

SYNOPSIS

11/25/2020

Review of “Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers”

Article citation: Bundgaard H, Bundgaard JS, Raaschou-Pedersen DET, von Buchwald C, Todsén T, Norsk JB, et al. Effectiveness of adding a mask recommendation to other public health measures to prevent SARS-CoV-2 infection in Danish mask wearers. *Ann Intern Med.* 2020 Nov 18 [Epub ahead of print]. Available from: <https://doi.org/10.7326/M20-6817>

One-minute summary

- This is a community-based unblinded **randomized controlled trial in five regions in Denmark** conducted between April 3 and June 2, 2020 to assess **if recommendations for wearing surgical masks outside the home would protect wearers from acquiring severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection**, the etiologic agent of Coronavirus Disease 2019 (COVID-19).
- **SARS-CoV-2 infection was detected in 42/2,392 (1.8%) vs. 53/2,470 (2.1%) individuals in the mask-wearing (intervention) and non-mask-wearing (control) groups respectively**, with a between-group difference of -0.3% (95% CI, -1.2% to 0.4%; P = .38), **odds ratio (OR) = 0.82 (95% CI, 0.54 to 1.23; P = .33)**.
- The authors performed a pre-specified per protocol analysis excluding mask group participants who reported non-adherence (7%), as well as an analysis excluding those without baseline SARS-CoV-2 results (n=18), with similar primary outcome results. In addition, the authors performed pre-specified subgroup analyses with no statistically significant interactions identified.
- 19.3% of study participants were lost to follow-up. Post-hoc, the authors performed multiple imputation accounting for this loss to follow-up, which yielded similar results.
- The authors concluded that recommendations to wear surgical masks to supplement other public health measures did not significantly reduce the SARS-CoV-2 infection rate among wearers by more than 50% in a community with modest (2%) infection rates, beyond other public health measures. **However, based on the 95% confidence intervals they could not exclude a range of effects compatible with a 46% reduction to a 23% increase in SARS-CoV-2 infections.**

Additional information

- Between April 3 and 24, 2020, 17,258 Danish citizens ≥ 18 years of age responded to recruitment via media advertisement, private company and public organization contacts. 6,024 eligible individuals were included based on the following criteria:
 - Without current or prior symptoms or diagnosis of COVID-19.
 - Reporting being outside of the home among others for ≥ 3 hours per day.
 - Not required to wear a mask at work.
- A total of 3,030 participants were randomly assigned to the recommendation to wear masks, and 2,994 were assigned to control; 4,862 completed the study (19.3% loss to follow-up):
 - 2,995 were followed from April 14 to 16 until May 15, 2020, when the country was under lockdown conditions (reopening occurred on May 18, 2020).
 - 3,029 were followed from May 2 to 4 until June 2, 2020.
- Each participant in the intervention group was given 50 three-layered disposable surgical masks with written and video instructions (including instructions to change masks if outside the home for >8 hours). Reported compliance with mask-wearing was:
 - 46% as instructed
 - 47% predominantly as instructed
 - 7% not as recommended
- The primary outcome explored was SARS-CoV-2 infection, defined as:
 - Positive oropharyngeal/nasal swab for SARS-CoV-2 by reverse transcriptase polymerase chain reaction (RT-PCR).
 - Detection of IgM and/or IgG antibodies to SARS-CoV-2.
 - Or, a COVID-19 diagnosis by a hospital.
- Participants were instructed to perform the point-of-care serology test at baseline and at the end of the trial using the written and video instructions provided.
 - Sensitivity and specificity of the serology test were 90.2% and 99.2%, respectively, as reported by the manufacturer and 82.5% and 99.5%, respectively, in an internal validation test of 651 blood donation samples in November 2019 and 155 PCR-confirmed patients with SARS-CoV-2 infection.
 - Of the 95 participants who met the primary outcome, 80 (84%) were diagnosed only by antibody test and 5 (5.3%) were positive for SARS-CoV-2 by RT-PCR (all 5 in the control group).
- A 1.9% seroprevalence of SARS-CoV-2 was reported in Danish blood donors between April 6 and May 9, 2020, similar to the incidence rates among the study participants.
- Participants were also instructed to perform the point-of-care RT-PCR tests, using test kits and the written and video instructions provided, at the end of the trial period or whenever these symptoms arose: cough, fever, headache, shortness of breath, pain in muscles/joints, taste disorders.
- All test results, time spent outside of home, time and adherence to mask use instructions and exposure to household members with COVID-19 were collected in the weekly follow-up emails.
- Among participants who reported COVID-19 in their households, 2/52 in the intervention group and 1/39 in the control group developed SARS-CoV-2 infection. The authors suggest that most of the infections were likely acquired outside of the home.
- In [subgroup analyses](#), there was a non-significant trend to higher effectiveness in females (OR = 0.65; 95% CI, 0.38-1.12; P = .20) and those who spent >4.5 hours outside the home (OR = 0.61; 95% CI, 0.30-1.21; P = .26).

- The authors performed a post hoc (not preplanned) analysis which included only participants who reported wearing face masks “exactly as instructed”. The primary outcome occurred in 22 participants (2.0%) in the mask group and 53 (2.1%) in the control group (between-group difference, -0.2 percentage point [95% CI, -1.3 to 0.9 percentage point]; P = .82; OR = 0.93 [95% CI, 0.56 to 1.54; P = .78]).

PHO reviewer’s comments

- Bundgaard et al. conducted a well-designed, practical, randomized controlled trial evaluating the effectiveness of mask recommendations to protect non-health care workers in a community setting. The results of this study are consistent with [previous research](#)¹ which has demonstrated either a small or lack of protective effect to the wearer from face masks worn in community settings.
- The mechanism of effectiveness for mask use in the community is likely to protect others *from* the mask-wearer, referred to as “source control”. This study was not designed to assess mask effectiveness as source control. There have been several ecological studies (from [Canada](#),² [Germany](#),³ and the [United States](#)⁴) that have demonstrated a significant beneficial effect from jurisdictional mask mandates in reducing COVID-19 case numbers.
- The authors appropriately acknowledged several notable study limitations. The study was conducted at a time of relatively low community transmission and was powered to detect a 50% protective effect from mask recommendations. The study cannot exclude an effect range between 46% reduction in risk to a 23% increase in risk. The study had a substantial (19%) proportion lost to follow-up, which was addressed through the use of multiple imputation. Approximately half of the intervention arm reported not using masks exactly as directed; however, in a post-hoc analysis, there was no difference when the study was restricted to only those that self-reported perfect adherence.
- Despite the study’s limitations, it adds important scientific evidence to public use of masks. Face masks likely offer little-to-no protection to the average wearer. Therefore, those wearing masks should remain vigilant to not underestimate the risks associated with community exposures and social interactions. Mask wearing is one component of layers of public health measures including frequent hand hygiene; physical distancing and limiting close contact with non-household members; and avoiding crowded environments and closed spaces.
- This study does not provide evidence that public mask wearing is ineffective for controlling COVID-19 through source control. The summation of the current body of evidence on mask use strongly supports public mask mandates as effective in controlling community transmission of COVID-19.

Additional references

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