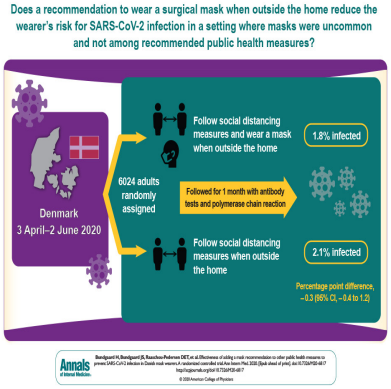
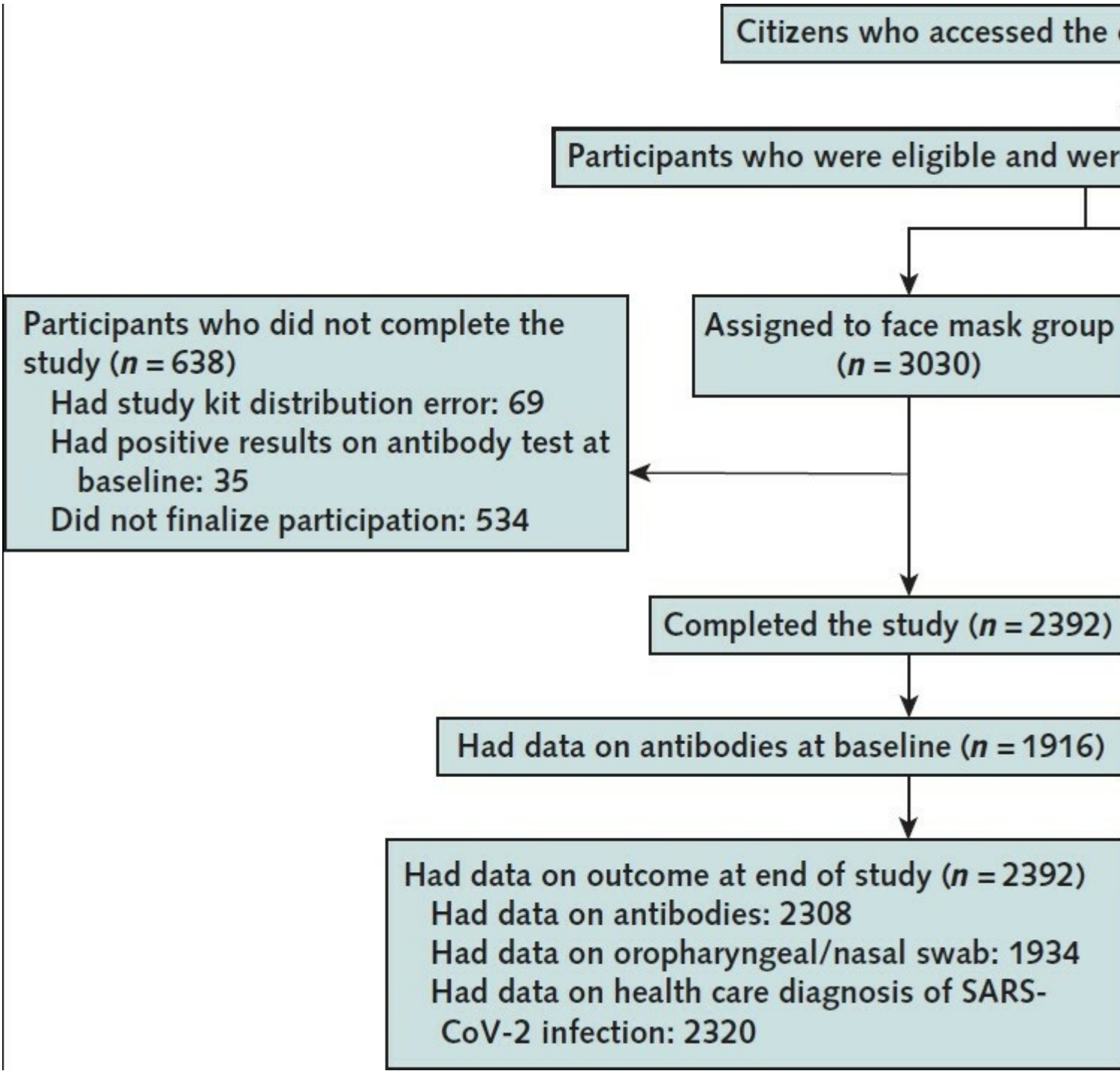


Effectiveness of masks to prevent SARS-CoV-2: A Randomized Controlled Trial

Description

> Conclusion: The recommendation to wear surgical masks to supplement other public health measures did not reduce the SARS-CoV-2 infection rate *[i.e., no statistically significant difference between groups was found at the coventional ?-level;* p = *0.38; (odds ratio [OR], 0.82 [CI, 0.54 to 1.23];* p = *0.33)]*. (Content in brackets added)

Visual summary



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Johan Skov Bundgaard, Daniel Emil Tadeusz Raaschou-Pedersen, Christian von Buchwald, et al. Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers: A Randomized Controlled Trial. **Annals of Internal Medicine** 0;0 [Epub ahead of print 18 November 2020]. doi:doi.org/10.7326/M20-6817

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Abstract

Background:

Observational evidence suggests that mask wearing mitigates transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It is uncertain if this observed association arises through protection of uninfected wearers (protective effect), via reduced transmission from infected mask wearers (source control), or both.

Objective:

To assess whether recommending surgical mask use outside the home reduces wearers' risk for SARS-CoV-2 infection in a setting where masks were uncommon and not among recommended public health measures.

Design:

Randomized controlled trial (DANMASK-19 [Danish Study to Assess Face Masks for the Protection Against COVID-19 Infection]). (ClinicalTrials.gov: NCT04337541)

Setting:

Denmark, April and May 2020.

Participants:

Adults spending more than 3 hours per day outside the home without occupational mask use.

Intervention:

Encouragement to follow social distancing measures for coronavirus disease 2019, plus either no mask recommendation or a recommendation to wear a mask when outside the home among other persons together with a supply of 50 surgical masks and instructions for proper use.

Measurements:

The primary outcome was SARS-CoV-2 infection in the mask wearer at 1 month by antibody testing, polymerase chain reaction (PCR), or hospital diagnosis. The secondary outcome was PCR positivity for other respiratory viruses.

Results:

A total of 3030 participants were randomly assigned to the recommendation to wear masks, and 2994 were assigned to control; 4862 completed the study. Infection with SARS-CoV-2 occurred in 42 participants recommended masks (1.8%) and 53 control participants (2.1%). The between-group difference was ?0.3 percentage point (95% CI, ?1.2 to 0.4 percentage point; $P = 0.38$) (odds ratio, 0.82 [CI, 0.54 to 1.23]; $P = 0.33$). Multiple imputation accounting for loss to follow-up yielded similar results. Although the difference observed was not statistically significant, the 95% CIs are compatible with a 46% reduction to a 23% increase in infection.

Limitation:

Inconclusive results, missing data, variable adherence, patient-reported findings on home tests, no blinding, and no assessment of whether masks could decrease disease transmission from mask wearers to others.

Conclusion:

The recommendation to wear surgical masks to supplement other public health measures did not reduce the SARS-CoV-2 infection rate among wearers by more than 50% in a community with modest infection rates, some degree of social distancing, and uncommon general mask use. The data were compatible with lesser degrees of self-protection.

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Category

1. General

Tags

1. COVID-19
2. Epidemiology
3. Health care providers
4. Infectious diseases
5. Lungs
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7. Pulmonary diseases
8. SARS coronavirus
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