Prof Carl Heneghan & Tom Jefferson

Landmark Danish study shows face masks have no significant effect

Do face masks work? Earlier this year, the UK government decided that masks could play a significant role in stopping Covid-19 and made masks mandatory in a number of public places. But are these policies backed by the scientific evidence?

Yesterday marked the publication of a long-delayed trial in Denmark which hopes to answer that very question. The 'Danmask-19 trial' was conducted in the spring with over 3,000 participants, when the public were not being told to wear masks but other public health measures were in place. Unlike other studies looking at masks, the Danmask study was a randomised controlled trial – making it the highest quality scientific evidence.

Around half of those in the trial received 50 disposable surgical face masks, which they were told to change after eight hours of use. After one month, the trial participants were tested using both PCR, antibody and lateral flow tests and compared with the trial participants who did not wear a mask.

In the end, there was no statistically significant difference between those who wore masks and those who did not when it came to being infected by Covid-19. 1.8 per cent of those wearing masks caught Covid, compared to 2.1 per cent of the control group. As a result, it seems that any effect masks have on preventing the spread of the disease in the community is small.

Some people, of course, did not wear their masks properly. Only 46 per cent of those wearing masks in the trial said they had completely adhered to the rules. But even if you only look at people who wore masks 'exactly as instructed', this did not make any difference to the results: 2 per cent of this group were also infected.

When it comes to masks, it appears there is still little good evidence they prevent the spread of airborne diseases. The results of the Danmask-19 trial mirror other reviews into influenza-like

illnesses. Nine other trials looking at the efficacy of masks (two looking at healthcare workers and seven at community transmission) have found that masks make little or no difference to whether you get influenza or not.

But overall, there is a troubling lack of robust evidence on face masks and Covid-19. There have only been three community trials during the current pandemic comparing the use of masks with various alternatives – one in Guinea-Bissau, one in India and this latest trial in Denmark. The low number of studies into the effect different interventions have on the spread of Covid-19 – a subject of global importance – suggests there is a total lack of interest from governments in pursuing evidence-based medicine. And this starkly contrasts with the huge sums they have spent on 'boutique relations' consultants advising the government.

The only trials which *have* shown masks to be effective at stopping airborne diseases have been 'observational studies' – which observe the people who ordinarily use masks, rather than attempting to create a randomised control group. These trials include six studies carried out in the Far East during the SARS CoV-1 outbreak of 2003, which showed that masks can work, especially when they are used by healthcare workers and patients alongside hand-washing.

But observational studies are prone to recall bias: in the heat of a pandemic, not very many people will recall if and when they used masks and at what distance they kept from others. The lack of random allocation of masks can also 'confound' the results and might not account for seasonal effects. A recent observational study paper had to be withdrawn because the reported fall in infection rates over the summer was reverted when the seasonal effect took hold and rates went back up.

This is why large, randomised trials like this most recent Danish study are so important if we want to understand the impact of measures like face masks. Many people have argued that it is too difficult to wait for randomised trials – but Danmask-19 has shown that these kind of studies are more than feasible.

And now that we have properly rigorous scientific research we can rely on, the evidence shows that wearing masks in the community does not significantly reduce the rates of infection.

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