

From: Raina MacIntyre <r.macintyre@unsw.edu.au>
Sent: Friday, 24 November 2023 08:21
To: cleanair@cleanairtas.com
Cc: DVCR RECS Human Ethics
Subject: Re: Bushfire study

Dear Mr Stott

Thank you for your letter. As advised, the whole investigator team on this study met and considered your letter and earlier email. After my first response, the one remaining issue was about having a surgical mask arm in the randomised clinical trial. As mentioned, the study began in 2020 and has run for three summers already and will be over in five months. This coming summer is the last year of the study. At the time you contacted us, the recruitment and randomisation was already complete, and participants allocated to arms and provided whichever device they were allocated.

The study was done because of the lack of level 1 evidence, which in healthcare is a randomised clinical trial, on protection against bushfire health effects. We acknowledge that you make important points, but the lack of trial data results in varied guidelines worldwide, and varied practices. The evidence itself is essential to inform better policy.

The following points were discussed in the investigator team meeting :

1. Some guidelines still recommend surgical masks – eg NSW Rural Fire service recommends any kind of mask, even a cloth mask during bushfire. <https://www.rfs.nsw.gov.au/plan-and-prepare/prepare-your-family/what-to-wear>
2. Bushfires are often sudden, and people may need to avail themselves of whatever is available to them at the time, which is more likely to be a surgical mask than a N95, so gathering evidence to inform better preparedness is important. This may be why the NSW RFS guidelines are as they are.
3. There is no RCT evidence on masks and respirators for this indication, and in healthcare, this is the gold standard against which policy is made. Gathering this evidence can change policy, ensure consistent policy, and improve protection for people. This also means people can be better prepared with the best protection readily available to them.
4. The recruitment and randomisation for 2023 was already complete before your complaint and the study has already run for three years. The study will finish early in 2024. Changing the study in the very last months will invalidate the whole study, and the time and effort of participants in the last three years.
5. We have experts in asthma and chronic obstructive pulmonary disease (COPD) in our research team, who pointed out that patients with asthma and COPD who have breathing difficulty often express a preference for surgical masks as they are more comfortable to wear when breathing is impaired.
6. We note that you did not suggest that randomising people to outdoor air avoidance (no PPE at all) is unethical.
7. Several potential participants expressed a preference for one intervention (sometimes a N95 and sometimes a surgical mask or no mask) and did not wish to be randomised or to accept the arm to which they were randomised. These people did not participate in the study.

To further address your concerns, we also conducted an interim analyses of the health effects experienced by participants in the trial. The interim analysis of data collected over the past 3 years shows no significant difference between surgical masks and respirators, which reassures us that the study is not harming

any participant. There may be many reasons for this, including non-compliance, cross-over (people using an intervention other than what they were allocated) and other factors, which we can only fully understand once the data are carefully analysed. We believe these are important real-world considerations that need to be well understood.

After carefully considering the points above, the investigator group agreed that the study should proceed with participants in the arms they were randomised to.

We have presented the interim analysis and the points above to the UNSW Ethics Committee, who agree that the study should proceed as planned. We hope this study will provide the level of evidence accepted by health decision makers to improve protection for Australians against smoke exposure. Thank you for your input.

Yours truly,

Raina MacIntyre

Regards

Raina

Raina MacIntyre (She/Her)

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