commentary.

We deemed that each questionnaire required a minimum of 50% of questions to be answered for data inclusion. Questions with a yes/

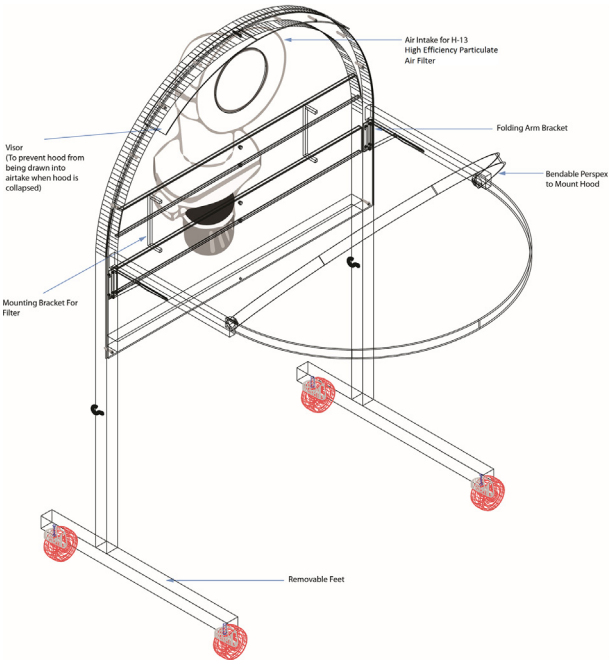

Fig. 1. Schematic diagram of the patient isolation hood. HEPA, high efficiency particulate air.

no answer were deemed 1/0 points for positive and negative responses, respectively. Questions with a scaled 1–10 answer had a value of 0 (negative response) for a value of 1–5 or 1 (positive response) for a value of 6–10. Questionnaires were deemed either overall favourable (50% or more positively answered) or unfavourable (less than 50% positively answered). A 75% or higher favourable response rate across all patient and HCW questionnaires was deemed favourable for isolation hood endorsement. Questions with more than one answer or no answer provided were excluded. The questionnaire included a question for HCWs about the proportion of time that the isolation hood was being actively and thus effectively used (hood down, fan on). This was considered important because if the hood was used for a short duration, it could indicate difficulty using the hood, poor patient/HCW tolerance, and so on.

2.2. SARS-CoV-2 infection data of HCWs

Treatment for patients with COVID-19 in the hospital occurred in the ED, ICU, and designated COVID-19 wards. We obtained prospective data of the observed rates of COVID-19 infections in ICU HCWs compared with other hospital HCWs (all de-identified). We calculated the proportion of registered nurses (RNs) and medical HCWs who developed COVID-19 both among ICU HCWs and other hospital HCWs working elsewhere within the health service. We did not distinguish between SARS-CoV-2 infections at work/home/elsewhere, only COVID-19 positivity. We considered that HCWs could become symptomatic or test positive for COVID-19 up to 14 d after study involvement. HCWs' data are reported from 20/6/2020 to 27/9/2020 (date of the last COVID-19 diagnosis at our institution).

Ethical and TGA approval

Ethical approval was obtained from the Melbourne Health Human Research Ethics Committee (MH HREC 2020.129). The isolation hood was registered with the TGA (CT-2020-CTN-01390-1).

3. Results

3.1. Patient characteristics

Twelve patients with confirmed COVID-19 and eight patients with suspected COVID-19 were enrolled from 20/6/2020 to 21/7/2020 (Fig. 2). Nineteen patients were treated in the ICU, and one was treated in the ED (only).

Of the 20 patients who received isolation hoods, 11 patients received invasive ventilation, five received noninvasive ventilation, and two received nebuliser therapy (Table 1).

Isolation hoods continued to be used even after this study (i.e., after all questionnaires were completed on 21/7/2020). After the 20-patient trial, 103 patients were screened for use of the isolation hood (40 excluded owing to behaviour of concern and delirium). A total of 34 patients with COVID-19 and 29 patients with suspected COVID-19 received isolation hoods after the study, i.e., from 22/7/2020 to 27/9/2020 (the last date an HCW at our institution was diagnosed with COVID-19).

3.2. HCW surveys

Of the 64 individual HCW surveys, 60 (94%) were eligible (≥50% of questions answered), and all 60 surveys were overall favourable (>75% questions answered in favour of the isolation hood) (see Table 2). HCWs were unanimous in preferring to use the isolation hood (Q1), perceiving the hood as safe (Q2), and understanding how the hood worked to reduce cross-contamination (Q4), and they found the hood to be in good working order (Q7). The final two questions (infection control/hood cleaning) in the HCW questionnaire remained unanswered as cleaning of the hood was undertaken by ICU research nurses rather than ICU nurses for the study, and after the study, the task was carried out by hospital cleaning staff. HCWs also made free-text comments, which are further detailed in Supplementary Appendix 4.

Table 3 shows the nurse-reported proportion of that nursing shift in which the isolation hood was used in the 'hood down, fan on' configuration (versus hood up, fan off *or* on). The reported proportions are exclusive of the time the hood was opened for necessary clinical reasons, e.g., for patient turning. A total of 84 logs were recorded; 51 of 84 (61%) HCWs reported using the isolation hood in the hood down/fan on configuration for more than 75% of the shift. Commonly reported reasons for not using the hood in this configuration were due to patient concerns and requests for a break from the isolation hood.

3.3. Patient responses

Eight participants (8/20, 40%) completed the questionnaire. Three patients died during their ICU admission, and nine patients did not complete the questionnaire. Seven of eight patient surveys were favourable (>75% questions answered in favour of the isolation hood). All eight patients who completed the patient questionnaire indicated that they thought that the isolation hood helped prevent COVID-19 cross infection, was safe and comfortable to use. Most (7/8 = 88%) patients thought that the hood was easy to open and that the temperature and humidity was comfortable (6/8 = 75%). Patients agreed less strongly that the hood provided comfortable temperature and humidity (5/8 = 62.5%) and that they could communicate adequately whilst inside the hood's canopy (5/8 = 62.5%).

Negative patient comments about the hood were with regard to (i) noise, "Just have to get staff to speak up, I just spoke up a little more, and it was ok" and "I had to yell and try to open the hood, which I couldn't do easily"; (ii) lighting, "The overhead lights bounced off the plastic a little bit, depending on the angle of the plastic, but not troublesome"; and (iii) temperature, "I felt a bit trapped and too hot".

Positive patient comments about the hood were as follows: "I liked how I can still see activity happening around me", "Normally I have to go in an isolation room when I come to hospital and it's very lonely. You can see nobody for hours.", "This hood lets me still be seen by staff and I don't feel forgotten about.", and "I felt that it helped to stop the spread of infectious diseases".

3.4. Adverse events

No patient-related safety adverse events were reported. All adverse events were technical concerns related to the isolation hood's design or operation. The data safety monitors received two near-incidents and nine nonincidents. Additional details of the nonincidents and rectification required are presented in Supplementary Appendix 4. The final nonincident involved an audible alarm that confirmed the fan was on (an additional feature to remind HCWs the fan should be on while the hood was down). The alarm remained on continuously, necessitating its removal. New prototypes were fitted with a light at the front of the hood to indicate that the fan was on.

3.5. COVID-19 infections in HCWs

All HCWs' COVID-19 infection data are from 20/6/2020 until 27/9/2020. The overall attack COVID-19 attack (infection) rate among

RNs was 3.4% (102/2994): ICUs, 2.2% (3/138); EDs, 3.2% (11/366); surgical wards, 1.2% (3/252); geriatric wards, 13.2% (26/197); and COVID-19 wards, 18.3% (32/175). The COVID-19 attack rate among medical staff members was as follows: all junior medical staff, 2.1% (24/932); senior medical staff, 0.7% (4/607); anaesthetists, 1.9% (2/104); aged care/rehabilitation, 6.7% (2/30); and all ICU medical staff, 8.6% (3/35).

4. Discussion

We report the first clinical evaluation of a novel patient isolation hood used during the COVID-19 pandemic. We found high levels of patient and HCW satisfaction: after the study, the isolation hoods became part of standard ICU therapy. No device-related patient adverse events were reported. Several technical adverse events were reported, which will inform future device design and development. No single question was answered negatively about the isolation hood. Improved safety (from COVID-19 cross infection) was the most common and pronounced reason why HCWs liked the isolation hood.

Patients thought that the isolation hood helped prevent COVID-19 cross infection and was safe and comfortable. Attack rates of COVID-19 infections in ICU nurses were lower than those in other nursing groups.

Aerosol-generating procedures such as noninvasive ventilation, endotracheal extubation, and nebuliser therapy were able to be delivered in our open-plan ICUs in the presence of isolation hoods without recourse to transports to/from an NPR. It is unclear, however, whether the use of isolation hoods affected clinical outcomes. Prior studies regarding the use of isolation hoods during pandemics, including COVID-19.[10–12,14] exist. Adir et al.[11] recently reported the positive responses of a survey that included nine HCWs. To our knowledge, this is the only study that reports HCWs' and patients' views about the use of an isolation hood during COVID-19.[11]

No major adverse events occurred during the study, and as we proceeded, new isolation hood prototypes were modified to have a lower centre of gravity, a fan-on light, and more robust plastic canopies. The least strongly supported theme for the isolation hood of the HCWs' survey related to communication and interference with patient care. Negative patient comments about the hood were mainly related to noise of the fan. This feedback will inform future design.

Of the total number of COVID-19 cases among HCWs in Victoria, Australia (3574 as of November 20, 2020), 73% of cases were

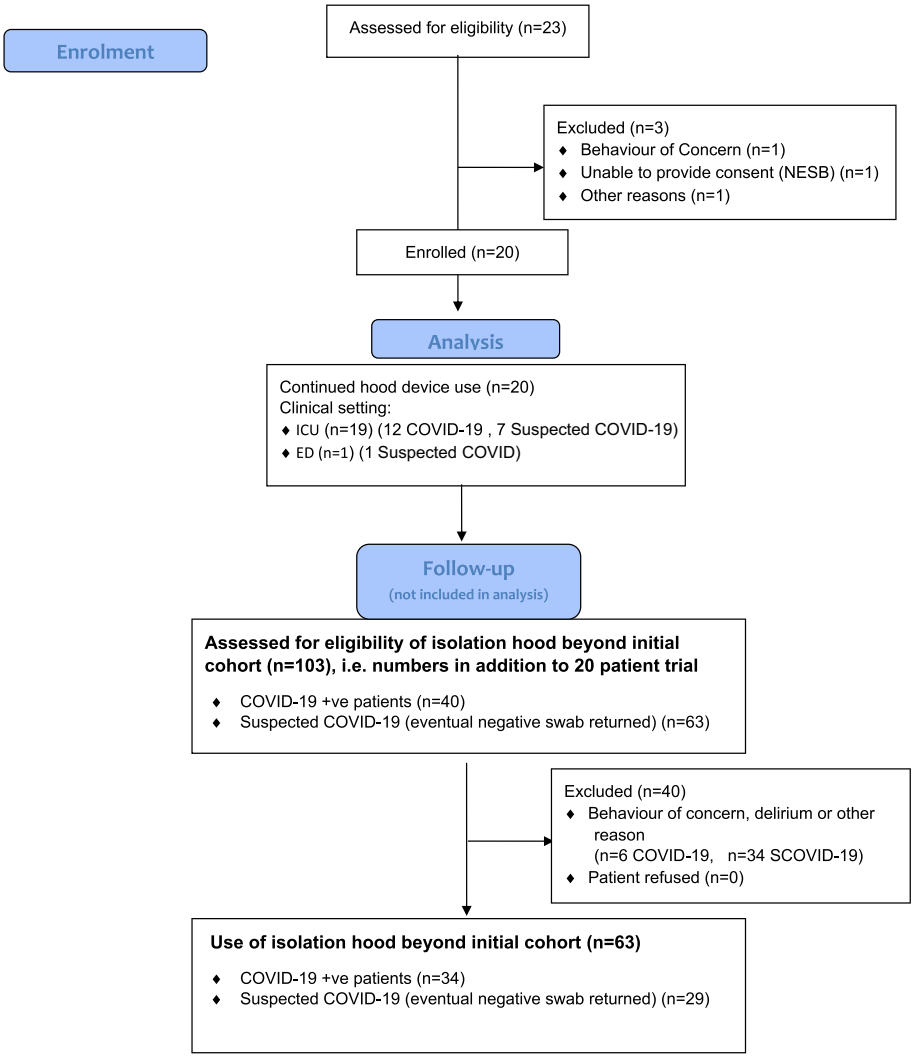

Fig. 2. CONSORT flow diagram. COVID-19, coronavirus disease 2019; ED, emergency department; ICU, intensive care unit.

Table 1
Demographics and therapies for the 20 patients who received isolation hoods.

Variable of interest	
Age (years), median (range)	65.5 (25–80)
Male/female	10/10
APACHE II score, median (range)	19 (9–34)
Alive/died (all three died in the ICU)	17/3
COVID-19 positive	12
Intubated participants	11
Intubation duration in days, median (range)	8 (1–15)
Documented extubations under the isolation hood	12
Noninvasive ventilation (NIV) recipients	5
NIV duration, in hours, median (range)	1 (1–15)
Nebuliser therapy recipients	2
Length of stay in the ICU, in days, median (range)	3 (1–29)
Length of stay in the ICU, in days, for those intubated during their ICU stay, median (range)	13 (1–29)
Length of isolation hood use, in days, median (range)	3 (1–29)
Length of stay in the hospital, in days, median (range)	5 (1–45)

APACHE II, Acute Physiology and Chronic Health Evaluation II; COVID-19, coronavirus disease 2019; ICU, intensive care unit.

acquired in a healthcare setting.[15] Observational data of infections in HCWs in Victoria indicate that COVID-19 infections in ICU HCWs are less common than among HCWs in COVID-19 wards, aged care workers in hospitals, and aged care workers in residential aged care facilities (Marion Kainer, personal communications). This study was conducted in open-plan ICUs with only one single NPR used solely for intubations/bronchoscopies/tracheostomies.

The ICU nurses' COVID-19 attack rates were the second lowest of any hospital nursing group. Potential factors other than the use of a patient isolation hood that could influence this observation are as follows: patients with COVID-19 admitted to the ICU who are typically a week from the symptom onset and potentially less infectious, improved ICU nurse-to-patient ratios, the use of invasive mechanical ventilation with exhaled gas high efficiency particulate air (HEPA) filtration, ICU nurses' PPE training, and different room ventilation. In Victoria, Australia, however, hospital building guidelines state that air exchange rates must be six per hour for ICUs *and* for all medical/surgical ward areas.[9] If these guidelines are implemented, the rate of air exchange is not a reason for different observed COVID-19 infection rates in HCWs. The ICU medical staff's COVID-19 attack rate was numerically higher than that of other medical staff groups. ICU medical staff routinely performed endotracheal intubation (wherein the isolation hood was unable to be used).

Our study has limitations. By its nature, it was unblinded and the single health centre sample size was small. We did not distinguish between nurse/doctor/other questionnaire responses or conduct detailed investigation of infection control procedures. Further bias may have arisen owing to ICU HCW and ICU researcher familiarity. We did not measure viral loads within/exterior to the isolation hoods. We had no ability to adjust for potential confounders. Although the observed attack rate in ICU RNs was low, it remains uncertain if the isolation hood reduces transmission of COVID-19 infections to HCWs: no causal inference may be drawn.

This study complements our preclinical assessment of the isolation hood's efficacy of limiting aerosol spread.[12] The results of this study support the conduct of translational research and implementation studies of the isolation hood in other hospital areas and other jurisdictions. This study provides evidence of the safety and comfort of an isolation hood as part of routine treatment of patients with COVID-19. There was a high rate of acceptance by patients and HCWs, and there is potential that family visits to the ICU/ward could be made more frequently. It is apparent that HCWs feel safer when treating patients using a personal ventilation hood. It is plausible the

Table 2
HCW survey: responses to questions.

Question	Theme	Number of favourable responses/total responses (%)
1	Prefer the hood compared with standard care for a patient with COVID-19	56/56 (100%)
2	Safety of using the device	60/60 (100%)
3	Interference with patient care	41/60 (68%)
4	Understanding of how the device protected healthcare workers	60/60 (100%)
7	Physical condition of the device at the start of the shift	58/58 (100%)
8	Ability to rapidly stow/remove the device in emergencies	40/56 (71%)
9	Robustness and mobility of the device	53/57 (93%)
10	Perceived reduced probability of contracting COVID-19 when using the device	56/60 (93%)
11	Effectiveness of instructions printed on the device	48/54 (89%)
12	Location of patient-access points	45/52 (87%)
13	Quality of device components	52/59 (88%)
14	Accumulation of moisture/exhalation/sputum	56/58 (97%)
15	HCWs' comfort performing AGPs with the device	21/23 (91%)
16	Ability of device to prevent cross-contamination	57/58 (98%)
17	Isolation hood prevents communication	15/22 (68%)
18	The patient appeared comfortable	17/22 (77%)

AGP, aerosol-generating procedure; COVID-19, coronavirus disease 2019; HCW, healthcare worker.

Table 3
HCWs' reported use of isolation hood in the 'hood down, fan on' configuration across a nursing shift.

Proportion of shift when hood was down, fan on	Number of responses (%)
0–24% of the shift	12 (14%)
25–49% of the shift	6 (7%)
50–74% of the shift	15 (18%)
75–100% of the shift	51 (61%)

HCW, healthcare worker.

isolation hood reduces transmission of COVID-19 infections to HCWs. Additional studies to define the role of this device are indicated.

CRediT authorship contribution statement

Forbes McGain: Conceptualisation, wrote the background, methods and ethics submission, Funding acquisition, assisted in data capture, Writing - original draft, Writing - review & editing. **Samantha Bates:** assisted in methods and ethics preparation, ran the data capture and management, Writing - original draft. **Jung Hoon Lee:** assisted in data capture, trial management, Writing - original draft. **Patrick Timms:** assisted in data capture and management, Writing - original draft. **Marion A. Kainer:** assisted in methods, Writing - original draft. **Craig French:** Writing - original draft. **Jason Monty:** Conceptualisation, Funding acquisition, Writing - original draft.

Conflict of Interest

A patent has been filed for the personal ventilation hood by the University of Melbourne/Western Health. The lead authors (F.M. and J.M.) were the leads in this patent application. All other authors have no conflicts of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.aucc.2021.05.001.

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