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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

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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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Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the cause of coronavirus disease 2019 (COVID-19), has infected more than 54 million persons (1,2). Measures to impede transmission in health care and community settings are essential (3). The virus is transmitted person-to-person, primarily through the mouth, nose, or eyes via respiratory droplets, aerosols, or fomites (4,5). It can survive on surfaces for up to 72 hours (6), and touching a contaminated surface followed by face touching is another possible route of transmission (7). Face masks are a plausible means to reduce transmission of respiratory viruses by minimizing the risk that respiratory droplets will reach wearers' nasal or oral mucosa. Face masks are also hypothesized to reduce face touching (8,9), but frequent face and mask touching has been reported among health care personnel (10). Observational evidence supports the efficacy of face masks in health care settings (11,12) and as source control in patients infected with SARS-CoV-2 or other coronaviruses (13).

An increasing number of localities recommend masks in community settings on the basis of this observational evidence, but recommendations vary and controversy

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exists (14). The World Health Organization (WHO) and the U.S. Centers for Disease Control and Prevention (15) strongly recommend that persons with symptoms or known infection wear masks to prevent transmission of SARS-CoV-2 to others (source control) (16). However, WHO acknowledges that we lack evidence that wearing a mask protects healthy persons from SARS-CoV-2 (prevention) (17). A systematic review of observational studies reported that mask use reduced risk for SARS, Middle East respiratory syndrome, and COVID-19 by 66% overall, 70% in health care workers, and 44% in the community (12). However, surgical and cloth masks were grouped in preventive studies, and none of the 3 included non–health care studies related directly to COVID-19. Another systematic review (18) and American College of Physicians recommendations (19) concluded that evidence on mask effectiveness for respiratory infection prevention is stronger in health care than community settings.

Observational evidence suggests that mask wearing mitigates SARS-CoV-2 transmission, but whether this observed association arises because masks protect uninfected wearers (protective effect) or because transmission is reduced from infected mask wearers (source control) is uncertain. Here, we report a randomized controlled trial (20) that assessed whether a recommendation to wear a surgical mask when outside the home among others reduced wearers' risk for SARS-CoV-2 infection in a setting where public health measures were in effect but community mask wearing was uncommon and not recommended.

METHODS

Trial Design and Oversight

DANMASK-19 (Danish Study to Assess Face Masks for the Protection Against COVID-19 Infection) was an investigator-initiated, nationwide, unblinded, randomized controlled trial (ClinicalTrials.gov: NCT04337541). The trial protocol was registered with the Danish Data Protection Agency (P-2020-311) (Part 10 of the **Supplement**, available at Annals.org) and published (21). The researchers presented the protocol to the independent regional scientific ethics committee of the Capital Region of Denmark, which did not require ethics approval (H-20023709) in accordance with Danish legislation (Parts 11 and 12 of the **Supplement**). The trial was done in accordance with the principles of the Declaration of Helsinki.

Participants and Study Period

During the study period (3 April to 2 June 2020), Danish authorities did not recommend use of masks in the community and mask use was uncommon (<5%) outside hospitals (22). Recommended public health measures included quarantining persons with SARS-CoV-2 infection, social distancing (including in shops and public transportation, which remained open), limiting the number of persons seen, frequent hand hygiene and cleaning, and limiting visitors to hospitals and nursing homes (23,24). Cafés and restaurants were closed during the study until 18 May 2020.

Eligible persons were community-dwelling adults aged 18 years or older without current or prior symptoms or diagnosis of COVID-19 who reported being outside the home among others for at least 3 hours per day and who did not wear masks during their daily work. Recruitment involved media advertisements and contacting private companies and public organizations. Interested citizens had internet access to detailed study information and to research staff for questions (Part 3 of the **Supplement**). At baseline, participants completed a demographic survey and provided consent for researchers to access their national registry data (Parts 4 and 5 of the **Supplement**). Recruitment occurred from 3 through 24 April 2020. Half of participants were randomly assigned to a group on 12 April and half on 24 April.

Intervention

Participants were enrolled and data registered using Research Electronic Data Capture (REDCap) software (25). Eligible participants were randomly assigned 1:1 to the mask or control group using a computer algorithm and were stratified by the 5 regions of Denmark (**Supplement Table 1**, available at Annals.org). Participants were notified of allocation by e-mail, and study packages were sent by courier (Part 7 of the **Supplement**). Participants in the mask group were instructed to wear a mask when outside the home during the next month. They received 50 three-layer, disposable, surgical face masks with ear loops (TYPE II EN 14683 [Abena]; filtration rate, 98%; made in China). Participants in both groups received materials and instructions for antibody testing on receipt and at 1 month. They also received materials and instructions for collecting an oropharyngeal/nasal swab sample for polymerase chain reaction (PCR) testing at 1 month and whenever symptoms compatible with COVID-19 occurred during follow-up. If symptomatic, participants were strongly encouraged to seek medical care. They registered symptoms and results of the antibody test in the online REDCap system. Participants returned the test material by prepaid express courier.

Written instructions and instructional videos guided antibody testing, oropharyngeal/nasal swabbing, and proper use of masks (Part 8 of the **Supplement**), and a help line was available to participants. In accordance with WHO recommendations for health care settings at that time, participants were instructed to change the mask if outside the home for more than 8 hours. At baseline and in weekly follow-up e-mails, participants in both groups were encouraged to follow current COVID-19 recommendations from the Danish authorities.

Antibody and Viral PCR Testing

Participants tested for SARS-CoV-2 IgM and IgG antibodies in whole blood using a point-of-care test (Lateral Flow test [Zhuhai Livzon Diagnostics]) according to the manufacturer's recommendations and as previously described (26). After puncturing a fingertip with a lancet, they withdrew blood into a capillary tube and placed 1 drop of blood followed by 2 drops of saline in the test chamber in each of the 2 test plates (IgM and IgG). Participants reported IgM and IgG results separately as

"1 line present" (negative), "2 lines present" (positive), or "I am not sure, or I could not perform the test" (treated as a negative result). Participants were categorized as seropositive if they had developed IgM, IgG, or both. The manufacturer reported that sensitivity was 90.2% and specificity 99.2%. A previously reported internal validation using 651 samples from blood donors before November 2019 and 155 patients with PCR-confirmed SARS-CoV-2 infection estimated a sensitivity of 82.5% (95% CI, 75.3% to 88.4%) and specificity of 99.5% (CI, 98.7% to 99.9%) (26). We (27) and others (28) have reported that oropharyngeal/nasal swab sampling for SARS-CoV-2 by participants, as opposed to health care workers, is clinically useful. Descriptions of RNA extraction, primer and probe used, reverse transcription, preamplification, and microfluidic quantitative PCR are detailed in Part 6 of the **Supplement**.

Data Collection

Participants received 4 follow-up surveys (Parts 4 and 5 of the **Supplement**) by e-mail to collect information on antibody test results, adherence to recommendations on time spent outside the home among others, development of symptoms, COVID-19 diagnosis based on PCR testing done in public hospitals, and known COVID-19 exposures.

Outcomes

The primary outcome was SARS-CoV-2 infection, defined as a positive result on an oropharyngeal/nasal swab test for SARS-CoV-2, development of a positive SARS-CoV-2 antibody test result (IgM or IgG) during the study period, or a hospital-based diagnosis of SARS-CoV-2 infection or COVID-19. Secondary end points included PCR evidence of infection with other respiratory viruses (**Supplement Table 2**, available at Annals.org).

Sample Size Calculations

The sample size was determined to provide adequate power for assessment of the combined composite primary outcome in the intention-to-treat analysis. Authorities estimated an incidence of SARS-CoV-2 infection of at least 2% during the study period. Assuming that wearing a face mask halves risk for infection, we estimated that a sample of 4636 participants would provide the trial with 80% power at a significance level of 5% (2-sided α level). Anticipating 20% loss to follow-up in this community-based study, we aimed to assign at least 6000 participants.

Statistical Analysis

Participants with a positive result on an antibody test at baseline were excluded from the analyses. We calculated CIs of proportions assuming binomial distribution (Clopper–Pearson).

The primary composite outcome (intention-to-treat) was compared between groups using the χ^2 test. Odds ratios and confidence limits were calculated using logistic regression. We did a per protocol analysis that included only participants reporting complete or predominant use of face masks as instructed. A conservative sensitivity analysis assumed that participants with a positive result on an antibody test at the end of the study who had not provided antibody test results at study entrance had had a positive result at entrance. To further examine the uncertainty of loss to follow-up, we did (post hoc) 200 imputations using the R package smcfcs, version 1.4.1 (29), to impute missing values of outcome. We included sex, age, type of work, time out of home, and outcome in this calculation.

Prespecified subgroups were compared by logistic regression analysis. In a post hoc analysis, we explored whether there was a subgroup defined by a constellation of participant characteristics for which a recommendation to wear masks seemed to be effective. We included sex, age, type of work, time out of home, and outcome in this calculation.

Two-sided *P* values less than 0.05 were considered statistically significant. Analyses were done using R, version 3.6.1 (R Foundation).

Role of the Funding Source

An unrestricted grant from the Salling Foundations supported the study, and the BESTSELLER Foundation donated the Livzon tests. The funders did not influence study design, conduct, or reporting.

Results

Participants

A total of 17 258 Danish citizens responded to recruitment, and 6024 completed the baseline survey and fulfilled eligibility criteria. The first participants (group 1; $n = 2995$) were randomly assigned on 12 April 2020 and were followed from 14 to 16 April through 15 May 2020. Remaining participants (group 2; $n = 3029$) were randomly assigned on 24 April 2020 and were followed from 2 to 4 May through 2 June 2020. A total of 3030 participants were randomly assigned to the recommendation to wear face masks, and 2994 were assigned not to wear face masks (**Figure**); 4862 participants (80.7%) completed the study. **Table 1** shows baseline characteristics, which were well balanced between groups. Participants reported having spent a median of 4.5 hours per day outside the home.

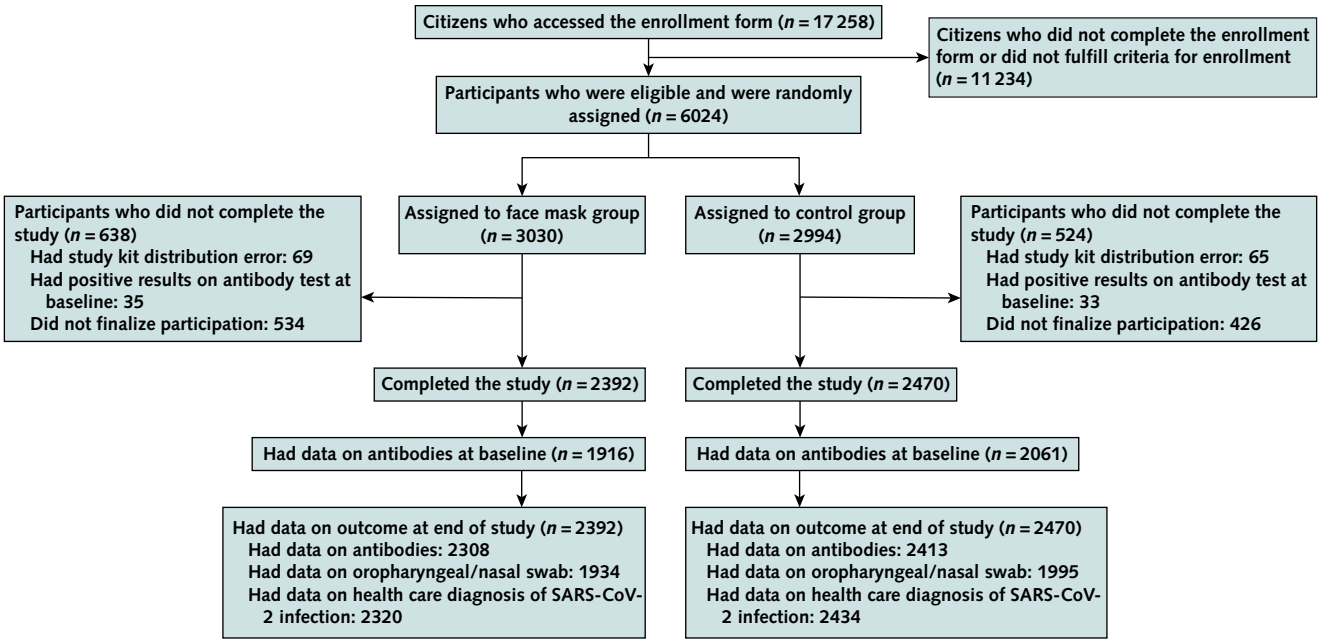
Adherence

Based on the lowest adherence reported in the mask group during follow-up, 46% of participants wore the mask as recommended, 47% predominantly as recommended, and 7% not as recommended.

Primary Outcome

The primary outcome occurred in 42 participants (1.8%) in the mask group and 53 (2.1%) in the control group. In an intention-to-treat analysis, the between-group difference was −0.3 percentage point (CI, −1.2 to 0.4 percentage point; $P = 0.38$) (odds ratio [OR], 0.82 [CI, 0.54 to 1.23]; $P = 0.33$) in favor of the mask group (**Supplement Figure 1**, available at Annals.org). When this analysis was repeated with multiple imputation for missing data due to loss to follow-up, it yielded similar results (OR, 0.81 [CI, 0.53 to 1.23]; $P = 0.32$). **Table 2**

Figure 1. Study flow diagram.



Inclusion and exclusion criteria are described in the Methods section, and criteria for completion of the study are given in the Supplement (available at Annals.org). SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

provides data on the components of the primary end point, which were similar between groups.

In a per protocol analysis that excluded participants in the mask group who reported nonadherence (7%), SARS-CoV-2 infection occurred in 40 participants (1.8%) in the mask group and 53 (2.1%) in the control group (between-group difference, −0.4 percentage point [CI, −1.2 to 0.5 percentage point]; $P = 0.40$) (OR, 0.84 [CI, 0.55 to 1.26]; $P = 0.40$). Supplement Figure 2 (available at Annals.org) provides results of the prespecified subgroup analyses of the primary composite end point. No statistically significant interactions were identified.

In the preplanned psensitivity analysis, those who had a positive result on an antibody test at 1 month but had not provided antibody results at baseline were considered to have had positive results at baseline ($n = 18$)—that is, they were excluded from the analysis. In this analysis, the primary outcome occurred in 33 participants (1.4%) in the face mask group and 44 (1.8%) in the control group (between-group difference, −0.4 percentage point [CI, −1.1 to 0.4 percentage point]; $P = 0.22$) (OR, 0.77 [CI, 0.49 to 1.22]; $P = 0.26$).

Three post hoc (not preplanned) analyses were done. In the first, which included only participants reporting wearing face masks "exactly as instructed," infection (the primary outcome) occurred in 22 participants (2.0%) in the face mask group and 53 (2.1%) in the control group (between-group difference, −0.2 percentage point [CI, −1.3 to 0.9 percentage point]; $P = 0.82$) (OR, 0.93 [CI, 0.56 to 1.54]; $P = 0.78$). The second post hoc analysis excluded participants who did not provide antibody test results at baseline; infection occurred in 33 participants (1.7%) in the face mask group and 44 (2.1%) in the control group (between-group difference, −0.4 percentage point [CI, −1.4 to 0.4 percentage point]; $P = 0.33$) (OR, 0.80 [CI, 0.51 to 1.27]; $P = 0.35$). In the third post hoc analysis, which investigated constellations of patient characteristics, we did not find a subgroup where face masks were effective at conventional levels of statistical significance (data not shown).

A total of 52 participants in the mask group and 39 control participants reported COVID-19 in their household. Of these, 2 participants in the face mask group and 1 in the control group developed SARS-CoV-2 infection, suggesting that the source of most observed infections was outside the home. Reported symptoms did not differ between groups during the study period (Supplement Table 3, available at Annals.org).

Secondary Outcomes

In the mask group, 9 participants (0.5%) were positive for 1 or more of the 11 respiratory viruses other than SARS-CoV-2, compared with 11 participants (0.6%) in the control group (between-group difference, −0.1

percentage point [CI, −0.6 to 0.4 percentage point]; P = 0.87) (OR, 0.84 [CI, 0.35 to 2.04]; P = 0.71). Positivity for any virus, including SARS-CoV-2, occurred in 9 mask participants (0.5%) versus 16 control participants (0.8%) (between-group difference, −0.3 percentage point [CI, −0.9 to 0.2 percentage point]; P = 0.26) (OR, 0.58 [CI, 0.25 to 1.31]; P = 0.19).

Discussion

In this community-based, randomized controlled trial conducted in a setting where mask wearing was uncommon and was not among other recommended public health measures related to COVID-19, a recommendation to wear a surgical mask when outside the home among others did not reduce, at conventional levels of statistical significance, incident SARS-CoV-2 infection compared with no mask recommendation. We designed the study to detect a reduction in infection rate from 2% to 1%. Although no statistically significant difference in SARS-CoV-2 incidence was observed, the 95% CIs are compatible with a possible 46% reduction to 23% increase in infection among mask wearers. These findings do offer evidence about the degree of protection mask wearers can anticipate in a setting where others are not wearing masks and where other public health measures, including social distancing, are in effect. The findings, however, should not be used to conclude that a recommendation for everyone to wear masks in the community would not be effective in reducing SARS-CoV-2 infections, because the trial did not test the role of masks in source control of SARS-CoV-2 infection. During the study period, authorities did not recommend face mask use outside hospital settings and mask use was rare in community settings (22). This means that study participants' exposure was overwhelmingly to persons not wearing masks.

The observed infection rate was similar to that reported in other large Danish studies during the study period (26,30). Of note, the observed incidence of SARS-CoV-2 infection was higher than we had estimated when planning a sample size that would ensure more than 80% power to detect a 50% decrease in infection. The intervention lasted only 1 month and was carried out during a period when Danish authorities recommended quarantine of diagnosed patients, physical distancing, and hand hygiene as general protective means against SARS-CoV-2 transmission (23). Cafés and restaurants were closed through 18 May, but follow-up of the second randomized group continued through 2 June.

The first randomized group was followed while the Danish society was under lockdown. Reopening occurred (18 May 2020) during follow-up of the second group of participants, but it was not reflected in the outcome because infection rates were similar between groups (**Supplement Figure 2**). The relative infection rate between mask wearers and those not wearing masks would most likely be affected by changes in applied protective means or in the virulence of SARS-CoV-2, whereas the rate difference between the 2 groups would probably not be affected solely by a higher–or lower–number of infected citizens.

Although we saw no statistically significant difference in presence of other respiratory viruses, the study was not sufficiently powered to draw definite conclusions about the protective effect of masks for other viral infections. Likewise, the study had limited power for any of the subgroup analyses.

Table 1. Characteristics of Participants Completing the Study

Characteristic	Face Mask Group (n = 2392)	Control Group (n = 2470)
Mean age (SD), *y*	47.4 (14)	47.0 (13)
Female sex, *n (%)*	1545 (64.6)	1571 (63.6)
Smoker, *n (%)*	478 (20.0)	499 (20.2)
Wears eyeglasses daily, *n (%)*	956 (40.0)	929 (37.6)
Capital Region resident, *n (%)**	1220 (51.0)	1289 (52.2)
Provided antibody test results at baseline, *n (%)*	1916 (80.1)	2061 (83.4)
Occupation, *n (%)*		
Shop employee	108 (4.5)	85 (3.4)
Cashier	101 (4.2)	96 (3.9)
Craftsperson	110 (4.6)	103 (4.2)
Office employee	265 (11.1)	312 (12.6)
Manager	111 (4.6)	108 (4.4)
Transportation employee	617 (25.8)	625 (25.3)
Service employee	107 (4.5)	104 (4.2)
Home care/nursing home employee	197 (8.2)	229 (9.3)
Early childhood care staff	89 (3.7)	88 (3.6)
Salesperson	37 (1.5)	47 (1.9)
Other	650 (27.2)	673 (27.2)

* According to national authority data, the Capital Region had a higher frequency of coronavirus disease 2019 than other Danish regions; see subgroup analyses in **Supplement Figure 2** (available at Annals.org).

Table 2. Distribution of the Components of the Composite Primary Outcome

Outcome Component	Face Mask Group (*n* = 2392), *n (%)*	Control Group (*n* = 2470), *n (%)*	Odds Ratio (95% CI)*
Primary composite end point	42 (1.8)	53 (2.1)	0.82 (0.54–1.23)
Positive antibody test result†			
IgM	31 (1.3)	37 (1.5)	0.87 (0.54–1.41)
IgG	33 (1.4)	32 (1.3)	1.07 (0.66–1.75)
Positive SARS-CoV-2 RT-PCR	0 (0)	5 (0.2)	–
Health care–diagnosed SARS-CoV-2 or COVID-19	5 (0.2)	10 (0.4)	0.52 (0.18–1.53)

COVID-19 = coronavirus disease 2019; RT-PCR = reverse transcriptase polymerase chain reaction; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
* Calculated using logistic regression. The between-group differences in frequencies of positive SARS-CoV-2 RT-PCR were not statistically significant ($P = 0.079$).
† 124 participants in the mask group and 140 in the control group registered "not done" or unclear results of the antibody test–i.e., they were included in the analysis because they sent an oropharyngeal swab for PCR.

The primary outcome was mainly defined by antibodies against SARS-CoV-2. This definition was chosen because the viral load of infected patients may be only transiently detectable (31,32) and because approximately half of persons infected with SARS-CoV-2 are asymptomatic (33,26). Masks have been hypothesized to reduce inoculum size (34) and could increase the likelihood that infected mask users are asymptomatic, but this hypothesis has been challenged (35). For these reasons, we did not rely solely on identification of SARS-CoV-2 in oropharyngeal/nasal swab samples. As mentioned in the Methods section, an internal validation study estimated that the point-of-care test has 82.5% sensitivity and 99.5% specificity (26).

The observed rate of incident SARS-CoV-2 infection was similar to what was estimated during trial design. These rates were based on thorough screening of all participants using antibody measurements combined with PCR, whereas the observed official infection rates relied solely on PCR test–based estimates during the period. In addition, authorities tested only a small subset of primarily symptomatic citizens of the entire population, yielding low incidence rates. On this basis, the infection rates we report here are not comparable with the official SARS-CoV-2 infection rates in the Danish population. The eligibility requirement of at least 3 hours of exposure to other persons outside the home would add to this difference. Between 6 April and 9 May 2020, we found a similar seroprevalence of SARS-CoV-2 of 1.9% (CI, 0.8% to 2.3%) in Danish blood donors using the Livzon point-of-care test and assessed by laboratory technicians (36). Testing at the end of follow-up, however, may not have captured any infections contracted during the last part of the study period, but this would have been true in both the mask and control groups and was not expected to influence the overall findings.

The face masks provided to participants were high-quality surgical masks with a filtration rate of 98% (37). A published meta-analysis found no statistically significant difference in preventing influenza in health care workers between respirators (N95 [American standard] or FFP2 [European standard]) and surgical face masks (38). Adherence to mask use may be higher than observed in this study in settings where mask use is common. Some mask group participants (14%) reported adverse reactions from other citizens (**Supplement Table 4**, available at Annals.org). Although adherence may influence the protective effect of masks, sensitivity analyses had similar results across reported adherence.

How SARS-CoV-2 is transmitted–via respiratory droplets, aerosols, or (to a lesser extent) fomites–is not firmly established. Droplets are larger and rapidly fall to the ground, whereas aerosols are smaller ($\leq$5 μm) and may evaporate and remain in the air for hours (39). Transmission of SARS-CoV-2 may take place through multiple routes. It has been argued that for the primary route of SARS-CoV-2 spread–that is, via droplets–face masks would be considered effective, whereas masks would not be effective against spread via aerosols, which might penetrate or circumnavigate a face mask (37,39). Thus, spread of SARS-CoV-2 via aerosols would at least partially explain the present findings. Lack of eye protection may also have been of importance, and use of face shields also covering the eyes (rather than face masks only) has been advocated to halt the conjunctival route of transmission (40, 41). We observed no statistically significant interaction between wearers and nonwearers of eyeglasses (**Supplement Figure 2**). Recent reports indicate that transmission of SARS-CoV-2 via fomites is unusual (42), but masks may alter behavior and potentially affect fomite transmission.

The present findings are compatible with the findings of a review of randomized controlled trials of the efficacy of face masks for prevention (as personal protective equipment) against influenza virus (18). A recent meta-analysis that suggested a protective effect of face masks in the non–health care setting was based on 3 observational studies that included a total of 725 participants and focused on transmission of SARS-CoV-1 rather than SARS-CoV-2 (12). Of 725 participants, 138 (19%) were infected, so the transmission rate seems to be higher than for SARS-CoV-2. Further, these studies focused on prevention of infection in healthy mask wearers from patients with a known, diagnosed infection rather than prevention of transmission from persons in their surroundings in general. In addition, identified comparators (control participants) not wearing masks may also have missed other protective means. Recent observational studies that indicate a protective association between mandated mask use in the community and SARS-CoV-2 transmission are limited by study design

and simultaneous introduction of other public health interventions (14, 43).

Several challenges regarding wearing disposable face masks in the community exist. These include practical aspects, such as potential incorrect wearing, reduced adherence, reduced durability of the mask depending on type of mask and occupation, and weather. Such circumstances may necessitate the use of multiple face masks during the day. In our study, participants used a mean of 1.7 masks per weekday and 1.3 per weekend day (**Supplement Table 4**). Wearing a face mask may be physically unpleasant, and psychological barriers and other side effects have been described (44). "Face mask policing" between citizens might reinforce use of masks but may be challenging. In addition, the wearer of a face mask may change to a less cautious behavior because of a false sense of security, as pointed out by WHO (17); accordingly, our face mask group seemed less worried (**Supplement Table 4**), which may explain their increased willingness to wear face masks in the future (**Supplement Table 5**, available at Annals.org). These challenges, including costs and availability, may reduce the efficacy of face masks to prevent SARS-CoV-2 infection.

The potential benefits of a community-wide recommendation to wear masks include combined prevention and source control for symptomatic and asymptomatic persons, improved attention, and reduced potential stigmatization of persons wearing masks to prevent infection of others (17). Although masks may also have served as source control in SARS-CoV-2–infected participants, the study was not designed to determine the effectiveness of source control.

The most important limitation is that the findings are inconclusive, with CIs compatible with a 46% decrease to a 23% increase in infection. Other limitations include the following. Participants may have been more cautious and focused on hygiene than the general population; however, the observed infection rate was similar to findings of other studies in Denmark (26,30). Loss to follow-up was 19%, but results of multiple imputation accounting for missing data were similar to the main results. In addition, we relied on patient-reported findings on home antibody tests, and blinding to the intervention was not possible. Finally, a randomized controlled trial provides high-level evidence for treatment effects but can be prone to reduced external validity.

Our results suggest that the recommendation to wear a surgical mask when outside the home among others did not reduce, at conventional levels of statistical significance, the incidence of SARS-CoV-2 infection in mask wearers in a setting where social distancing and other public health measures were in effect, mask recommendations were not among those measures, and community use of masks was uncommon. Yet, the findings were inconclusive and cannot definitively exclude a 46% reduction to a 23% increase in infection of mask wearers in such a setting. It is important to emphasize that this trial did not address the effects of masks as source control or as protection in settings where social distancing and other public health measures are not in effect.

Reduction in release of virus from infected persons into the environment may be the mechanism for mitigation of transmission in communities where mask use is common or mandated, as noted in observational studies. Thus, these findings do not provide data on the effectiveness of widespread mask wearing in the community in reducing SARS-CoV-2 infections. They do, however, offer evidence about the degree of protection mask wearers can anticipate in a setting where others are not wearing masks and where other public health measures, including social distancing, are in effect. The findings also suggest that persons should not abandon other COVID-19 safety measures regardless of the use of masks. While we await additional data to inform mask recommendations, communities must balance the seriousness of COVID-19, uncertainty about the degree of source control and protective effect, and the absence of data suggesting serious adverse effects of masks (45).

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References

1. **Helmy YA, Fawzy M, Elaswad A, et al.** The COVID-19 pandemic: a comprehensive review of taxonomy, genetics, epidemiology, diagnosis, treatment, and control. J Clin Med. 2020;9. [PMID: 32344679] doi:10.3390/jcm9041225

2. **Worldometer.** Pandemic, COVID-19 coronavirus. 2020. Accessed at www.worldometers.info/coronavirus on 29 October 2020.

3. **Qualls N, Levitt A, Kanade N, et al. CDC Community Mitigation Guidelines Work Group.** Community mitigation guidelines to prevent pandemic influenza — United States, 2017. MMWR Recomm Rep. 2017;66:1-34. [PMID: 28426646] doi:10.15585/mmwr.rr6601a1
4. **Richard M, Kok A, de Meulder D, et al.** SARS-CoV-2 is transmitted via contact and via the air between ferrets. Nat Commun. 2020;11:3496. [PMID: 32641684] doi:10.1038/s41467-020-17367-2
5. **Liu Y, Ning Z, Chen Y, et al.** Aerodynamic analysis of SARS-CoV-2 in two Wuhan hospitals. Nature. 2020;582:557-560. [PMID: 32340022] doi:10.1038/s41586-020-2271-3
6. **van Doremalen N, Bushmaker T, Morris DH, et al.** Aerosol and surface stability of SARS-CoV-2 as compared with SARS-CoV-1 [Letter]. N Engl J Med. 2020;382:1564-1567. [PMID: 32182409] doi:10.1056/NEJMc2004973
7. **Kwok YL, Gralton J, McLaws ML.** Face touching: a frequent habit that has implications for hand hygiene. Am J Infect Control. 2015;43:112-4. [PMID:25637115] doi:10.1016/j.ajic.2014.10.015
8. **Lucas TL, Mustain R, Goldsby RE.** Frequency of face touching with and without a mask in pediatric hematology/oncology health care professionals. Pediatr Blood Cancer. 2020:e28593. [PMID: 32672907] doi:10.1002/pbc.28593
9. **Chen YJ, Qin G, Chen J, et al.** Comparison of face-touching behaviors before and during the coronavirus disease 2019 pandemic. JAMA Netw Open. 2020;3:e2016924. [PMID: 32725247] doi:10.1001/jamanetworkopen.2020.16924
10. **Rebmann T, Carrico R, Wang J.** Physiologic and other effects and compliance with long-term respirator use among medical intensive care unit nurses. Am J Infect Control. 2013;41:1218-23. [PMID: 23768438] doi:10.1016/j.ajic.2013.02.017
11. **Wang X, Ferro EG, Zhou G, et al.** Association between universal masking in a health care system and SARS-CoV-2 positivity among health care workers. JAMA. 2020. [PMID: 32663246] doi:10.1001/jama.2020.12897
12. **Chu DK, Akl EA, Duda S, et al. COVID-19 Systematic Urgent Review Group Effort (SURGE) study authors.** Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis. Lancet. 2020;395:1973-1987. [PMID: 32497510] doi:10.1016/S0140-6736(20)31142-9
13. **Leung NHL, Chu DKW, Shiu EYC, et al.** Respiratory virus shedding in exhaled breath and efficacy of face masks. Nat Med. 2020;26:676-680. [PMID: 32371934] doi:10.1038/s41591-020-0843-2
14. **Lyu W, Wehby GL.** Community use of face masks and COVID-19: evidence from a natural experiment of state mandates in the US. Health Aff (Millwood). 2020;39:1419-1425. [PMID: 32543923] doi:10.1377/hlthaff.2020.00818
15. **Centers for Disease Control and Prevention.** CDC calls on Americans to wear masks to prevent COVID-19 spread. 14 July 2020. Accessed at www.cdc.gov/media/releases/2020/p0714-americans-to-wear-masks.html on 29 October 2020.
16. **Brooks JT, Butler JC, Redfield RR.** Universal masking to prevent SARS-CoV-2 transmission—the time is now. JAMA. 2020. [PMID: 32663243] doi:10.1001/jama.2020.13107
17. **World Health Organization.** Advice on the use of masks in the context of COVID-19: interim guidance. 5 June 2020.
18. **Xiao J, Shiu EYC, Gao H, et al.** Nonpharmaceutical measures for pandemic influenza in nonhealthcare settings—personal protective and environmental measures. Emerg Infect Dis. 2020;26:967-975. [PMID: 32027586] doi:10.3201/eid2605.190994
19. **Qaseem A, Etxeandia-Ikobaltzeta I, Yost J, et al.** Use of N95, surgical, and cloth masks to prevent COVID-19 in health care and community settings: living practice points from the American College of Physicians (version 1). Ann Intern Med. 2020;173:642-649. doi:10.7326/M20-3234
20. **Ford I, Norrie J.** Pragmatic trials. N Engl J Med. 2016;375:454-63. [PMID: 27518663] doi:10.1056/NEJMra1510059
21. **Bundgaard H, Bundgaard JS, Raaschou-Pedersen DET, et al.** Face masks for the prevention of COVID-19 - rationale and design of the randomised controlled trial DANMASK-19. Dan Med J. 2020;67. [PMID: 32829745]
22. **YouGov.** Personal measures taken to avoid COVID-19. 2020. Accessed at https://yougov.co.uk/topics/international/articles-reports/2020/03/17/personal-measures-taken-avoid-covid-19 on 27 October 2020.
23. **Danish Health Authority.** COVID-19: prevention of the spread of infection. 2 October 2020. Accessed at www.sst.dk/da/Udgivelser/2020/COVID-19-Forebyggelse-af-smittespredning on 26 October 2020.
24. **Danish Health Authority.** General guidance. 22 October 2020. Accessed at www.sst.dk/en/English/Corona-eng/Prevent-infection/General-guidance on 27 October 2020.
25. **Harris PA, Taylor R, Thielke R, et al.** Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform. 2009;42:377-81. [PMID: 18929686] doi:10.1016/j.jbi.2008.08.010
26. **Iversen K, Bundgaard H, Hasselbalch RB, et al.** Risk of COVID-19 in health-care workers in Denmark: an observational cohort study. Lancet Infect Dis. 2020. [PMID:32758438] doi:10.1016/S1473-3099(20)30589-2
27. **Therchilsen JH, von Buchwald C, Koch A, et al.** Self-collected versus healthcare worker-collected swabs in the diagnosis of severe acute respiratory syndrome coronavirus 2. Diagnostics. 2020;10:678. doi:10.3390/diagnostics10090678
28. **Tu YP, Jennings R, Hart B, et al.** Swabs collected by patients or health care workers for SARS-CoV-2 testing [Letter]. N Engl J Med. 2020;383:494-496. [PMID: 32492294] doi:10.1056/NEJMc2016321
29. **Bartlett J, Keogh R, Ekstrøm CT, et al.** Multiple imputation of covariates by substantive model compatible fully conditional specification. Version 1.4.1. CRAN; 2020.
30. **Pedersen OB, Nissen J, Dinh KM, et al.** SARS-CoV-2 infection fatality rate among elderly retired Danish blood donors - a cross-sectional study. Clin Infect Dis. 2020. [PMID: 33103182] doi:10.1093/cid/ciaa1627
31. **Pan Y, Zhang D, Yang P, et al.** Viral load of SARS-CoV-2 in clinical samples [Letter]. Lancet Infect Dis. 2020;20:411-412. [PMID: 32105638] doi:10.1016/S1473-3099(20)30113-4
32. **Wölfel R, Corman VM, Guggemos W, et al.** Virological assessment of hospitalized patients with COVID-2019. Nature. 2020;581:465-469. [PMID: 32235945] doi:10.1038/s41586-020-2196-x
33. **Oran DP, Topol EJ.** Prevalence of asymptomatic SARS-CoV-2 infection. A narrative review. Ann Intern Med. 2020;173:362-367. doi:10.7326/M20-3012
34. **Gandhi M, Rutherford GW.** Facial masking for covid-19. Reply [Letter]. N Engl J Med. 2020;383. [PMID: 33095525] doi:10.1056/NEJMc2030886
35. **Rasmussen AL, Escandón K, Popescu SV.** Facial masking for covid-19 [Letter]. N Engl J Med. 2020;383. [PMID: 33095523] doi:10.1056/NEJMc2030886
36. **Erikstrup C, Hother CE, Pedersen OBV, et al.** Estimation of SARS-CoV-2 infection fatality rate by real-time antibody screening of blood donors. Clin Infect Dis. 2020. [PMID:32584966] doi:10.1093/cid/ciaa849
37. **Rengasamy S, Miller A, Eimer BC, et al.** Filtration performance of FDA-cleared surgical masks. J Int Soc Respir Prot. 2009;26:54-70. [PMID:32661453]
38. **Long Y, Hu T, Liu L, et al.** Effectiveness of N95 respirators versus surgical masks against influenza: a systematic review and meta-analysis. J Evid Based Med. 2020;13:93-101. [PMID: 32167245] doi:10.1111/jebm.12381
39. **Klompas M, Baker MA, Rhee C.** Airborne transmission of SARS-CoV-2: theoretical considerations and available evidence. JAMA. 2020;324:441-442. [PMID: 32749495] doi:10.1001/jama.2020.12458

40. **Perencevich EN, Diekema DJ, Edmond MB.** Moving personal protective equipment into the community: face shields and containment of COVID-19. JAMA. 2020;323:2252-2253. [PMID: 32347911] doi:10.1001/jama.2020.7477
41. **Marra AR, Edmond MB, Popescu SV, et al.** Examining the need for eye protection for coronavirus disease 2019 (COVID-19) prevention in the community. Infect Control Hosp Epidemiol. 2020:1-2. [PMID: 32576322] doi:10.1017/ice.2020.314
42. **Meyerowitz EA, Richterman A, Gandhi RT, et al.** Transmission of SARS-CoV-2. A review of viral, host, and environmental factors. Ann Intern Med. 2020. doi:10.7326/M20-5008
43. **Mitze T, Kosfeld R, Rode J, et al.** Face masks considerably reduce COVID-19 cases in Germany: a synthetic control method approach. IZA Discussion Papers. June 2020.
44. **Lazzarino AI, Steptoe A, Hamer M, et al.** Covid-19: important potential side effects of wearing face masks that we should bear in mind [Letter]. BMJ. 2020;369:m2003. [PMID: 32439689] doi:10.1136/bmj.m2003
45. **Javid B, Weekes MP, Matheson NJ.** Covid-19: should the public wear face masks? [Editorial]. BMJ. 2020;369:m1442. [PMID: 32273278] doi:10.1136/bmj.m1442

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Supplementary Material*

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* This supplementary material was provided by the authors to give readers further details on their article. The material was reviewed but not copyedited.

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Part 2: Supplemental methods

Additional Details on Participants

Study population

Danish residents reporting to work out of home with exposure to other people for more than 3 hours per day during the COVID-19 pandemic.

Inclusion Criteria

- Older than 18 years of age and without symptoms associated with SARS-CoV-2 (or previously tested positive for SARS-CoV-2)
- Working out-of-home with exposure to other people for more than 3 hours per day
- Do not normally wear a face mask for daily work

Exclusion Criteria

- Previously tested positive for SARS-CoV-2
- Wear face mask at work

Definition of finalized participation

Completion of the study will be defined as those participants who at end of the trial have reported the results of the antibody-testing and/or submitted an oropharyngeal/nasal swap and/or have reported a positive COVID-19 PCR test at a hospital. Participants not receiving study package (distribution error) according to randomization will not be included.

Study kit content delivered to the participants

Following randomization participants received by currier a study package with all relevant equipment at their home address. All participants received; COVID-19 IgM and IgG antibody test-kits (Lateral flow test, Zhuhai Livzon Diagnostics Inc, Guangdong, China), oropharyngeal/nasal swab kits (Zymo Collection Swab, Zymo Research, Irvine, CA, USA) and detailed written and links video instructions with a help-line phone number. Participants randomised to wearing face masks additionally received surgical face masks with ear-loops (Type II, EN 14683, ABENA, Aabenraa, Denmark, made in CN) equivalent to a month's usage. A currier picked-up the return-material at the participants addresses.

Additional Details on Timeline

The study was designed in March 2020. Recruitment of participants was initiated the 3rd of April, 2020 and was finalized 24th April, 2020. At recruitment the participants answered a baseline questionnaire. Approximately half of the participants (Group 1) were randomized 12th April and study material was sent out to the participants 14th, 15th and 16th of April 2020. Participants were instructed to initiate the study as they received the material and finalize the study May 15th, 2020. The second half of the participants (Group 2) were randomized April 24th, 2020 and study material was sent out to the participants 2nd, 3rd and 4th of May 2020. These participants were also instructed to initiate the study as they received the

material and finalize the study June 2th 2020. Four digital surveys were sent to the participants distributed on a weekly basis during the course of the study.

The primary analysis will be conducted after all material have been collected and analysed (approximately July-August 2020).

Additional Details on Endpoints

The primary endpoint is a combined endpoint consisting of:

- Positive oropharyngeal/nasal swab with SARS-CoV-2 (PCR)
  and/or
- Antibody test; Development of positive SARS-CoV-2 antibody test (IgM or IgG) during the study period
  and/or
- SARS-CoV-2 infection diagnosed in a hospital/health care facility

Secondary endpoints

- Positive oropharyngeal/nasal swab (PCR);
  Para-influenza-virus type 1, Para-influenza-virus type 2, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Human coronavirus HKU1, Respiratory Syncytial-Virus A, Respiratory Syncytial-Virus B, Influenza A virus or Influenza B virus
- Positive oropharyngeal/nasal swab (PCR);
  SARS-COV-2, Para-influenza-virus type 1, Para-influenza-virus type 2, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Human coronavirus HKU1, Respiratory Syncytial-Virus A, Respiratory Syncytial-Virus B, Influenza A virus or Influenza B virus

Tertiary endpoints

- Returned swabs
- Psychological aspects of face mask wearing in the community
- Cost-effectiveness analyses on the use of surgical face masks
- Preference for self-conducted home swab vs. healthcare conducted swab at hospital or similar
- Symptoms of COVID-19
- Self-assessed compliance with health authority guideline on hygiene
- Willingness to wear face masks in the future
- Health care diagnosed COVID-19 or SARS-CoV-2 (antibodies and/or PCR), mortality ass with COVID-19 and all-cause mortality
- Presence of bacteria; Mycoplasma pneumonia, Haemophilia influenza and Legionella pneumophila (to be obtained from registries when made available).
- Frequency of infected house-hold members between the two groups
- Frequency of sick-leave between the two groups (to be obtained from registries when made available)
- Predictors of primary outcome or its components

Outcome analysis

The primary outcome and secondary outcomes will be examined by reporting frequency and percentages and the comparison will be performed using a chi-square test. Confidence intervals to proportions will be calculated assuming binomial distribution (Clopper-Pearson).

Subgroup analyses of the endpoints

- Gender
- Age (below vs. above median)

- Use of glasses
- Compliance
- Randomization group 1 vs. randomization group 2
- Hours spend out of home; below (<) vs. above (≥) mean-interval reported
- Health care region; The Capital Region vs. the other Danish health care regions combined

Subgroups analyses where masks/no-masks are sub-grouped identically will be reported as percentages and the comparison will be a logistic regression analysis where the p for interaction between mask and subgroups is presented.

The compliance group is only considered relevant for mask users. Each subgroup will be compared to the whole no-mask group with chi-square analysis. An overall difference will be examined using chi-square analysis where those allocated to no-mask are provided a separate category.

Additional Details on Changes in Protocol During Study

Change in Participant Inclusion and Outcome

Originally, the inclusion criteria included both that the citizens could not be included if they had "any symptoms associated with corona-virus (or previously tested positive for corona)" or if they had experienced fever during the last month. We believed that the phrase "any symptoms associated with corona-virus (or previously tested positive for corona)" included fever. Therefore, fever was removed as a separate criterion from the inclusion criteria. In the first protocol the primary outcome was defined as "reduction in COVID-19 infection frequency". The steering committee decided that a more thorough description of infection frequency was appropriate and we therefore included more details in the description. We altered the description to "Positive oropharyngeal/nasal swab with SARS-CoV-2 (PCR)" *and/or* "Antibody test; Development of positive SARS-CoV-2 antibody test (IgM or IgG) during the study period" *and/or* "SARS-CoV-2 infection diagnosed in a hospital/health care facility". In the first submitted protocol we did not include tertiary outcomes, however we revised the protocol to include additional outcomes, as we believed that information on compliance, psychological factors and opinion on future behaviour was highly relevant to assess face masks in more broad terms. Lastly, we included other respiratory viruses (detailed previously in the Supplement). The primary focus of the present trial is to assess prevention of COVID-19 infection, however the face masks could potentially prevent other viruses and therefore we aimed to investigate this as an additional outcome.

Additional Details on Statistical Analysis

Sample size

Power calculations were conducted applying the authorities expected incidence of COVID-19 of at least 2% during the study period; an expected reduction of the risk to 1% by wearing face masks can be demonstrated with a power of 80% and a p-value of 5%, by inclusion of a total of 4636 participants. With an expected fallout of 20% a total of 6000 participants will be included.

Statistical plan for main outcomes

Statistical analyses will be performed using R version 3.6.1 (R Core Team (2019). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/). Reporting of results will be in accordance with the CONSORT guidelines. P <0.05 will be considered statistically significant.

Handling of missing data

For the primary outcome analysis (intention to treat), we will include all participants who at the end of the study have reported the result of their antibody test and/or have returned the oropharyngeal/nasal swab and/or have a positive COVID-19 PCR test at a hospital.

A per protocol analysis will be done for all participants included in the intention to treat analysis who have reported complete or predominantly use of face mask as instructed (intervention group) versus the control group. This implies that only those reporting no use of masks are excluded.

A conservative sensitivity analysis will be done for all participants included in the intention to treat analysis assuming that participants with a positive antibody test at the end of the study and who had not provided the results of the antibody test at the entrance into the study, had a positive antibody-test at entrance, i.e. were excluded from the analysis.

Part 3: Participant information

Short and long participant information in Danish and translated into English are provided. The information relates to randomization group 1. The information to randomization group 2 is similar except for different dates.

Vil du deltage i forsknings-undersøgelsen;

"Reduktion af COVID-19 smitte ved brug af mundbind"

Op mod 600.000 danskere forventes at blive smittet med corona-virus. Virusset spredes hovedsageligt igennem luften ved dråber, men corona-virus (COVID-19) kan også spredes når man rører ved overflader med virus på som f.eks. et dørhåndtag og derefter rører ved sit ansigt. Normalt rører man ved sit ansigt i gennemsnit hvert andet minut. Dette videnskabelige forsøg har til formål at undersøge, om brug af mundbind kan mindske risikoen for at blive smittet med corona-virus. Mundbind beskytter nemlig både mod dråber i luften og mindsker berøring af ansigtet. Imidlertid er det ikke sikkert, at en maske beskytter – og samtidig er det forbundet med besvær at bruge maske. Vores mål er - *sammen med dig* - at finde ud af, hvad der er det rigtige; ***at bruge mundbind eller ikke at bruge mundbind***.

Du har mulighed for at deltage i undersøgelsen, hvis:

- Du er over 18 år og ikke har symptomer på corona-virus (eller tidligere er testet positiv).
- Du er udenfor hjemmet i gennemsnit mere end 3 timer dagligt. Dvs., at du typisk passer et arbejde eller tilsvarende færdes, hvor der er andre mennesker
- Du ikke anvender mundbind det meste af tiden i dit daglige arbejde (ring til os hvis du er i tvivl).

Hvad indebærer undersøgelsen?

Deltagere i undersøgelsen vil ved lodtrækning blive inddelt i to lige store grupper.

A) Den ene gruppe skal gå med mundbind når de er udenfor hjemmet – og i hjemmet når de har gæster
B) Den anden gruppe skal ikke bruge mundbind.

Begge grupper vil modtage

1) To selvtest til undersøgelse for om du allerede har antistoffer (dvs. til afsløring om du har haft corona-virus) mod corona-virus (den ene selvtest anvendelse umiddelbart efter, at du modtager det) – eller om du udvikler antistoffer underforløbet (den anden anvendes på slutdatoen for undersøgelsen, midt maj)

2) To sæt til podning med podepind i næse og/eller svælg. Føler du dig syg under forsøget, skal du pode dig sig selv og sende testen til os.

Se instruktionsvideo til antistoftest og til selv-podning – og til hvordan man bærer mundbind.

Nærmere instruktioner om, hvordan du skal sende testene tilbage, følger på hjemmesiden og vil blive sendt til dig på mail. Er du smittet skal du følge myndighedernes retningslinjer for corona-virus.

Ved afslutningen af studiet midt i maj 2020 skal alle foretage 1) en antistof-test og 2) en podning og indsende materialet til os. Vi undersøger materialet og melder tilbage til dig. Alle deltagere i forsøget skal under hele forløbet følge myndighedernes generelle rådgivning om smittespredning og søge læge ved sygdom.

Forsøget er godkendt af relevante danske myndigheder. De præcise datoer for start og slut sender vi til dig per e-mail eller SMS.

Hvis du har spørgsmål, så kontakt: Projektansvarlig, telefon: **38 68 66 58**

Med venlig hilsen - og tusind tak for din interesse for projektet

Professor, overlæge, dr.med. Henning Bundgaard, Christian Torp-Pedersen, Thomas Benfield, Kasper Iversen.

Do you want to participate in the research study;
"Reduction of COVID-19 infection by using a mask"

Up to 600.000 Danes are expected to be infected with the corona virus. The virus is mainly spread through the air by droplets, but corona virus (COVID-19) can also be transmitted when touching surfaces with viruses on - such as a door handle and followed by touching your face. On average a person usually touches ones face every two minutes. This scientific experiment aims to investigate whether the use of face masks can reduce the risk of becoming infected with the corona virus. Face masks protect both against droplets in the air and reduce contact with the face. However, it is not certain that a mask protects - and at the same time it is associated with difficulty to use the mask. Our goal is - together with you - to investigate what is correct; ***to use a face mask or not to use a face mask.***

You have the opportunity to participate in the study if:

- You are above 18 years and have no symptoms of corona virus (or have previously tested positive).

- You are outside home on average more than 3 hours a day. That is, you typically hold a job or engages at corresponding places where you are among other people.

- You do not wear a face mask most of the time in your daily work (call us if you are in doubt).

What does the study involve?

Participants in the study will be divided into two equally sized groups by drawing lots (randomization)

A) One group must wear a face mask when they are outside the home - and in the home when they have guests

B) The other group should not wear face masks.

Both groups will receive

1) Two self-tests to check if you already have antibodies (i.e. to detect if you have had corona virus) against corona virus (one self-test is to be used immediately after you receive it) - or if you develop antibodies during the course (the other is used on the end date of the study, mid-May)

2) Two sets of swabs for nose and/ or throat. If you feel ill during the study, you should test yourself and send the test to us.

Watch instructional videos for antibody testing and for swab test - and for how to wear a face mask.

Detailed instructions on how to send the tests back to us can be found on the website and will be sent to you by email. If you are infected you should follow the authorities corona virus guidelines.

At the end of the study in mid May 2020, all participants must conduct 1) an antibody test and 2) a swab test and send the material to us. We will examine the material and report back to you. Throughout the period, all participants in the study must follow the authorities' general advice on the spread of infection and seek medical attention in the event of illness.

The study has been approved by relevant Danish authorities. We will send you the exact start and end dates by e-mail or SMS.

If you have any questions, please contact: Project Manager, telephone: **38 68 66 58**

Sincerely - and thank you very much for your interest in the project

Professor, physician, dr.med. Henning Bundgaard, Christian Torp-Pedersen, Thomas Benfield, Kasper Iversen.

Deltagelse i forsknings-undersøgelsen;

”Reduktion af COVID-19 smitte ved brug af mundbind”

Vi håber, at du vil hjælpe os ved at deltage i denne vigtige forskning. Før du beslutter, om du vil deltage i undersøgelsen, vil vi her give dig grundig information om, hvad undersøgelsen går ud på, og hvorfor undersøgelsen er så vigtig. Hvis noget er uklart, eller hvis du behøver yderligere informationer, er du velkommen til at kontakte os.

Undersøgelsens formål:

- At undersøge om brug af MUNDBIND mindsker smitten af COVID-19.

Baggrund for undersøgelsen

Hvad er corona-virus?

Corona-virus dækker over forskellige typer virus, der almindeligvis bare er årsag til mild forkølelse. Nogle typer corona-virus kan dog føre til alvorlige infektioner i luftvejene. Den nye corona-virus eller COVID-19, som vi oplever nu, hedder på lægefaglig sprog SARS-CoV-2 og er ikke kendt fra tidligere. SARS står for ”*Severe Acute Respiratory Syndrom*”, på dansk ”*Akut Alvorlig Luftvejs-syndrom*”.

Da denne type corona-virus er ny, er der mange ting vi endnu ikke ved om den. Det betyder også, at vores immunsystem aldrig har mødt denne virus før. Vi har derfor ikke udviklet modstandsdygtighed overfor den og mange af os er derfor i risiko for at blive smittet og syge. Det forventes at 600.000 danskere bliver smittet med denne nye type af corona-virus (SARS-CoV-2) inden for de næste måneder.

Udbruddet med denne nye corona-virus startede i Kina i december 2019. Corona-virusset spredte sig hurtigt til landende omkring Kina, og har siden spredt sig til resten af verden. Det betød, at Verdenssundhedsorganisationen (WHO) d. 11. marts 2020 erklærede virus-udbruddet for at være en epidemi, der omfatter hele verden - en såkaldt pandemi.

Hvordan smitter corona-virus?

Virusset spredes hovedsageligt igennem luften ved, at virus kan sidde i vanddråber, som kan komme ud af vores mund og næse når vi hoster, nyser – eller måske endda når vi taler. Dråberne kan bevæge sig i en afstand på 1-2 meter. Er der længere end 1-2 meter falder corona-virus til jorden. Virus kan ikke smitte igennem huden, men trænger ind i kroppen gennem slimhinder i næsen, mund eller øjne.

Typisk bliver man smittet ved at være tæt på en person, der allerede er smittet med corona-virus eller ved, at man rører ved genstande, hvor der sidder corona-virus fra en smittet person. Det anslås, at corona-virus kan overleve på overflader i timer eller op til dage. Corona-virus kan således spredes ved, at vi med hånden rører overflader som dørhåndtag, lyskontakter eller bordoverflader og derefter fører hånden med virus til ansigtet. Dette er vigtig viden, da forskning har vist, at vi i gennemsnit rører vores ansigt med hånden hvert andet minut.

Imidlertid er det ikke sikkert, at en mundbind beskytter – og samtidig er det forbundet med besvær og økonomiske

omkostninger at bruge mundbind. Vores mål er sammen med dig at finde ud af, hvad der er det rigtige; ***at bruge mundbind eller ikke at bruge mundbind***.

Du har mulighed for at deltage i undersøgelsen, hvis:

- Du er over 18 år og ikke har ikke symptomer på corona-virus (eller tidligere er testet positiv).
- Du er udenfor hjemmet i mere end 3 timer i gennemsnit dagligt. Dvs. at du typisk passer dit arbejde og færdes, hvor der er andre mennesker
- Du ikke anvender mundbind i hovedparten af tiden i dit daglige arbejde (ring til os hvis du er i tvivl).

Hvad indebærer undersøgelsen?

Jer der deltager i undersøgelsen, vil ved lodtrækning blive inddelt i to lige store grupper.

C) Den ene gruppe skal gå med mundbind når de er udenfor hjemmet – og i hjemmet når de har gæster
D) Den anden gruppe skal/må *ikke* bruge mundbind.

Hvordan kommer undersøgelsen til at foregå?

Ved undersøgelsens start kommer du ved lodtrækning enten i gruppe A eller i gruppe B. Gruppe A skal udover at følge sundhedsmyndighederne almindelige råd - bære mundbind, når de bevæger sig uden for hjemmet eller får gæster. Er du i gruppe A vil vi tilsende dig mundbind på din hjemme-adresse til den første måneds forbrug (måske tilsendes af to omgange). Et mundbind holder kun ca. 8 timer, og du kan dermed bruge to mundbind per dag. Instruktionsvideo til mundbind kan findes nedenfor. Gruppe B skal gøre helt som de plejer og følge sundhedsmyndighedernes råd.

Test for antistoffer

Alle får tilsendt to testudstyr til at undersøge *om man allerede har haft sygdommen*, COVID-19.

Ved **START** (lige når du modtager test-udstyret) og ved **SLUTNINGEN** af undersøgelsen (midten af maj 2020), vil vi derfor bede dig om at foretage en test på dig selv – se *link til instruktionsvideo*;

1. Du skal prikke dig i en finger, så der kommer en dråbe blod ud (ligesom blodsukker-måling).
2. Denne dråbe sætter du på test-pladen.
3. Herefter aflæser du resultatet.
4. Dette resultat beder vi dig notere i det spørgeskema vi har sendt til dig.
5. Yderligere vil vi bede dig om at tage et billede af testpladen og sende dette billede til os på en email eller telefon (så kan vi også aflæse resultatet).

Podning

Alle får tilsendt **to corona-virus podnings-sæt; det ene kan bruges, hvis du føler dig syg i løbet af undersøgelses-perioden, det andet skal bruges, når undersøgelsen er slut**.

Vi forventer, at de fleste deltagere kun har brug for ét corona-virus test-sæt. Føler du dig derimod syg under forløbet af undersøgelsen skal du gøre som beskrevet i afsnittet nedenfor – *Hvad hvis jeg får symptomer på corona-virus under undersøgelsen?*

Hvad gør jeg hvis jeg får symptomer på corona-virus under undersøgelsen?

Hvis du ikke har symptomer på corona-virus undervejs i forløbet af undersøgelsen, skal du blot bruge den ene selvpodnings-test ved afslutningen.

Hvis du får symptomer på corona-virus undervejs kan du benytte det andet selvpodnings-sæt.

1) Du poder dig selv og sender prøven til os (vi har indsat *instruktionsvideo* til selv-podning nedenfor).
2) Vi undersøger din prøve og du får efterfølgende svar på prøven. Det er dog ***ikke*** sikkert, at du når at få svar på prøven inden undersøgelsen afsluttes – **SÅ HUSK OGSÅ AT SØGE LÆGE, HVIS DU FØLER DIG SYG**. Materialet fra podningen vil blive gemt til fremtidig forskning inden for infektioner.

Det er vigtigt igen at understrege, at podningen ikke er i stedet for at du bliver undersøgt af en læge. Hvis du føler dig syg skal du som sædvanligt kontakte din egen læge eller vagtlæge/1813. Hvis du bliver podet af anden årsag, vil vi bede dig informere os i de ugentligt tilsendte spørgeskemaer. Vi har brug for, at 6.000 personer deltager i undersøgelsen.

Krav til dig, hvis du deltager i undersøgelsen

Det er vigtigt at understrege, at du også under undersøgelsen ***forsat skal følge sundhedsmyndighedernes råd for både at beskytte dig selv og andre mod smitte og, at du skal kontakte din læge eller sygehus som ellers, hvis du føler dig syg***.

Hvis du ud fra lodtrækningen skal bruge mundbindet, er det afgørende, at du gør det korrekt. Hvis du ikke gør det vil undersøgelsen være værdiløs og medføre forkert rådgivning i fremtiden.

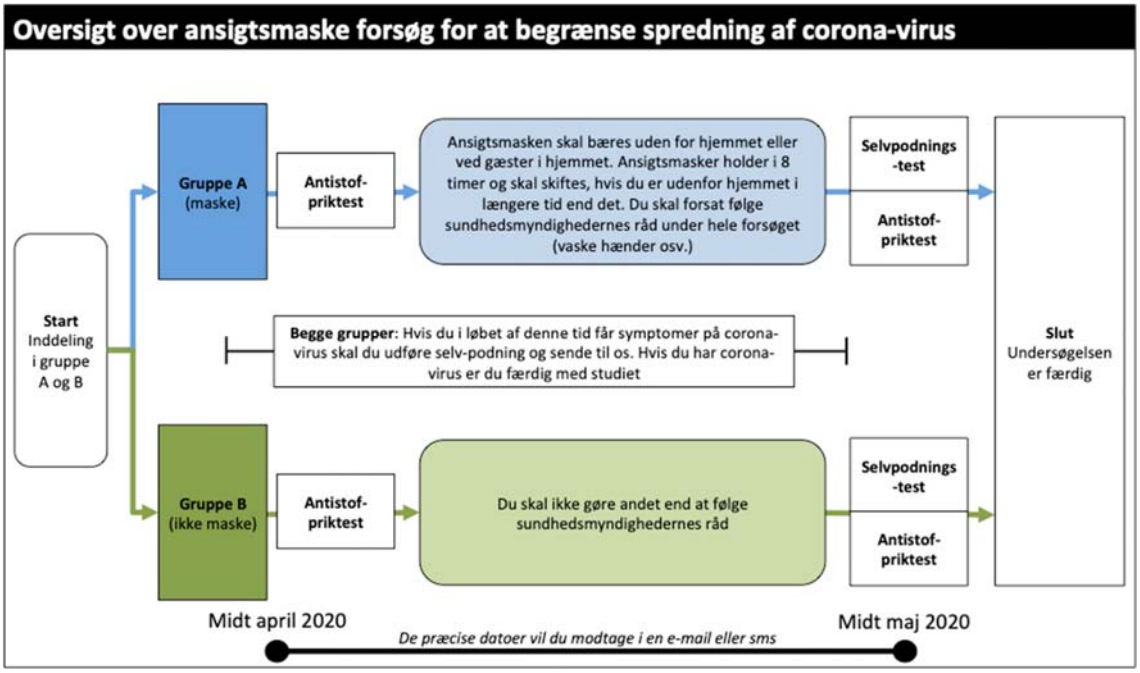
Korrekt brug af mundbind kræver to ting 1) .

1. **Tidspunkt**
   For det første skal du helt konsekvent bruge mundbidet, når du er udenfor dit hjem, eller hvis du har gæster på besøg
2. **Måde**
   For det andet skal du placere mundbindet korrekt så den dækker BÅDE NÆSE OG MUND, dvs. placeres over næsen og under hagen – *som vist i instruksvideoen*.

Hvis du *ikke* mener, at du kan følge disse krav, bør du *ikke* sige ja til at deltage i undersøgelsen

Oversigt over forløbet

Det er forskere fra Rigshospitalet, Herlev-Gentofte Hospital, Amager-Hvidovre Hospital og Nordsjællands Hospitaler, der står for undersøgelsen. Undersøgelsen udføres fra midten af april 2020 og indtil midt maj 2020. De præcise datoer, der passer til dig vil du få i en mail.



Hvorfor er det vigtigt, at du deltager i undersøgelsen

Undersøgelsen giver en enestående mulighed for at finde ud af, om mundbind kan begrænse smitte med corona-virus. Hvis mundbind viser at mindske smitten med virus, vil det også kunne bruges til at stoppe spredning af andre virus-infektioner. Denne forskning øger sundhedsvæsenets viden om corona-virus, hvilket er grundlaget for at stoppe smitten i samfundet.

Frivillig deltagelse og vederlag

Din deltagelse i undersøgelsen er naturligvis frivillig. Som deltager vil du være med til at hjælpe dansk forskning med at stoppe corona-virus smitten. Vi har ikke mulighed for at betale dig for at være med, til gengæld vil du gratis modtage alle mundbind og corona-virus tests på din hjemme-adresse og forsendelser til og fra din adresse er betalt af projektet.

Midler til projektet og interessekonflikter

Dette projekt er støttet af Salling Group. Disse midler vi gå til køb af mundbind, test-udstyr og forsendelse. Ingen af forskerne har økonomiske interesser i forbindelse med dette studie.

Risici, bivirkninger og ulemper

Der er ingen kendte risici eller bivirkninger forbundet med brug af mundbimd.

Adgang til forsøgsresultater

Når forsøgsperioden er afsluttet og alle data er bearbejdet, vil du have mulighed for at få oplyst undersøgelsens samlede resultat. Resultaterne fra undersøgelsen vil blive offentliggjort i en artikel, som udgives i et videnskabeligt tidsskrift efter undersøgelsens afslutning. Du skal dog være opmærksom på, at der kan gå noget tid før, at en artikel er færdig og udgivet. Vi vil også skrive i danske aviser – da denne undersøgelse kan have stor betydning for hele samfundet. Resultaterne af din og de andres anstrengelser sørger vi for kommer ud til flest mulige mennesker. Den enkelte deltager vil selvfølgelig være fuldstændig anonym i denne sammenhæng.

Dine personlige oplysning

Dine personlige oplysninger vil blive behandlet strengt fortroligt. Dine personlige oplysninger vil altid blive håndteret i overensstemmelse med loven om databeskyttelse og privatlivets fred. Alle oplysningerne om forsøgspersonen beskyttes efter Lov om behandling af personoplysninger og Sundhedsloven. Såfremt du ønsker det, har du krav på at få adgang til de personlige oplysninger, der er indsamlet om dig, og du kan få rettet unøjagtigheder. Intet data vil blive ført ud af landet.

Undersøgelsen er godkendt af relevante danske myndigheder.

Hvis du har spørgsmål eller lyst til at høre mere, så kontakt:

Projektansvarlig, telefon: 38 68 66 58

Med venlig hilsen - og tusind tak for din interesse for studiet

Professor, overlæge, dr.med. Henning Bundgaard, professor, overlæge, dr.med. Christian Torp-Pedersen, professor, overlæge, dr.med. Thomas Benfield og professor, overlæge, dr.med. Kasper Iversen

Participation in the research study;

"Reduction of COVID-19 infection by using a face mask"

We hope you will help us by participating in this important research. Before you decide if you want to participate in the study, we will here give you thorough information about what the study is about and why the study is so important. If anything is unclear or if you need further information, please feel free to contact us.

Purpose of the study:

- To investigate whether the use of FACE MASK reduces transmission of COVID-19 infection.

Background to the study

What is corona virus?

Corona virus covers different types of viruses that are usually just the cause of a mild cold. However, some types of corona virus can lead to serious respiratory infections. The new corona virus or COVID-19 that we are experiencing now is in medical terms called SARS-CoV-2 and is not previously known. SARS stands for "*Severe Acute Respiratory Syndrome*", in Danish "*Akut Alvorlig Luftvejs-syndrom*".

Since this type of corona virus is new, there are many things we do not yet know about it. It also means that our immune system has never encountered this virus before. We have therefore not developed resistance to it and many of us are therefore at risk of becoming infected and ill. It is expected that 600.000 Danes will be infected with this new type of corona virus (SARS-CoV-2) within the next months.

The outbreak of this new corona virus started in China in December 2019. The corona virus spread rapidly to countries around China, and has since spread to the rest of the world. This meant that on 11 March 2020, the World Health Organization (WHO) declared the virus outbreak to be an epidemic that covers the whole world - a so-called pandemic.

How is corona virus transmitted?

The virus is mainly spread through the air as the virus can be in water droplets, which can come out of our mouth and nose when we cough, sneeze - or maybe even when we talk. The droplets can move at a distance of 1-2 meters. If there is more than 1-2 meters, the corona virus falls to the ground. Virus cannot infect through the skin, but enters the body through mucous membranes in the nose, mouth or eyes.

Typically, one becomes infected by being close to a person who is already infected with corona virus or by touching objects with corona virus from an infected person. It is estimated that corona virus can survive on surfaces for hours or up to days. Corona virus can thus be spread by touching surfaces such as door handles, light switches or table surfaces by hand and then bringing the hand with the virus to the face. This is important knowledge as research has shown that on average we touch our face with our hand every two minutes.

However, it is not certain that a face mask protects - and at the same time it is associated with inconvenience and financial costs to use a face mask. Our goal is together with you to find out what is right; to use a face mask or not to use a face mask.

You have the opportunity to participate in the study if:

- You are above 18 years and have no symptoms of corona virus (or have previously tested positive).

- You are outside home on average more than 3 hours a day. That is, you typically hold a job or engages at corresponding places where you are among other people.

- You do not wear a face mask most of the time in your daily work (call us if you are in doubt).

What does the study involve?

Participants in the study will be divided into two equally sized groups by drawing lots (randomization)

A) One group must wear a face mask when they are outside the home - and in the home when they have guests

B) The other group should not wear face masks.

How will the investigation take place?

At the start of the study, you will be drawn by lot either to group A or in group B. In addition to following the health authorities' requirements, group A must wear a face mask when they are outside their home or have guests. If you are in group A, we will send you face masks at your home address for the first month's usage (perhaps sent in two installments). A face mask only is working for approx. 8 hours, so you can use two face masks per day. Instructional video for face masks can be found below. Group B must do exactly as they usually do and follow the advice from the health authorities.

Test for antibodies

All participants will receive two tests to check *if they have already had the disease*, COVID-19.

At **START** (just when you receive the tests) and at the **END** of the study (mid-May 2020), we will therefore ask you to perform a test on yourself - see link to instructional video;

1. Take the finger pricker and prick the tip of your finger so that a drop of blood comes out (like blood sugar measurement).
2. Put this drop on the test plate.
3. Then read the result.
4. We ask you to note this result in the questionnaire we have sent you.
5. In addition, we will ask you to take a picture of the test plate and send this picture to us by email or phone (then we can also read the result).

Swab test

Everyone is sent **two corona virus swab test kits; one can be used if you feel sick during the study period, the other should be used at the end of the study.**

We expect that most participants will only need one corona virus test kit. If, on the other hand, you feel sick during the course of the study period, you should do as described in the section below - *What if I get symptoms of corona virus during the study period?*

What should I do if I get symptoms of corona virus during the study period?

If you have no symptoms of corona virus during the course of the study, simply use one self-test at the end of the study.

If you get symptoms of corona virus during the study period, you can use the second self-test kit.

1) You use the swab test and send the test to us (we have inserted instruction video for swab self-test below).

2) We examine your test and you will receive a subsequent answer to the test. However, it is ***not*** certain that you will have time to get an answer to the test before the study period ends - **SO REMEMBER TO SEEK A DOCTOR IF YOU FEEL SICK**. The material from the swab-test will be saved for future research in the field of infections.

It is important to emphasize again that you should still seek examination by a doctor despite the test. If you feel ill, contact your own doctor or an emergency doctor / 1813 as usual. If you are tested for any other reason, we will ask you to inform us in the weekly questionnaires sent to us. We need 6,000 people to take part in the study.

Requirements for you if you participate in the study

It is important to emphasize that you must ***continue to follow the advice from the health authorities during the study period in order to protect yourself and others from infection, and that you must contact your doctor or hospital independent of the participation in the trial, if you feel ill.***

If you are in the face mask group based on the draw (randomization), it is crucial that you use the mask correctly. If you do not, the study will be worthless and lead to incorrect advice in the future.

Proper use of face mask requires two things 1).

1. **Time**

First, you should consistently use the face mask when you are outside your home or if you have guests visiting

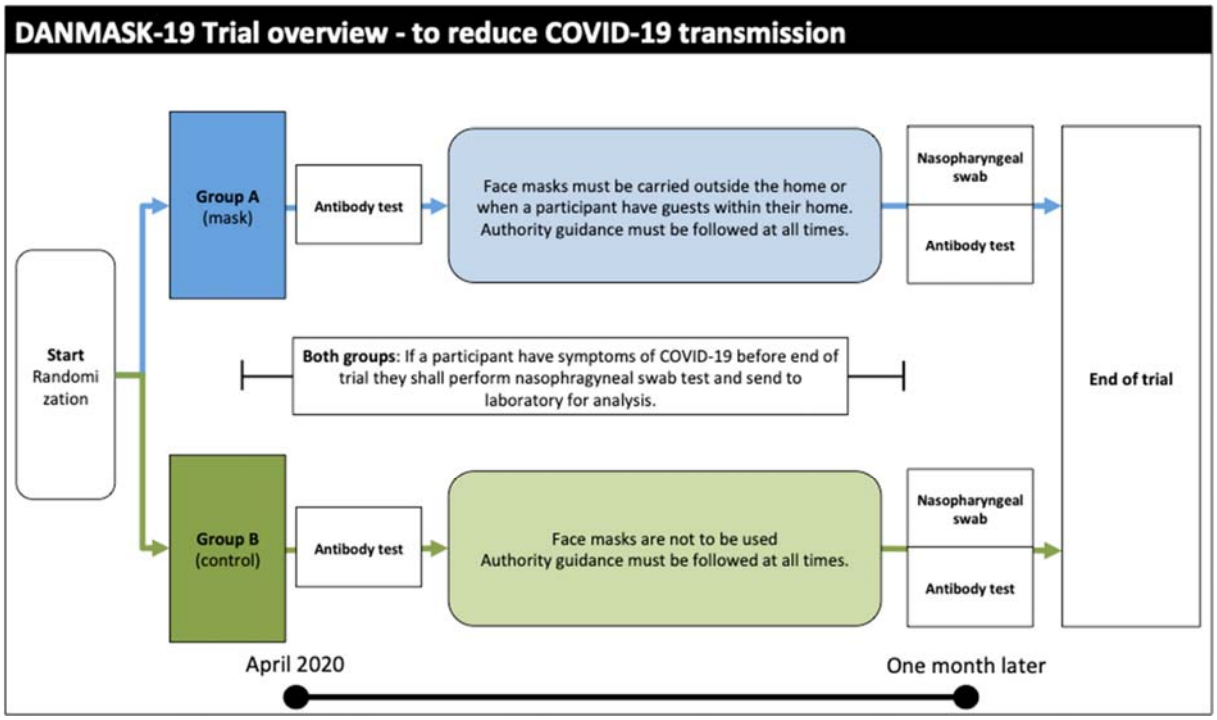
2. **Method**

Second, place the face mask correctly so that it covers BOTH NOSE AND MOUTH, i.e. placed over the nose and under the chin - as shown in the instruction video.

If you do *not* think you can follow these requirements, you should participate in the study

Overview of the course

Researchers from Rigshospitalet, Herlev-Gentofte Hospital, Amager-Hvidovre Hospital and Nordsjællands Hospitals are responsible for the study. The study will be conducted from mid-April 2020 until mid-May 2020. You will receive the exact dates in an email.



Why it is important that you participate in the study

The study provides a unique opportunity to find out if face masks can reduce transmission with corona virus. If face masks are shown to reduce infection with viruses, it could also be used to stop the spread of other viral infections. This research increases healthcare knowledge about the corona virus, which is the basis for stopping transmission in society.

Voluntary participation and remuneration

Your participation in the study is of course voluntary. As a participant, you will help Danish research to stop the corona virus infection. We do not have the option to pay you for the participation, however you will receive all face masks and corona virus tests for free at your home address and shipments to and from your address are paid for by the project.

Funds for the project and conflicts of interest

This project is supported by Salling Group. These funds cover costs for purchasing face masks, test equipment and shipping. None of the researchers have financial interests in this study.

Risks, side effects and disadvantages

There are no known risks or side effects associated with using face masks.

Access to study results

When the study period is over and all data has been processed, you will have the opportunity to be informed of the overall result of the study. The results of the study will be published in an article in a scientific journal after the end of the study. However, you should be aware that it may take some time before an article is finished and published. We will also write in Danish newspapers - as this study can have importance for the whole society. We will ensure that the results of your and others' efforts will reach out to as many people as possible. The individual participant will of course be completely anonymous in this context.

Your personal information

Your personal information will be treated with strict confidence. Your personal information will always be handled in accordance with the law on data protection and privacy. All information about the participant is protected in accordance with the Personal Data Processing Act and the Danish Healthcare Act. If you want, you have the right to gain access to the personal information collected on you and you may have inaccuracies corrected. No data will be taken out of the country.

The study has been approved by relevant Danish authorities.

If you have any questions, please contact: Project Manager, telephone: **38 68 66 58**

Sincerely - and thank you very much for your interest in the project

Professor, physician, dr.med. Henning Bundgaard, Christian Torp-Pedersen, Thomas Benfield, Kasper Iversen.

Part 4: Participant surveys – English Translation

Enrolment questionnaire

Information

Thank you for your interest in the Mask Project. To determine whether you qualify for the project and in order to send you masks, we ask you to fill out the information form.

We would like to use your Danish Social Security Number (cpr. no.) to get information from the Danish registries, in particular we wish to get information about infection with the corona virus diagnosed in a hospital. If you wish not to disclose your Danish Social Security Number, please change the last four digits to "0001" if you are male or "0000" if you are female.

PLEASE NOTE that we will only ask for personal information if you qualify for participation. Please read the Participant Information.

I have read and understand the Participant Information and wish to participate. I am aware that I am being drawn by lot to continue working without a mask - or commits me to use mask the next month. I am willing to answer a questionnaire about my current condition every week for a month - and conduct tests for Corona. I also agree that my information will be linked to health information and other register information in a secure manner in Denmark's Statistics.	○ Yes ○ No
Do you think you have had a Corona infection?	○ Yes ○ No
Do you already wear a facial mask?	○ Yes ○ No
Are you at least 18 years old?	○ Yes ○ No
Do you daily work outside of your home for at least 3 hours where you are in contact with other people?	○ Yes ○ No
Tell us about your job	○ Cashier ○ Service employee ○ Manager ○ Office ○ Other
If you answered "Other". Please write your job title	_____

Do you wear glasses full-time when at work?	○ Yes ○ No
Do you smoke?	○ Yes ○ No
Full name	_____
Address: Street, number, floor	_____
Zip code	_____
City	_____
Danish mobile phone number	_____
Danish social security number	_____
Repeat Danish social security number	_____
Danish social security numbers do not match	_____

Survey week 1

Which group do you belong to?	○ I wear mask ○ I do not wear mask ○ I still have not received the material
Are you using the mask according to our recommendation?	○ Yes, exactly as described ○ Yes, predominantly as described ○ No, not at all
What is the reason that you only follow the recommendation predominantly or not at all?	○ My work does not allow regular use of mask ○ The mask becomes wet quickly making it no longer useable ○ I do not want to wear a mask
How much time on a daily basis do or did you spend outside among other people / or how much time do you expect to spend outside among other people in the first week of the study?	○ More than 10 hours ○ 6-10 hours ○ 3-6 hours ○ Less than 3 hours
What did the blue antibody test show (“IgM”)? (One answer)	○ 1 line ○ 2 lines (The second line counts even if it is faded) ○ I am unsure about the result – or I could not conduct the test
What did the red antibody test show (“IgG”)? (One answer)	○ 1 line ○ 2 lines (The second line counts even if it is faded) ○ I am unsure about the result – or I could not conduct the test
Have you had any of the following symptoms after you were selected for the study?	○ Cough ○ Fever ○ Headache ○ Shortness of breath ○ Pain in muscles/joints ○ Taste disorders ○ No symptoms
When the study is complete you will perform a throat (pharynx)- and nose swab. Until then you must ONLY swab if you have symptoms indicating COVID-19.	○ Yes

Have you performed a swab? (One answer)	○ No
If you have any other comments, please write them here (max 200 words):	_____

Mask

Have you been to Italy, Spain, USA, China or Austria in the last 14 days?	○ Yes ○ No
Have you been in contact with somebody who has been in one of the abovementioned countries in the last 14 days?	○ Yes ○ No
Do you live with someone who has had Corona?	○ Yes ○ No
Do you work with someone who has had Corona?	○ Yes ○ No
Have you taken care of or helped someone who had Corona?	○ Yes ○ No

No mask

Have you been to Italy, Spain, USA, China or Austria in the last 14 days?	○ Yes ○ No
Have you been in contact with somebody who has been in one of the abovementioned countries in the last 14 days	○ Yes ○ No
Do you live with someone who has had Corona?	○ Yes ○ No
Do you work with someone who has had Corona?	○ Yes ○ No
Have you taken care of or helped someone who has had Corona?	○ Yes ○ No

Non-participant

Have you had a fever?	○ Yes ○ No
Which date did it start?	_____
Were/are you snotty?	○ Yes

	○ No
Were/are you coughing?	○ Yes ○ No
Were/are you having shortness of breath?	○ Yes ○ No

Survey week 2

Which group do you belong to?	○ I wear a mask ○ I do not wear mask
There can be many reasons why, despite this study, one chooses to wear a mask or not wear a mask. For this study, we need to know whether you did in fact wear a mask or not. (One answer) ***(Only included in survey for round 2)***	○ Use mask most of the time when I am out ○ Use mask some of the time ○ No, not at all
Are you using the mask according to our recommendation?	○ Yes, exactly as described ○ Yes, predominantly as described ○ No, not at all
What is the reason that you only follow the recommendation predominantly or not at all?	○ My work does not allow regular use of mask ○ The mask gets wet quickly making it no longer useable ○ I do not want to wear a mask
Do you feel safer with the mask? (One answer)	○ Yes ○ No ○ Do not know
How do others react to you wearing a mask? (One answer)	○ Most people find it very reasonable that I protect myself and others ○ Most people neither look nor say anything about it ○ Most people find it strange and I get negative comments about it
How would you evaluate your own behaviour compared to the guidelines on Corona from the health authorities? (One answer)	○ I am very careful with hand wash / disinfection and social distancing ○ I perform hand wash / disinfection a couple of times a day and keep a small social distance ○ I am not very careful with hand wash / disinfection or social distancing
How much time daily have you on average been out among other people over the past week?	○ More than 10 hours ○ 6-10 hours ○ 3-6 hours ○ Less than 3 hours
Have you been diagnosed with COVID-19 by a doctor or at the hospital? ***(Only included in survey for round 1)***	○ Yes ○ No

Which date did you test positive for COVID-19?	_____
Has somebody at your place of residence been tested positive?	○ Yes ○ No
You only need to test for antibodies at the start and the end of the study. If you did not report on the first test in the previous survey, please do it here. Do you wish to report the result of the first antibody test? You must NOT use the last antibody test now.	○ Yes ○ No
What did the blue antibody test show ("IgM")? (One answer)	○ 1 line ○ 2 lines (The second line counts even if it is faded) ○ I am unsure about the result – or I could not conduct the test
What did the red antibody test show ("IgG")? (One answer)	○ 1 line ○ 2 lines (The second line counts even if it is faded) ○ I am unsure about the result – or I could not conduct the test
Have you had any of the following symptoms after you were selected for the study?	○ Cough ○ Fever ○ Headache ○ Shortness of breath ○ Pain in muscles/joints ○ Taste disorders ○ No symptoms
Have you been sick in the last week?	○ Yes ○ No
When the study is complete you will perform a throat (pharynx)- and nose swab. Until then you must ONLY swab if you have symptoms indicating COVID-19. Have you performed a swab? (One answer)	○ Yes ○ No
If you have any other comments, please write them here (max 200 words):	

Survey week 3

Which group do you belong to?	○ I wear a mask ○ I do not wear mask

Has somebody at your place of residence been tested positive for COVID-19 at the doctor or hospital after the start of the Mask Project?	○ Yes ○ No
Have your concerns about getting COVID-19 during the Mask Project become: (One answer)	○ Greater ○ Smaller ○ Unchanged
Are you using the mask according to our recommendation?	○ Yes, exactly as described ○ Yes, predominantly as described ○ No, not at all
What is the reason that you only follow the recommendation predominantly or not at all?	○ My work does not allow regular use of mask ○ The mask gets wet quickly making it no longer useable ○ I do not want to wear a mask
Do you feel safer with the mask? (One answer)	○ Yes ○ No ○ Do not know
How do others react to you wearing a mask? (One answer)	○ Most people find it very reasonable that I protect myself and others ○ Most people neither look nor say anything about it ○ Most people find it strange and I get negative comments about it
Do the use of mask change your level of physical activity?	○ Yes, I am less active because of the mask ○ No, it has not changed ○ Do not know
How many masks do you use per day on weekdays? (One answer)	○ 1 ○ 2 ○ 3 ○ More than 3
How many masks do you use per day on weekends? (One answer)	○ 1 ○ 2 ○ 3 ○ More than 3
How would you evaluate your own behaviour compared to the guidelines on Corona from the health authorities? (One answer)	○ I am very careful with hand wash / disinfection and social distancing

	○ I perform hand wash / disinfection a couple of times a day and keep a small social distance ○ I am not very careful with hand wash / disinfection or social distancing ○
If you had been in the group wearing masks, do you think that you would have been more out in public, in shops, busses, trains and the like?	○ Yes ○ No ○ Do not know
On average, how much time on a daily basis have you spent outside among other people over the past week?	○ More than 10 hours ○ 6-10 hours ○ 3-6 hours ○ Less than 3 hours
Have you been diagnosed with COVID-19 by a doctor or at the hospital?	○ Yes ○ No
Which date did you test positive for COVID-19?	_____
You only need to test for antibodies at the start and the end of the study. If you did not report on the first test in the previous survey, please do it here. Do you wish to report the result of the first antibody test? You must NOT use the last antibody test now.	○ Yes ○ No
What did the blue antibody test show ("IgM")? (One answer)	○ 1 line ○ 2 lines (The second line counts even if it is faded) ○ I am unsure about the result – or I could not conduct the test
What did the red antibody test show ("IgG")? (One answer)	○ 1 line ○ 2 lines (The second line counts even if it is faded) ○ I am unsure about the result – or I could not conduct the test
Have you had any of the following symptoms after you were selected for the study?	○ Cough ○ Fever ○ Headache ○ Shortness of breath

	○ Pain in muscles/joints ○ Taste disorders ○ No symptoms
Have you been sick in the last week?	○ Yes ○ No
If you have any other comments, please write them here (max 200 words):	

Survey week 4

Which group do you belong to?	○ I wear a mask ○ I do not wear mask
Has somebody at your place of residence been tested positive for COVID-19 at the doctor or hospital after the start of the Mask Project?	○ Yes ○ No
Have your concerns about getting COVID-19 during the Mask Project become: (One answer)	○ Greater ○ Smaller ○ Unchanged
Are you using the mask according to our recommendation?	○ Yes, exactly as described ○ Yes, predominantly as described ○ No, not at all
What is the reason that you only follow the recommendation predominantly or not at all?	○ My work does not allow regular use of mask ○ The mask gets wet quickly making it no longer useable ○ I do not want to wear a mask
Do you feel safer with the mask? (One answer)	○ Yes ○ No ○ Do not know
How do others react to you wearing a mask? (One answer)	○ Most people find it very reasonable that I protect myself and others ○ Most people neither look nor say anything about it ○ Most people find it strange and I get negative comments about it
Do the use of mask change your level of physical activity?	○ Yes, I am less active because of the mask ○ No, it has not changed ○ Do not know
How would you evaluate your own behaviour compared to the guidelines on Corona from the health authorities? (One answer)	○ I am very careful with hand wash / disinfection and social distancing ○ I perform hand wash / disinfection a couple of times a day and keep a small social distance ○ I am not very careful with hand wash / disinfection or social distancing

If you had been in the group wearing masks, do you think that you would have been more out in public, in shops, busses, trains and the like?	○ Yes ○ No ○ Do not know
On average, how much time on a daily basis have you spent outside among other people over the past week?	○ More than 10 hours ○ 6-10 hours ○ 3-6 hours ○ Less than 3 hours
Have you been diagnosed with COVID-19 by a doctor or at the hospital during the study period?	○ Yes ○ No
Which date did you test positive for COVID-19?	_____
In connection with answering this survey you must perform a swab and an antibody test. Please see the attached guide for how to perform the tests.	○ Yes ○ No
What did the blue antibody test show ("IgM")? (One answer)	○ 1 line ○ 2 lines (The second line counts even if it is faded) ○ I am unsure about the result – or I could not conduct the test
What did the red antibody test show ("IgG")? (One answer)	○ 1 line ○ 2 lines (The second line counts even if it is faded) ○ I am unsure about the result – or I could not conduct the test
Have you had any of the following symptoms after you were selected for the study?	○ Cough ○ Fever ○ Headache ○ Shortness of breath ○ Pain in muscles /joints ○ Taste disorders ○ No symptoms
In conclusion of the study, have you performed the planned throat- and nose swab? ***Note for participants in round 2: You can wait with performing the swab until shortly before the collection by BRING***	○ Yes ○ No
Have you scheduled a time with BRING for collection of the swab test?	○ Yes

	○ No
If you could choose – would you in the future wear a mask once this study has ended?	○ Yes – until COVID-19 is over ○ Yes – during future, similar infectious outbreaks in society ○ No ○ Do not know
In the future, what would you prefer if you had to be swab tested?	○ Self-swab at home – and I think it was easy ○ Self-swab at home – but I think it was difficult ○ Swab at the hospital by health care professional
If you have any other comments, please write them here (max 200 words):	_____

Part 5: Participant Surveys – Original Danish Version

Deltagelsesspørgeskema

Oplysninger

Tak for din interesse for maskeprojekt. For at afgøre om du er egnet og for at kunne sende dig masker bedes du udfylde dette skema.

Hvis ønsker at bruge dit cpr-nummer til at søge oplysninger i danske registre om især Coronainfektion diagnosticeret på et hospital. Hvis du ikke ønsker at oplyse dit cpr-nummer kan du lade de sidste 4 cifre være "0001" hvis du er mand og "0000" hvis du er kvinde.

BEMÆRK at du kun bliver spurgt om personlige oplysninger, hvis du er egnet til at deltage. Læse evt. Deltagerinformationen

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Jeg har læst og forstået deltagerinformationerne og ønsker at deltage. Jeg er klar over at jeg ved lodtrækning bliver bedt om at fortsætte arbejdet uden maske - eller forpligter mig til at bruge maske den næste måned. Jeg er indstillet på at svare på et spørgeskema om min aktuelle tilstand hver uge i en måned - og gennemføre test for Corona Jeg er også indforstået med at mine oplysninger vil blive koblet til oplysninger om helbred og andre registeroplysninger på en beskyttet måde i Danmarks Statistik.	○ Ja ○ Nej
Mener du at have haft Corona infektion?	○ Ja ○ Nej
Bruger du i forvejen ansigtsmaske?	○ Ja ○ Nej
Er du mindst 18 år gammel	○ Ja ○ Nej
Arbejder du udenfor hjemmet i mindst 3 timer dagligt, hvor du har kontakt med andre mennesker	○ Ja ○ Nej
Fortæl om dit arbejde	○ Kassemedarbejder ○ Servicemedarbejder ○ Bestyrer ○ Kontor ○ Andet
Du svarede "Andet", Skriv din stillingsbetegnelse	

	_____
Bruger du briller hele tiden når du arbejder?	○ Ja ○ Nej
Ryger du?	○ Ja ○ Nej
Fuldt navn	_____
Addresse: Gade, nummer, etage	_____
Postnummer	_____
Bynavn	_____
Dansk mobiltelefonnummer	_____
Dansk CPR-nummer	_____
Gentag CPR-nummer	_____
CPR-numre matcher ikke	_____

Spørgeskema uge 1

Hvilken gruppe tilhører du? (Et svar)	○ Jeg går med maske ○ Jeg går uden maske ○ Jeg afventer at modtage materiale
Bruger du så masken, som vi har anbefalet? (et svar)	○ Ja, helt som beskrevet ○ Ja, overvejende som beskrevet ○ Nej, overhovedet ikke
Hvad er årsagen til at du kun delvist eller ikke overholder anbefalingen	○ Mit arbejde tillader ikke fast brug af maske ○ Masken bliver hurtigt våd og derfor ikke brugbar ○ Jeg vil ikke gå med maske
Hvor meget er du eller har du været ude blandt andre mennesker / eller forventer du at være ude blandt andre mennesker dagligt den første uge af forsøget?	○ Mere end 10 timer ○ 6-10 timer ○ 3-6 timer ○ Mindre end 3 timer
Hvad viste den blå antistof-test ("IgM")? (et svar)	○ 1 streg ○ 2 streger (Nummer 2 streg tæller også i de tilfælde, hvor den er ugyldig) ○ Jeg er ikke sikker på resultatet – eller jeg kunne ikke udføre testen
Hvad viste den røde antistof-test ("IgG")? (et svar)	○ 1 streg ○ 2 streger (Nummer 2 streg tæller også i de tilfælde, hvor den er ugyldig) ○ Jeg er ikke sikker på resultatet – eller jeg kunne ikke udføre testen
Har du haft nogle af følgende symptomer efter, at blev udvalgt til forsøget?	○ Hoste ○ Feber ○ Hovedpine ○ Åndenød ○ Smerter I muskler/led ○ Smagsforstyrrelser ○ Ingen symptomer
Du skal pode dig selv, når undersøgelsen er færdig, men indtil da skal du KUN pode dig, hvis du har symptomer, der kunne tyde på,	○ Ja

at du har COVID-19. Har du foretaget podning? (et svar)	○ Nej
Hvis du har andre kommentarer til os, kan du skrive dem i feltet nedenfor; (kommentarfelt, maks 200 ord)	_____

Maske

Har du være i Italien, Spanien, USA, Kina eller Østrig indenfor de sidste 14 dage	○ Ja ○ Nej
Har du været i kontakt med nogen som har været i de ovennævnte lande indenfor 14 dage	○ Ja ○ Nej
Bor du sammen med nogen der har haft Corona	○ Ja ○ Nej
Arbejder du sammen med nogen der har haft Corona	○ Ja ○ Nej
Har du passet eller hjulpet nogen der har haft Corona	○ Ja ○ Nej

Ingen maske

Har du være i Italien, Spanien, USA, Kina eller Østrig indenfor de sidste 14 dage	○ Ja ○ Nej
Har du været i kontakt med nogen som har været i de ovennævnte lande indenfor 14 dage	○ Ja ○ Nej
Bor du sammen med nogen der har haft Corona	○ Ja ○ Nej
Arbejder du sammen med nogen der har haft Corona	○ Ja ○ Nej
Har du passet eller hjulpet nogen der har haft Corona	○ Ja ○ Nej

Ikke deltager

Har du haft feber?	○ Ja ○ Nej
Hvilken dato begyndte det	_____
Var/er du snottet??	○ Ja

	○ Nej
Havde/har du hoste?	○ Ja ○ Nej
Havde/har du åndenød?	○ Ja ○ Nej

Spørgeskema uge 2

Hvilken gruppe tilhører du? (Et svar)	○ Jeg går med maske ○ Jeg går uden maske
Der kan være mange grunde til at man trods dette forsøg bærer maske eller ikke bærer maske. Til forsøgets resultat har vi brug for at vide om Du faktisk bruger maske eller ikke? (Et svar) ***(Kun inkluderet I spørgeskema for runde 2)***	○ Bruger maske det meste af tiden når jeg er ude ○ Bruger maske som beskrevet ○ Bruger ikke maske
Bruger du så masken, som vi har anbefalet? (et svar)	○ Ja, helt som beskrevet ○ Ja, overvejende som beskrevet ○ Nej, overhovedet ikke
Hvad er årsagen til at du kun delvist eller ikke overholder anbefalingen	○ Mit arbejde tillader ikke fast brug af maske ○ Masken bliver hurtigt våd og derfor ikke brugbar ○ Jeg vil ikke gå med maske
Føler du, at masken (mundbindet) gør dig mere tryg? (Et svar)	○ Ja ○ Nej ○ Ved ikke
Hvordan reagerer andre på, at du har mundbind på? (Et svar)	○ De fleste synes, at det er rigtig fornuftigt at jeg beskytter mig selv og andre ○ De fleste hverken kigger eller siger noget til det ○ De fleste synes, at det er mærkeligt og jeg får nogle negative kommentarer
Hvordan vil du vurdere din egen adfærd ift. Sundhedsmyndighedernes råd under corona-krisen (Et svar)	○ Jeg er meget omhyggelig med håndvask / sprit og at holde afstand ○ Jeg udfører håndvask / sprit et par gange om dagen og at holder lidt afstand ○ Jeg er ikke særlig omhyggelig med at udføre håndvask / sprit eller holde afstand til andre
Hvor meget har du gennemsnitligt været ude blandt andre mennesker dagligt den seneste uge?	○ Mere end 10 timer ○ 6-10 timer ○ 3-6 timer ○ Mindre end 3 timer
Har du fået påvist COVID-19 hos læge/på sygehus? ***(Kun inkluderet i spørgeskema til runde 1)***	○ Ja ○ Nej
Hvilken dato blev du testet positiv for COVID-19?	

Er nogen på din bopæl blevet testet positive?	○ Ja ○ Nej
Du skal kun teste antistoffer ved forsøgets start og slut. Hvis du ikke fik noteret første prøve sidst vi sendte skema, kan du gøre det nu. Ønsker du at rapportere resultat af første antistofprøve? Du skal IKKE bruge den sidste antistoftest nu.	○ Ja ○ Nej
Hvad viste den blå antistof-test ("IgM")? (et svar)	○ 1 streg ○ 2 streger (Nummer 2 streg tæller også i de tilfælde, hvor den er ugyldig) ○ Jeg er ikke sikker på resultatet – eller jeg kunne ikke udføre testen
Hvad viste den røde antistof-test ("IgG")? (et svar)	○ 1 streg ○ 2 streger (Nummer 2 streg tæller også i de tilfælde, hvor den er ugyldig) ○ Jeg er ikke sikker på resultatet – eller jeg kunne ikke udføre testen
Har du haft nogle af følgende symptomer efter, at blev udvalgt til forsøget?	○ Hoste ○ Feber ○ Hovedpine ○ Åndenød ○ Smerter I muskler/led ○ Smagsforstyrrelser ○ Ingen symptomer
Har du været syg den seneste uge?	○ Ja ○ Nej
Du skal pode dig selv, når undersøgelsen er færdig, men indtil da skal du KUN pode dig, hvis du har symptomer, der kunne tyde på, at du har COVID-19. Har du foretaget podning? (et svar)	○ Ja ○ Nej
Hvis du har andre kommentarer til os, kan du skrive dem i feltet nedenfor; (kommentarfelt, maks 200 ord)	

Spørgeskema uge 3

Hvilken gruppe tilhører du? (Et svar)	○ Jeg går med maske

	○ Jeg går uden maske
Har nogen i din husstand efter starten af maskeprojektet fået påvist COVID-19 ved læge / på sygehus? (Et svar)	○ Ja ○ Nej
Er din bekymring for at få COVID-19 under maskeforsøget blevet? (Et svar)	○ Større ○ Mindre ○ Uændret
Bruger du så masken, som vi har anbefalet? (et svar)	○ Ja, helt som beskrevet ○ Ja, overvejende som beskrevet ○ Nej, overhovedet ikke
Hvad er årsagen til at du kun delvist eller ikke overholder anbefalingen	○ Mit arbejde tillader ikke fast brug af maske ○ Masken bliver hurtigt våd og derfor ikke brugbar ○ Jeg vil ikke gå med maske
Føler du, at masken (mundbindet) gør dig mere tryg? (Et svar)	○ Ja ○ Nej ○ Ved ikke
Hvordan reagerer andre på, at du har mundbind på? (Et svar)	○ De fleste synes, at det er rigtig fornuftigt at jeg beskytter mig selv og andre ○ De fleste hverken kigger eller siger noget til det ○ De fleste synes, at det er mærkeligt og jeg får nogle negative kommentarer
Ændrer brugen af mundbind din fysiske aktivitet? (Et svar)	○ Ja, jeg er mindre fysisk aktiv på grund af mundbindet ○ Nej, det har ikke ændret noget ○ Ved ikke
Hvor mange masker bruger du om dagen i hverdagen? (Et svar)	○ 1 ○ 2 ○ 3 ○ Flere end 3
Hvor mange masker bruger du om dagen i weekenden? (Et svar)	○ 1 ○ 2 ○ 3 ○ Flere end 3

Hvordan vil du vurdere din egen adfærd ift. Sundhedsmyndighedernes råd under corona-krisen (Et svar)	○ Jeg er meget omhyggelig med håndvask / sprit og at holde afstand ○ Jeg udfører håndvask / sprit et par gange om dagen og at holder lidt afstand ○ Jeg er ikke særlig omhyggelig med at udføre håndvask / sprit eller holde afstand til andre
Hvis du havde været i maskegruppen, tror du så, at du ville være mere ude i det offentlige rum, i butikker, busser, toge og lignende? (Et svar)	○ Ja ○ Nej ○ Ved ikke
Hvor meget har du været ude blandt andre mennesker dagligt gennem den seneste uge?	○ Mere end 10 timer ○ 6-10 timer ○ 3-6 timer ○ Mindre end 3 timer
Har du fået påvist COVID-19 hos læge/på sygehus?	○ Ja ○ Nej
Hvilken dato blev du testet positiv for COVID-19?	_____
Du skal kun teste antistoffer ved forsøgets start og slut. Hvis du ikke fik noteret første prøve sidst vi sendte skema, kan du gøre det nu. Ønsker du at rapportere resultat af første antistofprøve? Du skal IKKE bruge den sidste antistoftest nu.	○ Ja ○ Nej
Hvad viste den blå antistof-test ("IgM")? (et svar)	○ 1 streg ○ 2 streger (Nummer 2 streg tæller også i de tilfælde, hvor den er ugyldig) ○ Jeg er ikke sikker på resultatet – eller jeg kunne ikke udføre testen
Hvad viste den røde antistof-test ("IgG")? (et svar)	○ 1 streg ○ 2 streger (Nummer 2 streg tæller også i de tilfælde, hvor den er ugyldig) ○ Jeg er ikke sikker på resultatet – eller jeg kunne ikke udføre testen
Har du haft nogle af følgende symptomer efter, at blev udvalgt til forsøget?	○ Hoste ○ Feber ○ Hovedpine ○ Åndenød ○ Smerter I muskler/led

	○ Smagsforstyrrelser ○ Ingen symptomer
Har du været syg den seneste uge?	○ Ja ○ Nej
Hvis du har andre kommentarer til os, kan du skrive dem i feltet nedenfor; (kommentarfelt, maks 200 ord)	_____

Spørgeskema uge 4

Hvilken gruppe tilhører du? (Et svar)	○ Jeg går med maske ○ Jeg går uden maske
Har nogen i din husstand efter starten af maskeprojektet fået påvist COVID-19 ved læge / på sygehus? (Et svar)	○ Ja ○ Nej
Er din bekymring for at få COVID-19 under maskeforsøget blevet? (Et svar)	○ Større ○ Mindre ○ Uændret
Bruger du så masken, som vi har anbefalet? (et svar)	○ Ja, helt som beskrevet ○ Ja, overvejende som beskrevet ○ Nej, overhovedet ikke
Hvad er årsagen til at du kun delvist eller ikke overholder anbefalingen	○ Mit arbejde tillader ikke fast brug af maske ○ Masken bliver hurtigt våd og derfor ikke brugbar ○ Jeg vil ikke gå med maske
Føler du, at masken (mundbindet) gør dig mere tryg? (Et svar)	○ Ja ○ Nej ○ Ved ikke
Hvordan reagerer andre på, at du har mundbind på? (Et svar)	○ De fleste synes, at det er rigtig fornuftigt at jeg beskytter mig selv og andre ○ De fleste hverken kigger eller siger noget til det ○ De fleste synes, at det er mærkeligt og jeg får nogle negative kommentarer
Ændrer brugen af mundbind din fysiske aktivitet? (Et svar)	○ Ja, jeg er mindre fysisk aktiv på grund af mundbindet ○ Nej, det har ikke ændret noget ○ Ved ikke
Hvordan vil du vurdere din egen adfærd ift. Sundhedsmyndighedernes råd under corona-krisen (Et svar)	○ Jeg er meget omhyggelig med håndvask / sprit og at holde afstand ○ Jeg udfører håndvask / sprit et par gange om dagen og at holder lidt afstand ○ Jeg er ikke særlig omhyggelig med at udføre håndvask / sprit eller holde afstand til andre
Hvis du havde været i maskegruppen, tror du så, at du ville være mere ude i det offentlige rum, i butikker, busser, toge og lignende?	○ Ja

(Et svar)	○ Nej ○ Ved ikke
Hvor meget har du været ude blandt andre mennesker dagligt gennem den seneste uge?	○ Mere end 10 timer ○ 6-10 timer ○ 3-6 timer ○ Mindre end 3 timer
Har du fået påvist COVID-19 hos læge/på sygehus?	○ Ja ○ Nej
Hvilken dato blev du testet positiv for COVID-19?	_____
I forbindelse med besvarelsen af dette spørgeskema skal du foretage en podnings- og antistoftest. Se venligst vedhæftede vejledning til, hvordan testene skal udføres.	
Hvad viste den blå antistof-test ("IgM")? (et svar)	○ 1 streg ○ 2 streger (Nummer 2 streg tæller også i de tilfælde, hvor den er ugyldig) ○ Jeg er ikke sikker på resultatet – eller jeg kunne ikke udføre testen
Hvad viste den røde antistof-test ("IgG")? (et svar)	○ 1 streg ○ 2 streger (Nummer 2 streg tæller også i de tilfælde, hvor den er ugyldig) ○ Jeg er ikke sikker på resultatet – eller jeg kunne ikke udføre testen
Har du haft nogle af følgende symptomer efter, at blev udvalgt til forsøget?	○ Hoste ○ Feber ○ Hovedpine ○ Åndenød ○ Smerter I muskler/led ○ Smagsforstyrrelser ○ Ingen symptomer
Har du foretaget den planlagte podning af næse og svælg som afslutning på forsøget? (Et svar)	○ Ja ○ Nej
Har du aftalt tid til afhenting af podesæt med BRING? (Et svar)	○ Ja ○ Nej
Hvis du selv kunne vælge – vil du så gå med mundbund i fremtiden, når undersøgelsen er færdig? (Et svar)	○ Ja – indtil COVID-19 er overstået

	○ Ja – ved fremtidige lignende infektiøse udbrud i samfundet ○ Nej ○ Ved ikke
Hvordan vil du foretrække det, hvis du i fremtiden skal podes? (Et svar)	○ Selvpodning i hjemmet - og jeg synes, at det var let ○ Selvpodning i hjemmet – men jeg synes, at det var svært ○ Podning på hospital af sundhedspersonale
Hvis du har andre kommentarer til os, kan du skrive dem i feltet nedenfor; (kommentarfelt, maks. 200 ord)	_____

Part 6: Viral PCR testing

Below is a detailed description of the laboratory methods for the analysis of the oropharyngeal/ nasal swab testing. The laboratory technicians were blinded to the participants' group assignment.

RNA extraction

Viral RNA was extracted from swab samples in DNA/RNA Shield (Zymo Research) using Quick-RNA Microprep Kit (Zymo Research) with the below modifications. 200 µl sample were incubated for 1 min with proteinase K (Qiagen) in a final concentration of 0.2 µg/µl prior to treatment with lysis buffer (Quick-RNA Microprep Kit). Only a single washing step using 400 µl RNA Wash Buffer (Quick-RNA Microprep Kit) was performed before elution in 15µl RNase free water.

Primer and probe used

Three different primer/probe set targeting SARS-Cov-2 were used in the present study 1. E_Sarbeco (Corman et al., 2020): F ACAGGTACGTTAATAGTTAATAGCGT, FAM ACACTAGCCATCCTTACTGCGCTTCG-BBQ, R ATATTGCAGCAGTACGCACACA. 2. CoV_Wuhan/SARS_FP4, CoV_Wuhan/SARS_RP4, CoV_Wuhan/SARS_P4 (SSI). N_Sarbeco (Corman et al., 2020): F CACATTGGCACCCGCAATC, FAM-ACTTCCTCAAGGAACAACATTGCCA-BBQ, R GAGGAACGAGAAGAGGCTTG. The following other primer/probes targeting the below RNA viruses were also used during qPCR of each sample. Human coronavirus 229E : COR229-1, COR229-2, COR229 p (SSI); Human coronavirus NL63: HCoV-NL63f, HCoV-NL63r, HCoV-NL63p (SSI); Human coronavirus OC43: OC43-1, OC43-2, OC43-p (SSI); Human coronavirus HKU1: HCoV-HKU1f, HCoV-HKU1r, HCoV-HKU1p (SSI); Respiratory syncytial virus A: RSVQA1, RSVQA2, RSVQA (SSI); Respiratory syncytial virus B: RSVQB1, RSVQB2, RSVQB (SSI); Parainfluenza type 1: PIV1_F, PIV1_R, PIV1_P (SSI); Parainfluenza type 2: PIV2_F, PIV2_R, PIV2_P (SSI); Influenza B: Bf RATR 2014, Br RATR 2014, Bp RATR 2014 (SSI), Influenza A : Mf RATR 2014, Mr RATR 2014, Mp RATR 2014 (SSI); Influenza A: H1v 2010 f, H1v 2010 r, H1v 2010 probe (SSI) ; Influenza A: N2bf 2010, N2br 2010, N2b 2010 Probe (SSI); Influenza A: NF, NR, NP (DTU), Influenza A (H1pdm): F CTAGTGGTACCGAGATATGCA, FAM-CGCAATGGAAAGAAATGCTGGATCTGG-BHQ1, R TATTGCAATCGTGGACTGGTGT; Influenza A (M-gene): F AGATGAGTCTTCTAACCGAGGTCG, FAM-TCAGGCCCCCTCAAAGCCGA-BHQ1, R TGCAAAGACACTTTCCAGTCTCTG. RNase P : F AGATTTGGACCTGCGAGCG, FAM-TTCTGACCTGAAGGCTCTGCGCG-BHQ1, R – GAGCGGCTGTCTCCACAAGT. Sensitivity and specificity of each primer probe assay were validated on the Biomark (Fluidigm) platform as described below based on serial dilutions of several different positive controls including SARS-CoV-2, Human coronavirus 229E, NL63, OC43 and HKU1, Respiratory syncytial virus A and B, Parainfluenza type 1 and 2, Influenza virus A and B.

Reverse-transcription and pre-amplification

Reverse-transcription and pre-amplification were performed one step in a final volume of 20 µL using Takara One-Step PrimeScript III RT-qPCR Mix x2 (Takara). A 200nM primer mix containing all primers (E_Sarbeco, CoV_Wuhan/SARS, N_Sarbeco, COR229, HCoV-NL63, OC43, HCoV-HKU1 RSVQA, RSVQB, PIV1, PIV2, Bf RATR 2014, M RATR

2014, H1v 2010, N2b 2010, H1pdm and M) were prepared and used in the one step reverse-transcription and pre-amplification in a final concentration of 20nM, 3µl template RNA were included in each reaction. The reverse-transcription/pre-amplification was performed using a T3 thermocycler (Biometra) and the flowing program: 10 min at 55°C, 3 min at 95°C followed by 23 cycles at 95°C for 15 sec, and 58°C for 30 sec. The pre-amplified complementary DNA (cDNA) was stored at –20°C until microfluidic qPCR.

Microfluidic qPCR

Dynamic arrays 192.24 (Fluidigm) combining 192 samples with 24 different primer/probe pairs were used for microfluidic qPCR. Primer and probe was mixed with 2x assay loading reagent (Fluidigm) in final volume of 4 µl and a final concentration: 25µM primers and 7.5µM probe. Subsequently 4µl sample mix containing 2µL of TaqMan gene expression master mix (Applied Biosystems), 0.2 µL of 20x sample loading reagent (Fluidigm), and 1.8µL of pre-amplified cDNA. Dynamic arrays 192.24 (Fluidigm) were primed in the IFC controller RX (Fluidigm) and subsequently placed in the BioMark (Fluidigm) using the following cycling conditions: 50°C for 2 min, 95°C for 10 min, followed by 40 cycles of 95°C for 15 s, and 60°C for 60 s. Positive controls for SARS-CoV-2 and each of the other RNA viruses diagnosed were included on each dynamic array, negative controls including non-template controls and non-template pre-amplification control (nuclease-free water) were also included. Data, including Cq values and amplification curves, were acquired on the BioMark system and analyzed (Real-time PCR analysis software v.4.1.3; Fluidigm).

Part 7: Study Kit Content

Participants received a package containing the following materials at randomization.

Study Kit Content

#	Quantity	Material
1	2	Swab kit
2	2	Antibody test kits (IgM & IgG)
3	2	10 mL NaCl water for the antibody test
4	2	Blood lancets, automatic
5	2-4	Blood lancets, manual (extra material)
6	2-4	Disinfection swabs
7	2	Capillary tubes
8	2	Return label
9	2	Return package
10	1	Instruction guide (see below for Danish version and English translation)
11	50	Face mask (only to participants randomised to wear face mask)
12	1	A badge to wear on the cloth saying; I am testing face masks – for you and me

Part 8: Instructions guides

Instruction Guide for Face Mask Group (Danish)

The instruction was sent to the participants in the face mask group in the study kit. The instruction was a double printed A4 page and both sides can be seen below.

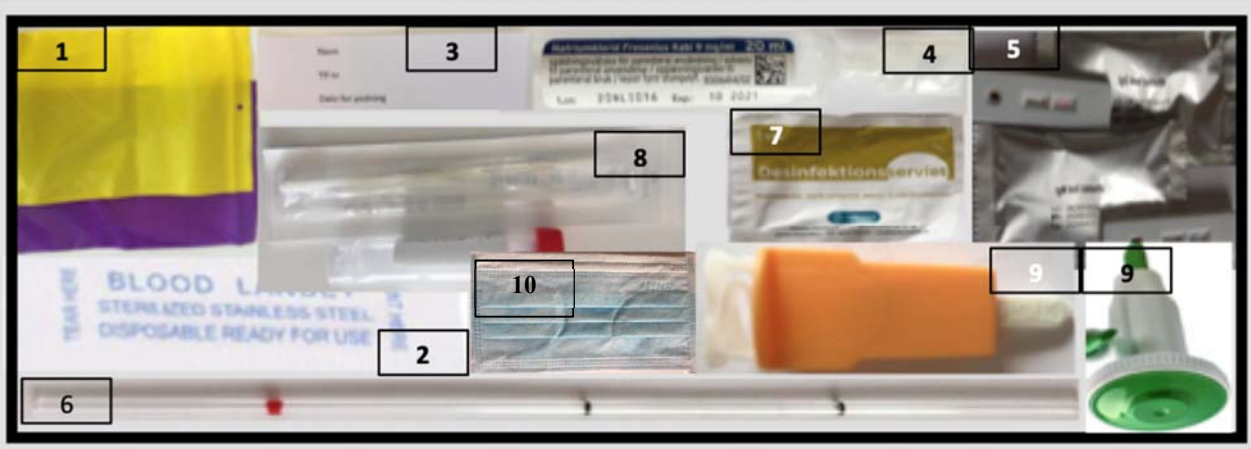
Kære deltager – i mundbindsgruppen

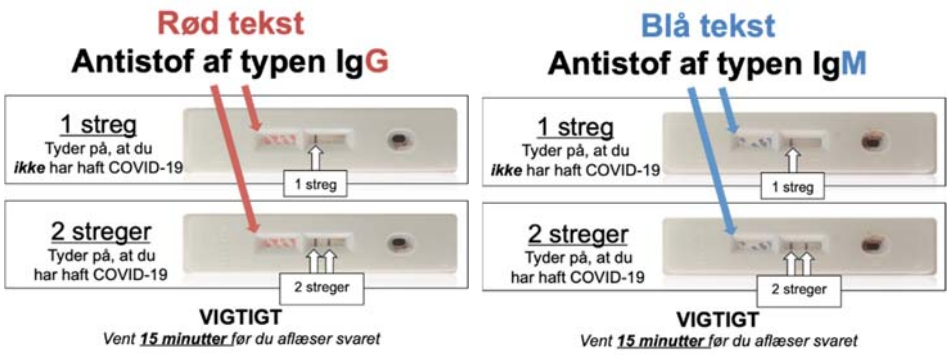
Mange tak for at du vil være med i undersøgelsen *"Reduktion af COVID-19 smitte ved brug af mundbind"*

Tjekliste (Posen indeholder følgende – og alt du har brug for i løbet af undersøgelsen)

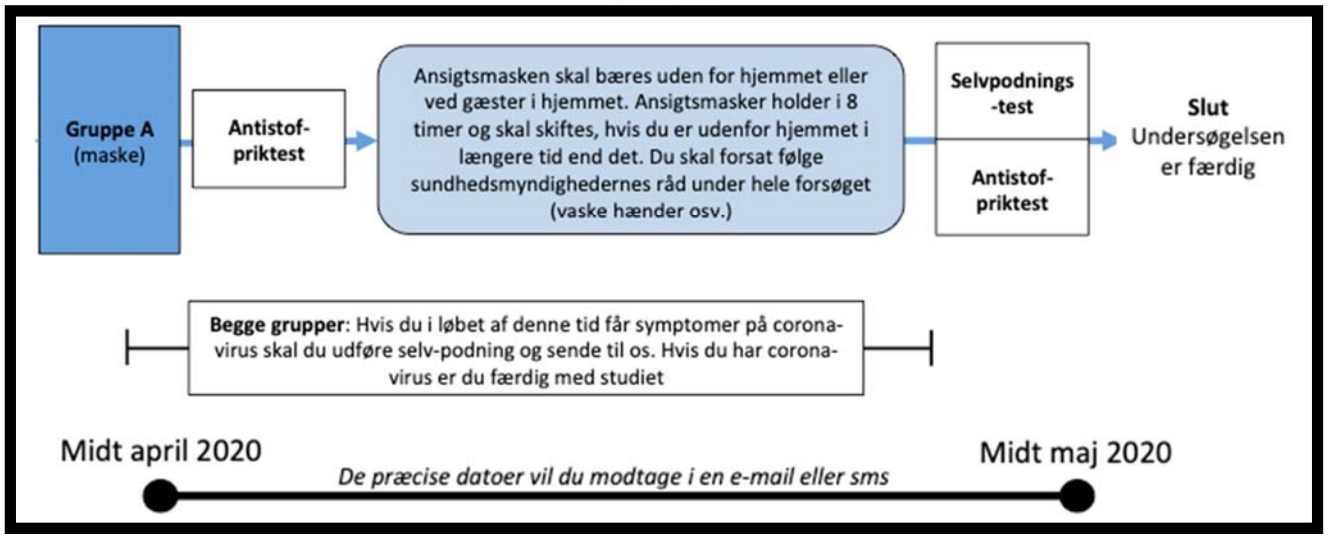
1) *2x returposer (lilla eller gule)*
2) *2-4x bloddråbe lancetter, forskellige*
3) *2x returneringsseddel*
4) *2x 10ml saltvand*
5) *2x antistof-tests sæt (IgM & IgG)*
6) *2x kapillærrør*
7) *2-4x spritswaps*
8) *2x pode-sæt*
9) *2x bloddråbe prikker*
10) *20-50x mundbind**

*Nogle får mundbind tilsendt af to omgange, hvis ikke de har fået 50 i første omgang.





Placer masken over næsen og under hagen. Husk håndhygiejne ved maskebrug



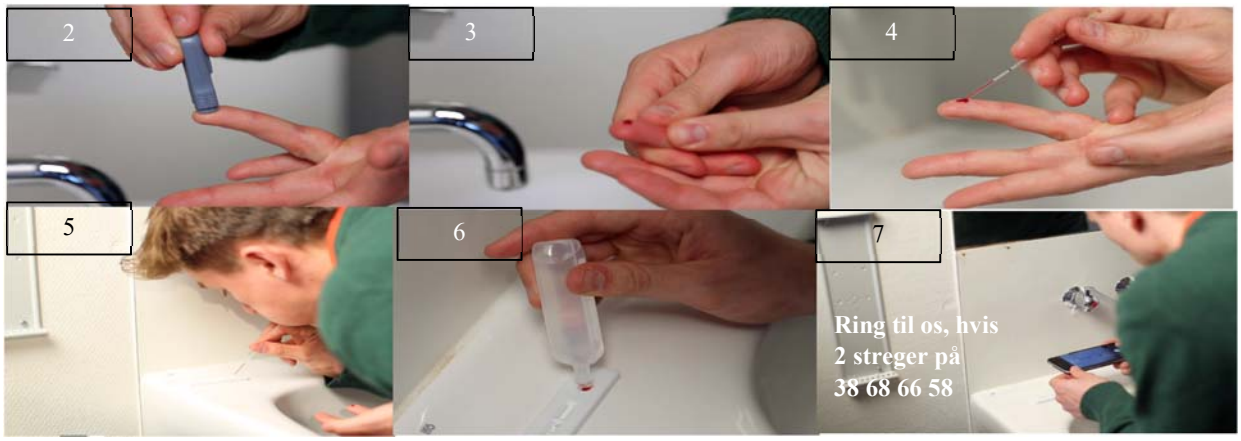
Instruktion til selv-podning og anti-stof selv-test (der findes også videoer af dette)

Anti-stof selv-test: Kræver: 1-2x bloddråbe-lancetter/ prikker, 1x kapillær-rør, 1x 10 ml saltvand, 2x antistof tests, 1 x spritswap.

QR kode

https://vimeo.com/406950456

1) *Varm dine fingre og hænder ved at gnide dem sammen. Vælg en finger, som du vil prikke og sprit den af.*
2) *Tag bloddråbe-prikker og prik spidsen af din finger. Det skal gøres med et fast tryk på toppen. Det føles som et stik. Benyt bloddråbe-lancetten, hvis ikke det lykkedes med prikker.*
3) *Masser din finger således, at en bloddråbe dannes.*
4) *Tag et kapillærrør op og læg spidsen af den på bloddråben. Bloddråben suges automatisk op.*
5) *Før kapillærrøret ned i det lille hul på antistoftesten og pust blodet ud. Put evt bloddråben direkte i hullet fra finger*
6) *Placér to dråber saltvand (Natriumklorid) i det lille hul efter blodet. Gentag 3), 4), 5) og 6) på nr. 2. (I alt 1 IgM og 1 IgG)*
7) *Tag et billede af testpladerne. Vi har sendt et link til dig, hvor vi beder dig give dit svar på testen.*

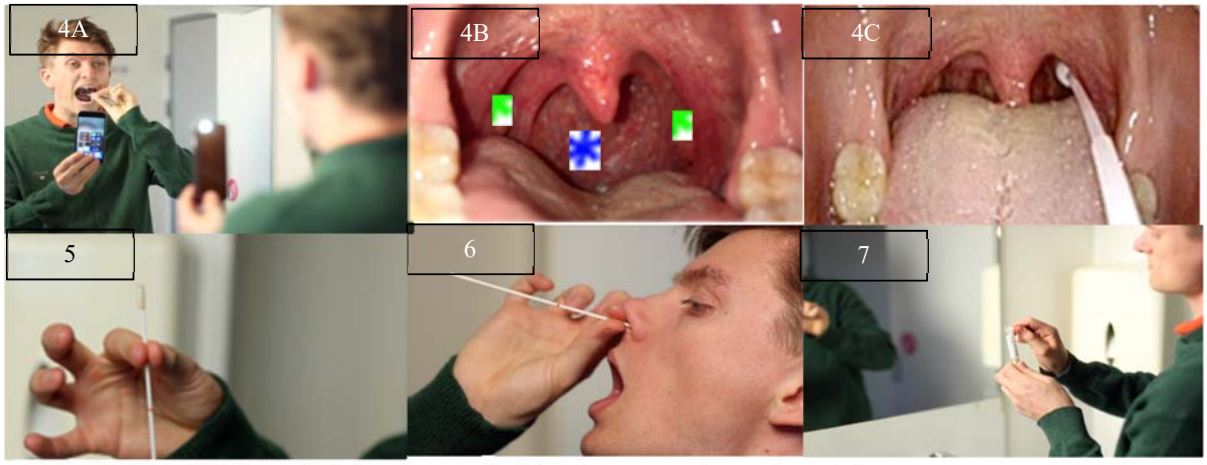


Selv-podnings-test: *Kræver: 1 x podesæt, farvet pose m. klistermærke, papirlap med dit navn*

https://vimeo.com/406958297

QR kode

1) *Pust næse og tjek, hvilket næsebor der er bedst luft gennemstrømning.*
2) *Pak podesættet ud. Sørg for, at væsken i tuben ikke ryger ud – evt. i en kop.*
3) *Stil dig foran et spejl med god belysning – brug gerne din telefon. Tag vatpinden ud af indpakningen.*
4) *4A- Åbn munden på vid gab og sig "ah". 4B og 4C - Før nu vatpinden ind i munden og lad den røre bagvæggen af dit svælg (*) og mandlerne (*).*
5) *Den samme podepind skal nu også bruges til at tage en prøve fra næsen. Tag derfor fat med to fingre 3-4 cm ned under vattotten på podepindens spids.*
6) *Tag vatpinden og før den 4 cm i det valgte næsebor. Rul vatpinden 3 gange mod huden i næseborets bund.*
7) *Nu er du færdig med at pode. Tag vatpinden og før spidsen ned i glasset med væsken. Knæk den overskydende pind af og luk tuben.*
8) *Send nu glasset med podepind retur i den farvede pose med 1) Papirlap med dit navn 2) klistermærke udenpå med vores adresse. Aflever denne pose i din lokale pakkeshop. Vi betaler forsendelsen.*



Med venlig hilsen - og tusind tak for din interesse for studiet. Telefon: 38 68 66 58

Professor, overlæge, dr.med. Henning Bundgaard, professor, overlæge, dr.med. Christian Torp- Pedersen, professor, overlæge, dr.med. Thomas Benfield og professor, overlæge, dr.med. Kasper Iversen

The instruction was sent to the participants in the control group in the study kit. The instruction was a double printed A4 page and both sides can be seen below.

Kære deltager – ikke mundbindsgruppen

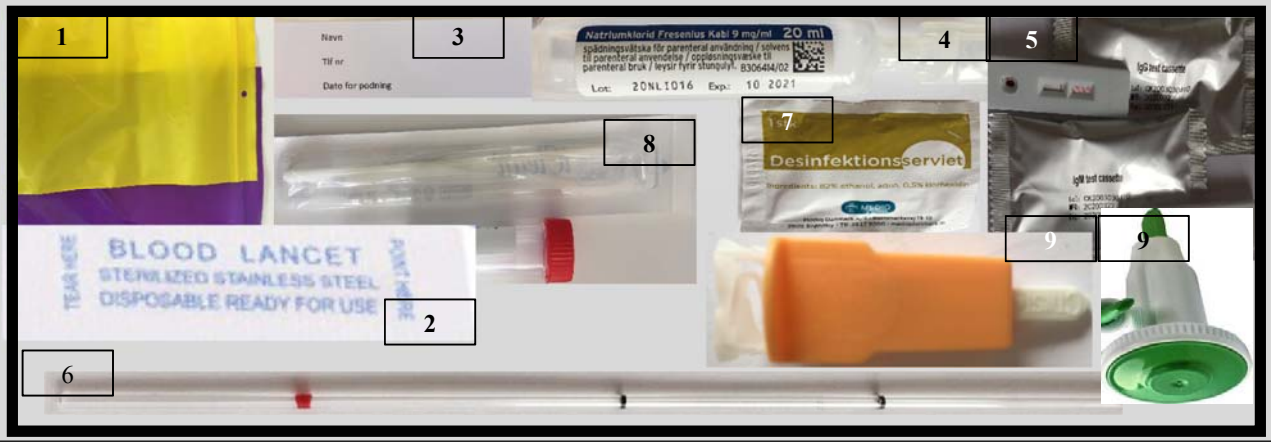
Mange tak for at du vil være med i undersøgelsen *"Reduktion af COVID-19 smitte ved brug af mundbind"*

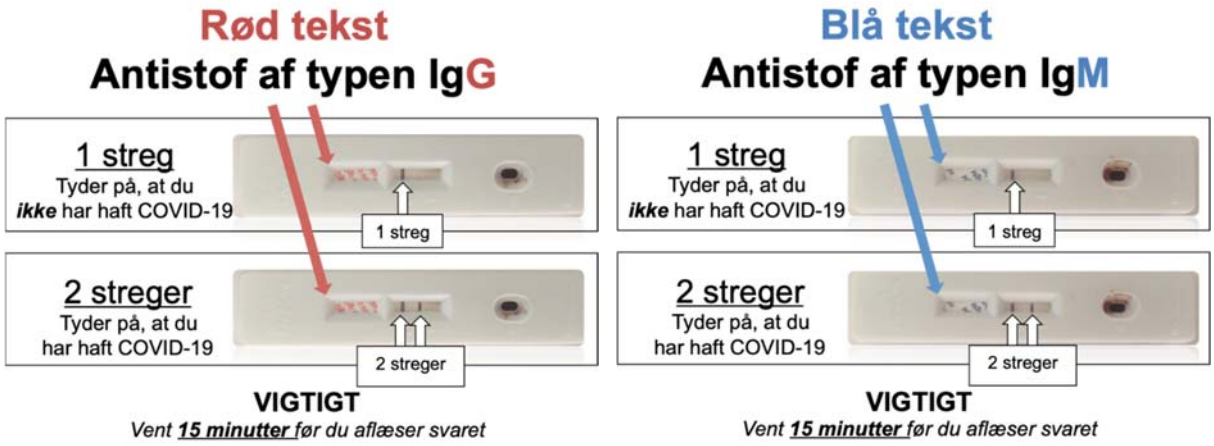
.

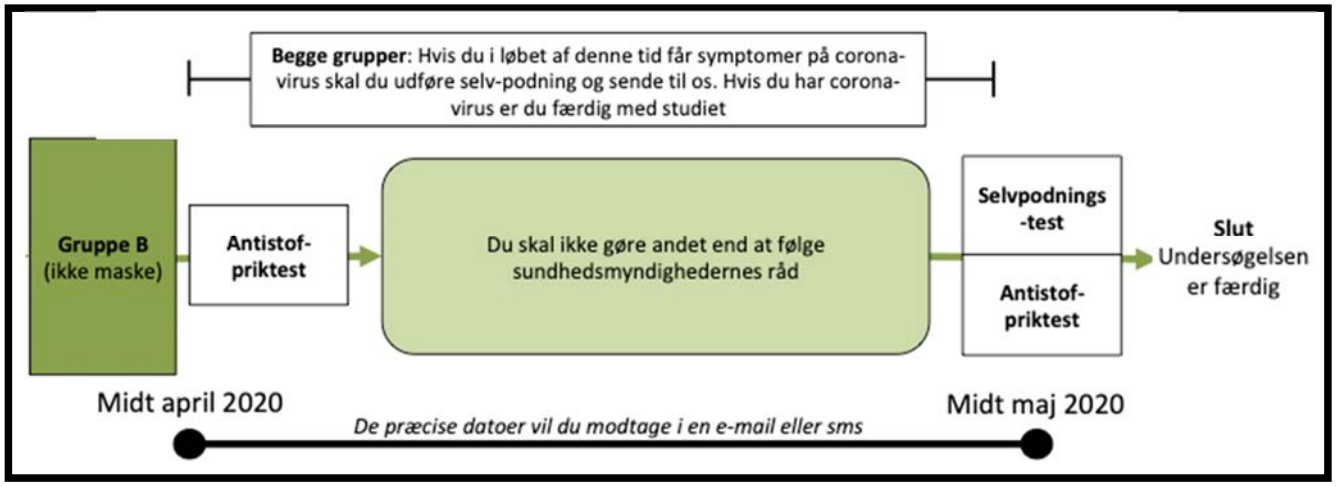
Tjekliste (Posen indeholder følgende – og alt du har brug for i løbet af undersøgelsen)

1) *2x returposer (lilla eller gule)*
2) *2-4x bloddråbe lancetter*
3) *2x returneringsseddel*
4) *2x 10ml saltvand*
5) *2x antistof-tests sæt (IgM & IgG)*
6) *2x kapillærrør*
7) *2-4x spritswaps*
8) *2x pode-sæt*
9) *2x bloddråbe prikker*

*Du modtager kun mundbind, hvis du er udvalgt til det.







Instruktion til selv-podning og anti-stof selv-test (der findes også videoer af dette)

Anti-stof selv-test: Kræver: 1-2x bloddråbe-lancetter/ prikker, 1x kapillær-rør, 1x 10 ml saltvand, 2x antistof tests, 1 x spritswap.

8) *Varm dine fingre og hænder ved at gnide dem sammen. Vælg en finger, som du vil prikke og sprit den af.*
9) *Tag bloddråbe-prikker og prik spidsen af din finger. Det skal gøres med et fast tryk på toppen. Det føles som et stik. Benyt bloddråbe-lancetten, hvis ikke det lykkedes med prikker.*
10) *Masser din finger således, at en bloddråbe dannes.*
11) *Tag et kapillærrør op og læg spidsen af den på bloddråben. Bloddråben suges automatisk op.*
12) *Før kapillærrøret ned i det lille hul på antistoftesten og pust blodet ud. Put evt bloddråben direkte i hullet fra finger*
13) *Placér to dråber saltvand (Natriumklorid) i det lille hul efter blodet. Gentag 3), 4), 5) og 6) på nr. 2. (I alt 1 IgM og 1 IgG)*
14) *Tag et billede af testpladerne. Vi har sendt et link til dig, hvor vi beder dig give dit svar på testen.*

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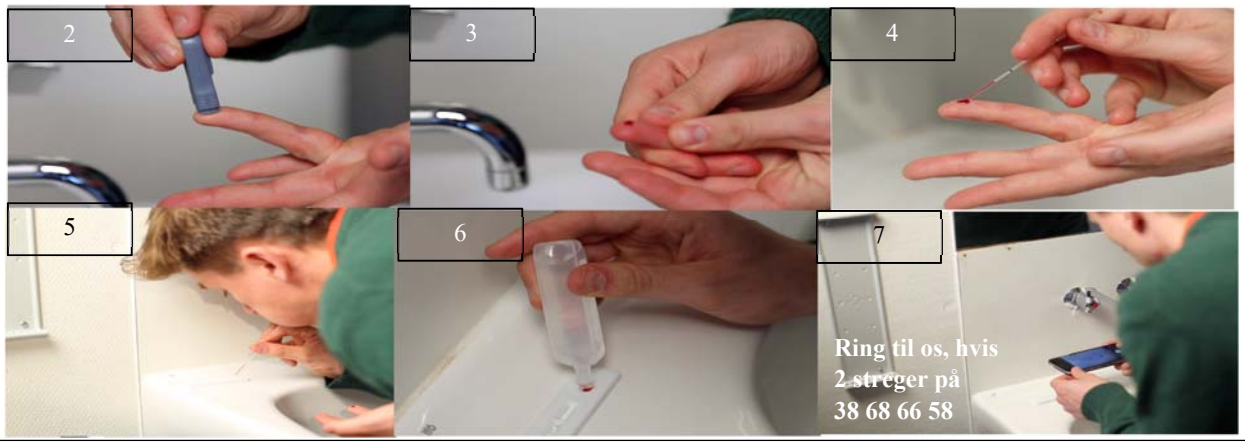

Selv-podnings-test: *Kræver: 1 x podesæt, farvet pose m. klistermærke, papirlap med dit navn*

9) *Pust næse og tjek, hvilket næsebor der er bedst luft gennemstrømning.*
10) *Pak podesættet ud. Sørg for, at væsken i tuben ikke ryger ud – evt. i en kop.*
11) *Stil dig foran et spejl med god belysning – brug gerne din telefon. Tag vatpinden ud af indpakningen.*
12) *4A- Åbn munden på vid gab og sig "ah". 4B og 4C - Før nu vatpinden ind i munden og lad den røre bagvæggen af dit svælg (*) og mandlerne (*).*
13) *Den samme podepind skal nu også bruges til at tage en prøve fra næsen. Tag derfor fat med to fingre 3-4 cm ned under vattotten på podepindens spids.*
14) *Tag vatpinden og før den 4 cm i det valgte næsebor. Rul vatpinden 3 gange mod huden i næseborets bund.*
15) *Nu er du færdig med at pode. Tag vatpinden og før spidsen ned i glasset med væsken. Knæk den overskydende pind af og luk tuben.*
16) *Send nu glasset med podepind retur i den farvede pose med 1) Papirlap med dit navn 2) klistermærke udenpå med vores adresse. Aflever denne pose i din lokale pakkeshop. Vi betaler forsendelsen.*

https://vimeo.com/406958297

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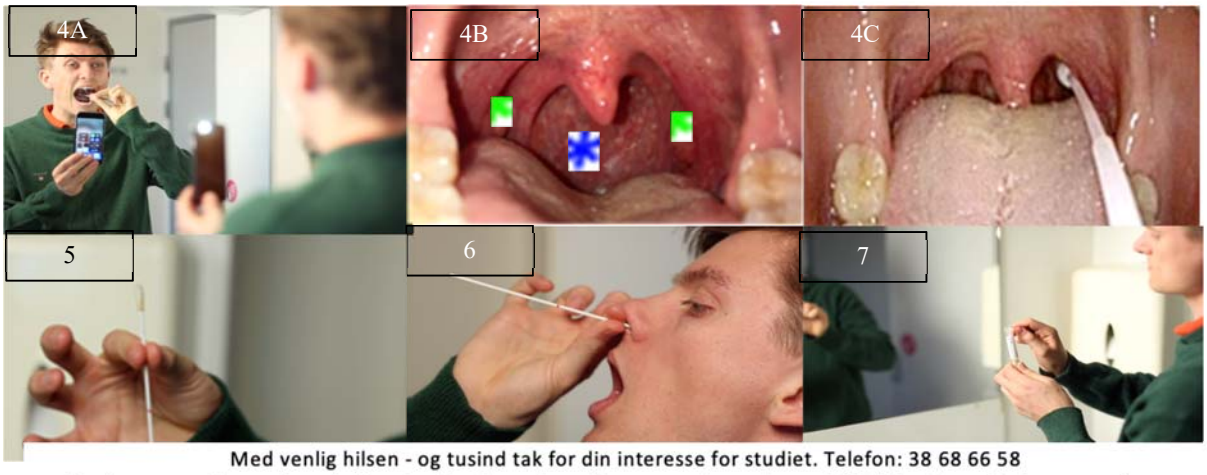

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Instruction Guide for Face Mask Group (English)

The instruction was sent to the participants in the face mask group in the study kit. The instruction was a double printed A4 page and both sides can be seen below.

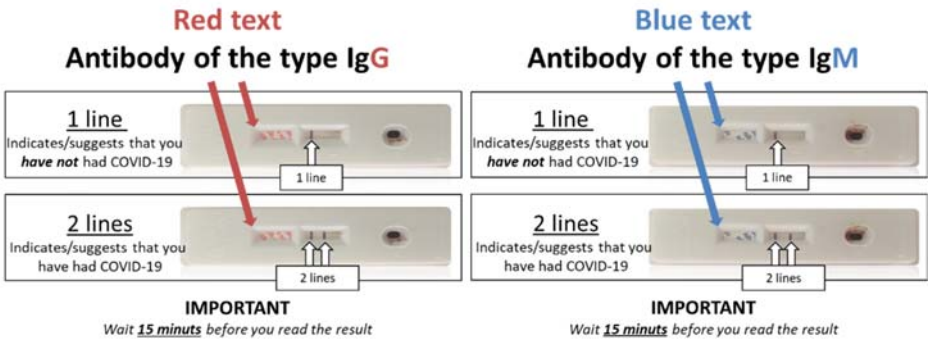
Dear participant – mask group

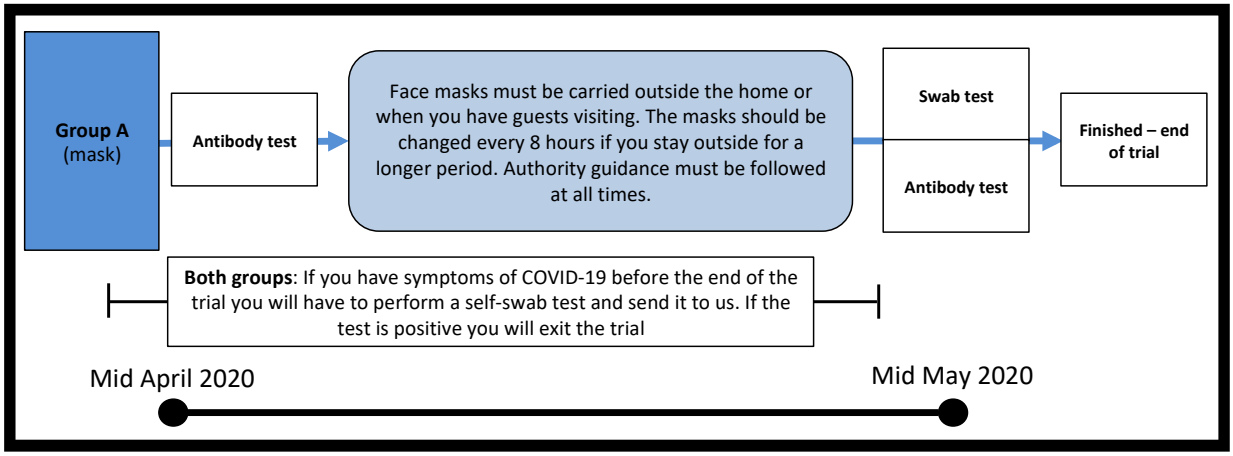
Thank you very much for participating in the study "*Reduction in COVID-19 infection using surgical facial masks outside the healthcare system*"

Check list (The bag contains the following – and everything you will need during the study)

1) *2x return bags (purple or yellow)*
2) *2-4x blood lancets, different types*
3) *2x return notes*
4) *2x 10ml saltwater*
5) *2x antibody test sets (IgM & IgG)*
6) *2x capillary tube*
7) *2-4x disinfection swaps*
8) *2x swab test set*
9) *2x aut. blood lancets*
10) *20-50x masks**

*You will receive masks in two rounds, if you have not received 50 masks initially





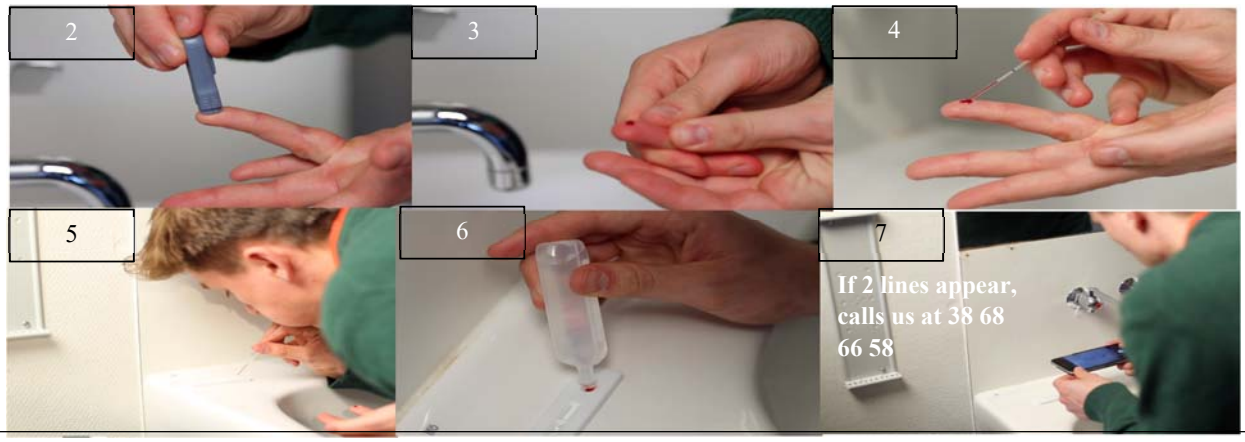
Instruction for self-swab and antibody self-test (videos of the procedures are available as well)

Antibody self-test: You will need: 1-2x blood lancets /aut. blood lancets, 1 x capillary tube, 1x 10 ml saltwater, 2x antibody tests, 1 x disinfection swap.

QR kode

https://vimeo.com/406950456

1. *Warm your fingers and hands by rubbing them together. Choose a finger to prick and disinfect it.*
2. *Take the finger pricker and prick the tip of your finger. This must be done with a firm push on the top. It stings a little. If the aut. blood lancet (finger pricker) fails, use the blood lancet.*
3. *Massage your finger so that a blood droplet forms.*
4. *Take a capillary tube and place its tip by the blood droplet. The droplet will be sucked up automatically.*
5. *Place the capillary tube in the small hole on the antibody test and blow out the blood. You can also place your finger with the droplet directly into the hole.*
6. *After the blood, place two drops of saltwater (sodium chloride) in the small hole. Repeat 3), 4), 5) and 6) on test nr. 2 (In total 1 IgM and 1 IgG).*
7. *Take a picture of the test plates. We have sent you a link where we ask you to give us the test results.*

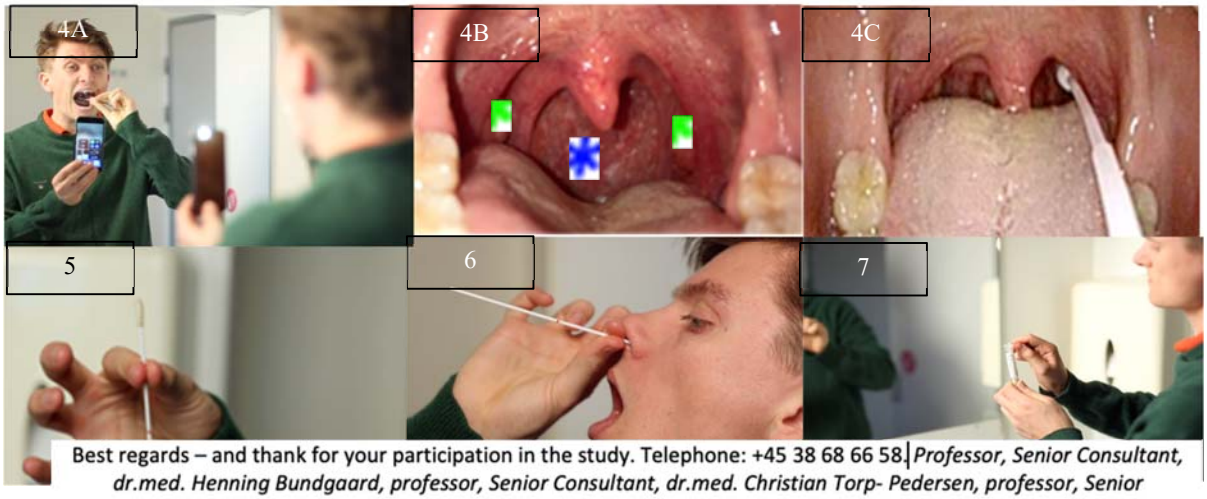


Self-swab test: *You will need: 1 x swap test set, colored bag with sticker, return note with your name*

1. *Blow your nose and check which nostril has the best air flow.*
2. *Unpack the swab test set. Make sure that the liquid stays in the tube – for instance by placing the tube in a cup.*
3. *Stand in front of a properly lit mirror – consider using your phone's flashlight. Unpack the cotton swab.*
4. *4A- Open your mouth wide open and say "ah". 4B and 4C - Now place the cotton swab in your mouth and let it touch the back of your throat (*) and the tonsils (*).*
5. *Use the same cotton swab to swab you nose. Hold the cotton swab with two fingers placed 3-4 cm below the cotton ball.*
6. *Take the cotton swab and place it 4 cm inside the chosen nostril. Roll the cotton swab 3 times against the skin on the base of the nostril.*
7. *You are now finished with the swab. Take the cotton swab and place the tip in the tube with liquid. Crack excess part of the cotton swab and close the tube.*
8. *Place the tube with the cotton swab in the colored bag. Send it to us with 1) a return note with your name, 2) sticker with our address. Hand in the bag in your local packaging shop. We will pay the shipping.*

https://vimeo.com/406958297

QR kode



Best regards – and thank for your participation in the study. Telephone: +45 38 68 66 58. *Professor, Senior Consultant, dr.med. Henning Bundgaard, professor, Senior Consultant, dr.med. Christian Torp- Pedersen, professor, Senior Consultant, dr.med. Thomas Benfield and professor, Senior Consultant, dr.med. Kasper Iversen*

Instruction Guide for Control Group (English)

The instruction was sent to the participants in the control group in the study kit. The instruction was a double printed A4 page and both sides can be seen below.

Dear participant – no mask group

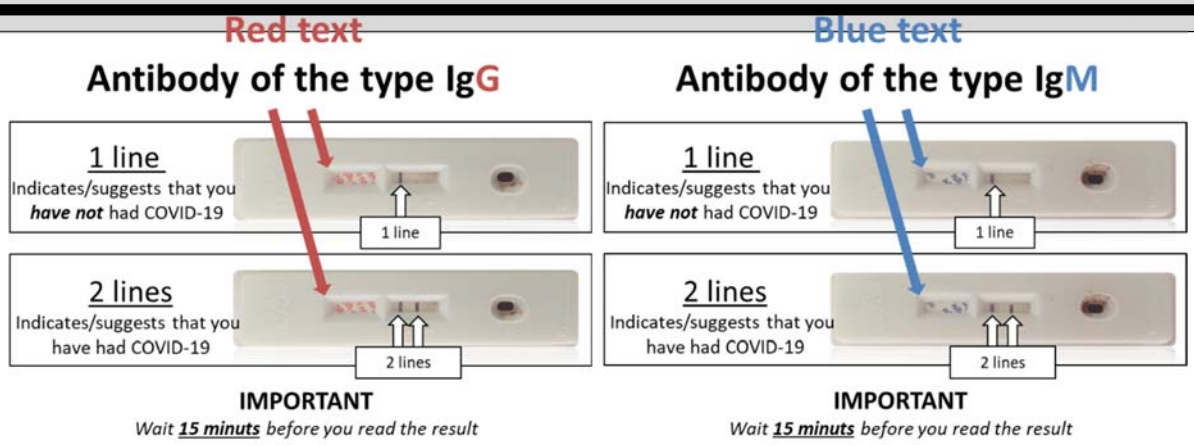
Thank you very much for participating in the study "*Reduction in COVID-19 infection using surgical facial masks outside the healthcare system*"

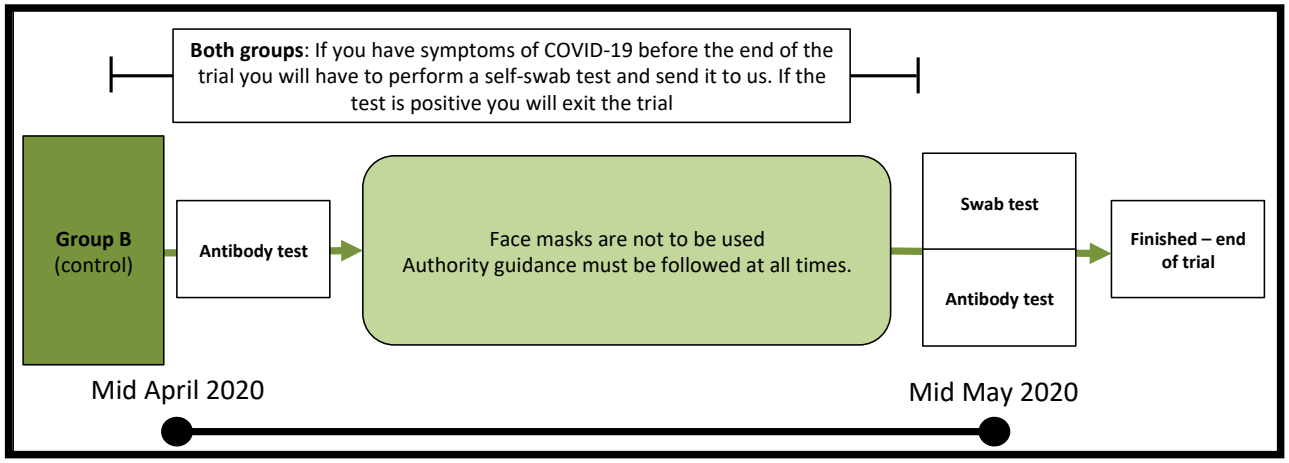
Check list (The bag contains the following – and everything you will need during the study)

1) *2x return bags (purple or yellow)*
2) *2-4x blood lancets*
3) *2x return notes*
4) *2x 10ml saltwater*
5) *2x antibody test sets (IgM & IgG)*
6) *2x capillary tube*
7) *2-4x disinfection swaps*
8) *2x swab test set*
9) *2x aut. blood lancet*

You will only receive masks if you have been selected for this.

- 





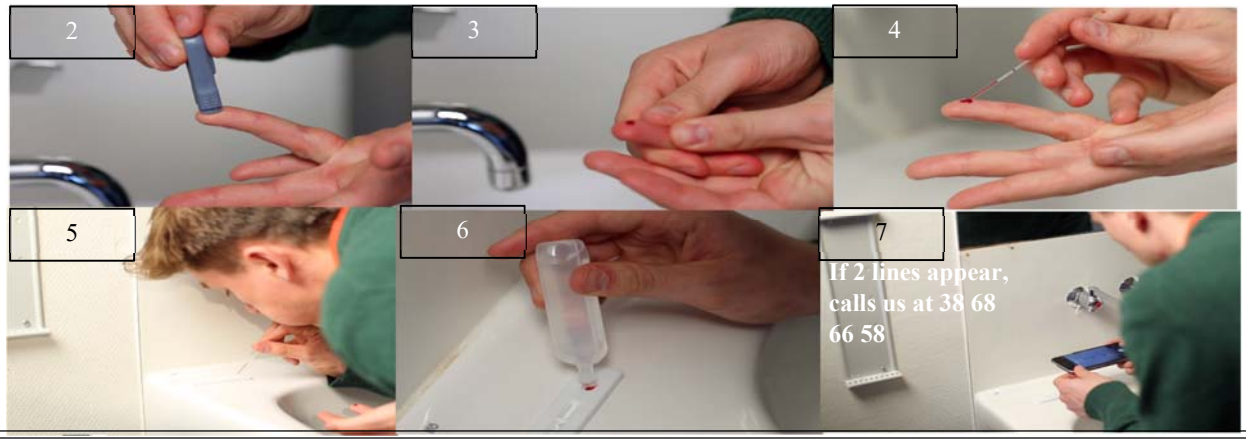
Instruction for self-swab and antibody self-test (videos of the procedures are available as well)

Antibody self-test: You will need: 1-2x blood lancets /aut. blood lancets, 1 x capillary tube, 1x 10 ml saltwater, 2x antibody tests, 1 x disinfection swap.

QR kode

https://vimeo.com/406950456

8. *Warm your fingers and hands by rubbing them together. Choose a finger to prick and disinfect it.*
9. *Take the finger pricker and prick the tip of your finger. This must be done with a firm push on the top. It stings a little. If the aut. blood lancet (finger pricker) fails, use the blood lancet.*
10. *Massage your finger so that a blood droplet forms.*
11. *Take a capillary tube and place its tip by the blood droplet. The droplet will be sucked up automatically.*
12. *Place the capillary tube in the small hole on the antibody test and blow out the blood. You can also place your finger with the droplet directly into the hole.*
13. *After the blood, place two drops of saltwater (sodium chloride) in the small hole. Repeat 3), 4), 5) and 6) on test nr. 2 (In total 1 IgM and 1 IgG).*
14. *Take a picture of the test plates. We have sent you a link where we ask you to give us the test results.*



Self-swab test: *You will need: 1 x swap test set, colored bag with sticker, return note with your name*

https://vimeo.com/406958297

9. *Blow your nose and check which nostril has the best air flow.*
10. *Unpack the swab test set. Make sure that the liquid stays in the tube – for instance by placing the tube in a cup.*
11. *Stand in front of a properly lit mirror – consider using your phone's flashlight. Unpack the cotton swab.*
12. *4A- Open your mouth wide open and say "ah". 4B and 4C - Now place the cotton swab in your mouth and let it touch the back of your throat (*) and the tonsils (*).*
13. *Use the same cotton swab to swab you nose. Hold the cotton swab with two fingers placed 3-4 cm below the cotton ball.*
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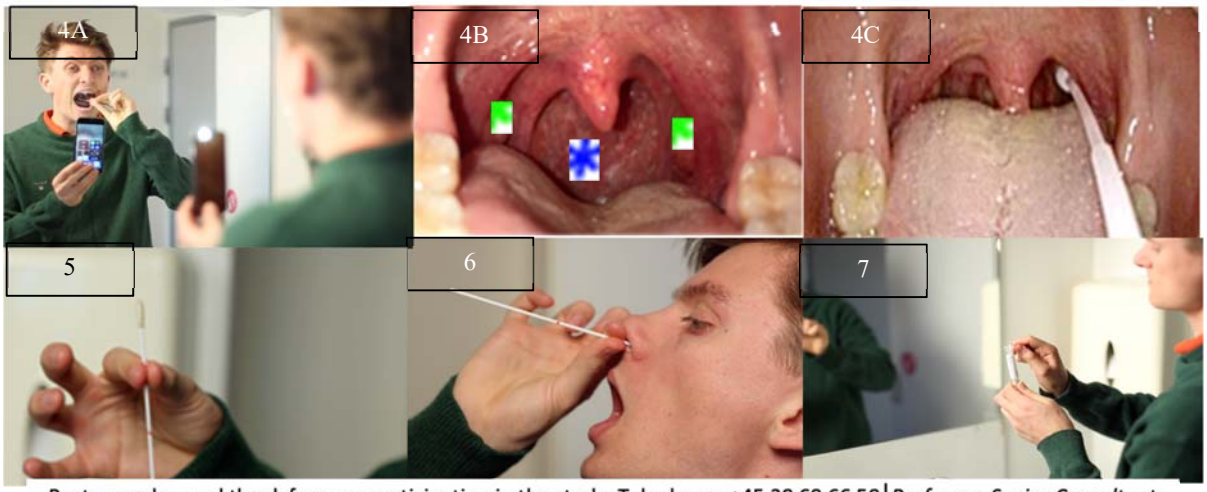
15. *You are now finished with the swab. Take the cotton swab and place the tip in the tube with liquid. Crack the excess part of the cotton swab and close the tube.*
16. *Place the tube with the cotton swab in the colored bag. Send it to us with 1) a return note with your name, 2) sticker with our address. Hand in the bag in your local packaging shop. We will pay the shipping.*

QR kode



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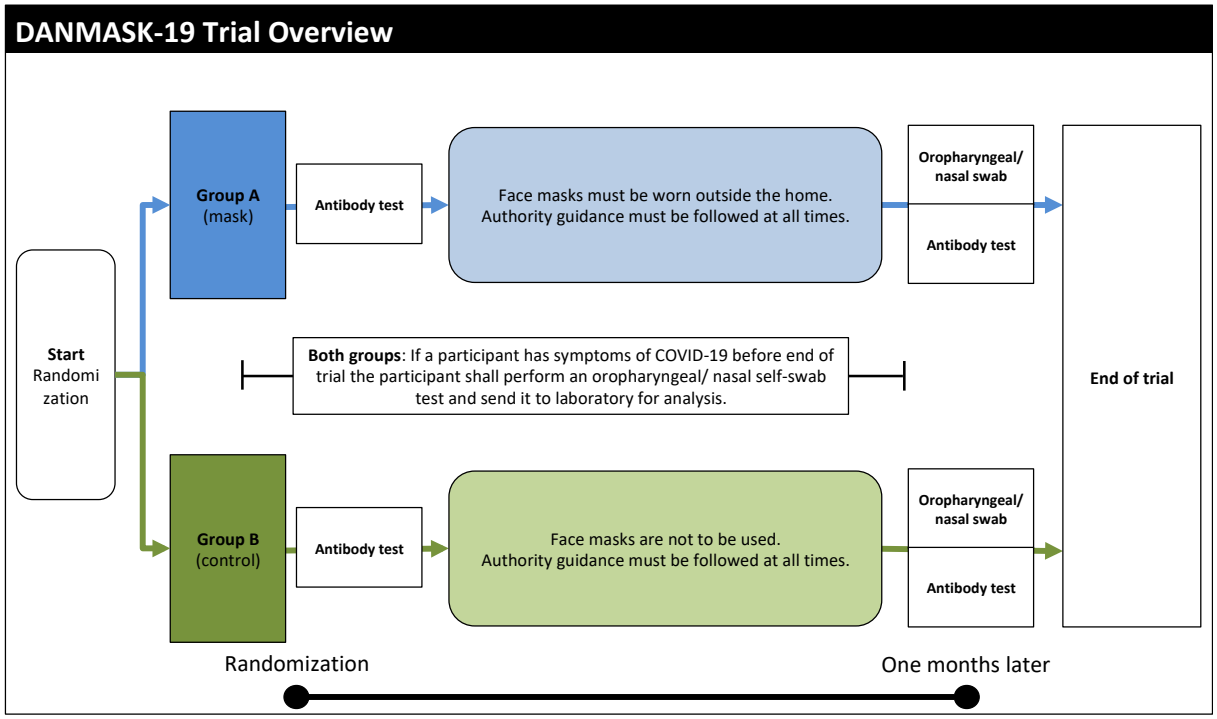
Instruction Videos

Instruction Videos

Video	URL	QR code
Antibody testing	https://vimeo.com/406950456	
Swab procedure	https://vimeo.com/406958297	
Face mask instruction	https://vimeo.com/406952695	

All three videos were accessible without password and were distributed through e-mail at randomization, by QR-code on delivered material and by SMS. The QR code enabled easy access by smartphone photo application. The videos were constructed specifically to this trial.

Part 9: DANMASK-19 Trial Overview



Part 10:

Original Protocol: DANMASK-19 Trial

Face mask for the protection against COVID-19 infection - a randomized controlled trial

Table of contents

Trial registration
ClinicalTrials.gov Identifier: NCT04337541. Registered April 7, 2020

Protocol version

This protocol **was carried out according to** *SPIRIT guidance,* Version: 1. April 7th 2020

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Name and contact information for the trial sponsor

This is a sponsor-investigator initiated study.

Background and rationale

During the present coronavirus disease-19 (COVID-19) pandemic with Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), the use of face masks have been suggested as a potential tool to slow the COVID-19 pandemic since the initial outbreak in China.[1] Currently, face masks are used in accordance with advice by national authorities leading to discrepancy across the world.[2] A major health authority as Centers for Disease and Control Prevention (CDC) in the United States recommend face covering,[3] whereas the World Health Organization (WHO) in their guidance (April 6, 2020) acknowledge that face mask may prevent spread, however as limited evidence exists on the use in the community for healthy individuals as a preventive measure for COVID-19, WHO believes that face masks should be reserved for health care workers and that masks in the community may create false sense of security with neglect of other essential measures.[4]

In Denmark, the Danish Health Authorities recommend that health care staff uses face masks when examining patients suspected of COVID-19 and when handling confirmed cases. However, the use of face mask in the community is not currently recommended due to lack of evidence in Denmark. Several challenges regarding wearing disposable face masks in the community exist. This includes practical aspects such as potential incorrect wearing, reduced compliance, reduced durability of the mask depending on kind of work, weather etc. Such circumstances may necessitate shifts of the mask during the day. Wearing a face mask may be physically unpleasant, and there may also be psychological barriers. Additionally, the wearer of a face mask may change to a less cautious behaviour due to a sense of safety as pointed out by WHO. Furthermore, the eyes of individuals carrying a face masks are still exposed. Such challenges may reduce the efficacy of the face mask to avoid viral infection.

Other health authorities around the world have different recommendations on the use of face masks[5]. Due to the current lack of evidence Shou Feng et al. concluded in the Lancet paper; ”*Universal use of face masks could be considered if supplies permit. In parallel, urgent research on the duration of protection of face masks, the measures to prolong life of disposable masks, and the invention on reusable masks should be encouraged.”* [5]

The primary transmission route of SARS-COV-2 infection is thought to be through the mouth via respiratory droplets or perhaps even through aerosols containing the virus.[6] From the mouth the virus may spread to both the airways and the intestinal canal. Moreover, it is known that SARS-COV-

2 can survive on surfaces for up to 72 hours.[6] Touching a contaminated surface may therefore be a route of transfer of the virus to the mouth or nose via the hand and thus lead to infection. A study of 26 medical students showed that they touched their face on average 23 times per hour. Furthermore, of all their facial touches, 44% involved contact with a mucous membrane.[7] A Japanese questionnaire study reported a 15% risk reduction of influenza infection when wearing a face mask.[8]

Face masks can be made by different materials and have various designs including N95 masks, surgical face masks and homemade masks.[9] A study comparing surgical face masks and homemade masks found that both masks significantly reduced the number of microorganisms, however the surgical mask was 3 times more effective in blocking transmission.[10] N95 masks (respirators) and surgical face masks are expected to have almost similar effectiveness for health care workers based on protection of infection with influenza virus.[11] A recent systematic review and meta-analysis investigated the effectiveness of N95 respirators versus surgical masks and concluded that N95 respirators compared with surgical masks is not associated with a reduced risk of laboratory confirmed influenza. They suggest that N95 respirators should be reserved for high-risk medical staff.[12] Similar results have been found in other studies.[13][14] Surgical face masks may therefore be effective against COVID-19 transmission.[15][16][17]

Thus, face masks can probably protect against virus infection in two ways:

a) By reducing the risk of virus entering the mouth or nose via respiratory droplets or aerosols.
b) By reducing face-touching with virus-contaminated fingers and hands.

Given the present knowledge it must be expected that a very large proportion of the world's population will be infected, and a substantial proportion will develop COVID-19 symptoms. I Denmark, it is estimated that approximately 10 % of the Danish populations, equivalent to 600.000 Danes, will contract COVID-19 during the current wave of the pandemic. It is assumed that several waves of COVID-19 will occur. The epidemic in Denmark expects to peek in April. During April and May estimations are that more than 2% of the population will be infected per month.

Objective

To investigate whether the use of face masks in the community will reduce the frequency of COVID-19 infection.

Research question

In a group of healthy people in the Danish community settings, will the use of masks compare to not using mask reduce the frequency of COVID-19 infection measured over a month during the peak in the epidemic?

Trial design

This study is an unblinded randomized controlled trial with a parallel study design. The two groups are randomized with an allocation of 1:1. Randomisation is by a computer algorithm and stratified by region.

Study Setting

The study will be conducted in the community setting in Denmark.

Eligibility Criteria

Adults working out-of-home with exposure to other people for more than 3 hours per day, and who have not previously been infected with COVID-19 and who are not recommended to wear face masks at work according to Danish authorities.

Inclusion criteria:

- *Older than 18 years of age and without symptoms associated with SARS-COV2 (or previously tested positive for SARS-COV2).*
- *Working out-of-home with exposure to other people for more than 3 hours per day.*
- *Do not normally wear a face mask for daily work*

Exclusion criteria:

- *Previously tested positive for SARS-COV2*
- *Have had a fever in the last month*

Registration for participation

People who are interested in participating get access to detailed project information via a link from the hospital's homepage and through this information access to project-staff in case of questions or

need of further information. If the individual then decides to participate he or she registers in RedCap Software (Tennessee, USA) through the same link and answers a survey.

Intervention description

Participants will be randomly assigned 1:1 to one of the two arms: no intervention or wearing face mask for a 30-day period.

1. **Intervention (face masks) group:**
    a. Use of surgical face mask, and encouraged to follow the authority's COVID-19 related recommendations
2. **Control group:**
    a. No use of surgical face mask, and encouraged to follow the authority's COVID-19 related recommendations

Following randomization participants will receive a package with all the relevant equipment at their home address. The equipment contains to all participants; COVID-19 IgM and IgG antibody test-kits (Livzon lateralflowtest), nasopharyngeal swab kits and detailed written instructions with a help-line phone number. Participants randomised to wearing face masks will additionally receive 50 surgical face masks with ear-loops (Type II, EN 14683, ABENA, Aabenraa, Denmark, made in CN) equivalent to a month’s usage. All participants will, guided by the written material and video instructions, conduct antibody (IgM and IgG) testing at day 0 and day 30 in addition to a nasopharyngeal swab at day 30 as well as during the period if symptoms of COVID-19 develops. At all time during the study period participants can call a hotline with medical expertise and guidance. During the period, we will send surveys to the participants on a weekly basis.

Guidance on the use of face masks are in accordance with WHO recommendations.[4] Participants in the face mask arm will be instructed in consistent use of surgical face masks outside of their home. The instruction will be given in writing and as a via video instruction. The weekly surveys will also serve to optimize compliance.

If the participants feel sick, they will self-register their symptoms in an online REDCap survey and perform a nasopharyngeal swab and send it by currier to the hospital for analysis. If the swab is positive for SARS-COV2 the participant will be referred to a hospital if relevant.

Strategies to improve adherence to interventions

Participants will be contacted once weekly to optimize compliance.

Outcomes

Primary outcome:

- The difference in number of COVID-19 infected individuals as assessed by the composite outcome of positive nasopharyngeal swap, positive antibody test and a hospital-based diagnosis of COVID-19 infection between the two study groups.

Secondary outcomes:

- Infections with other viruses detected by the nasopharyngeal swap between the study groups.
- Frequencies (and changes) in positive IgM and IgG antibody tests at start and at the end of the study period between groups.
- Participant self-assessment and level of compliance including, e.g. survey-response, returned nasopharyngeal swaps and alignment between participants self-reading of the antibody tests and our reading at the return of the tests.
- Affected household members with COVID-19 between groups.
- Cost-effectiveness analysis on the use of surgical face masks
- Frequency of sick leave between the two study groups
- The psychological impact of wearing face masks

Sample size

With an expected incidence of COVID-19 of 2% in the study period, an expected reduction of the risk to 1% by wearing face masks can be demonstrated with a power of 80% and a p-value of 5%, by inclusion of a total of 4,636 participants. With an expected fallout of 20% a total of 6,000 participants will be included.

Participant testing

Participants will, guided by video instruction, conduct antibody (IgM and IgG) testing at day 0 and day 30 in addition to a nasopharyngeal swab at day 30 as well as during the period if symptoms of COVID-19 develops. Antibody testing results will be collected through a survey. In addition, participants are to take photos of the test in order for us to clarify if test uncertainty occurs. Nasopharyngeal swab tests will be sent from the participant to the laboratory shortly following procedure.

Recruitment

We advertise for the project to private companies and to public organisations and in local and national media.

Blinding

The study is unblinded.

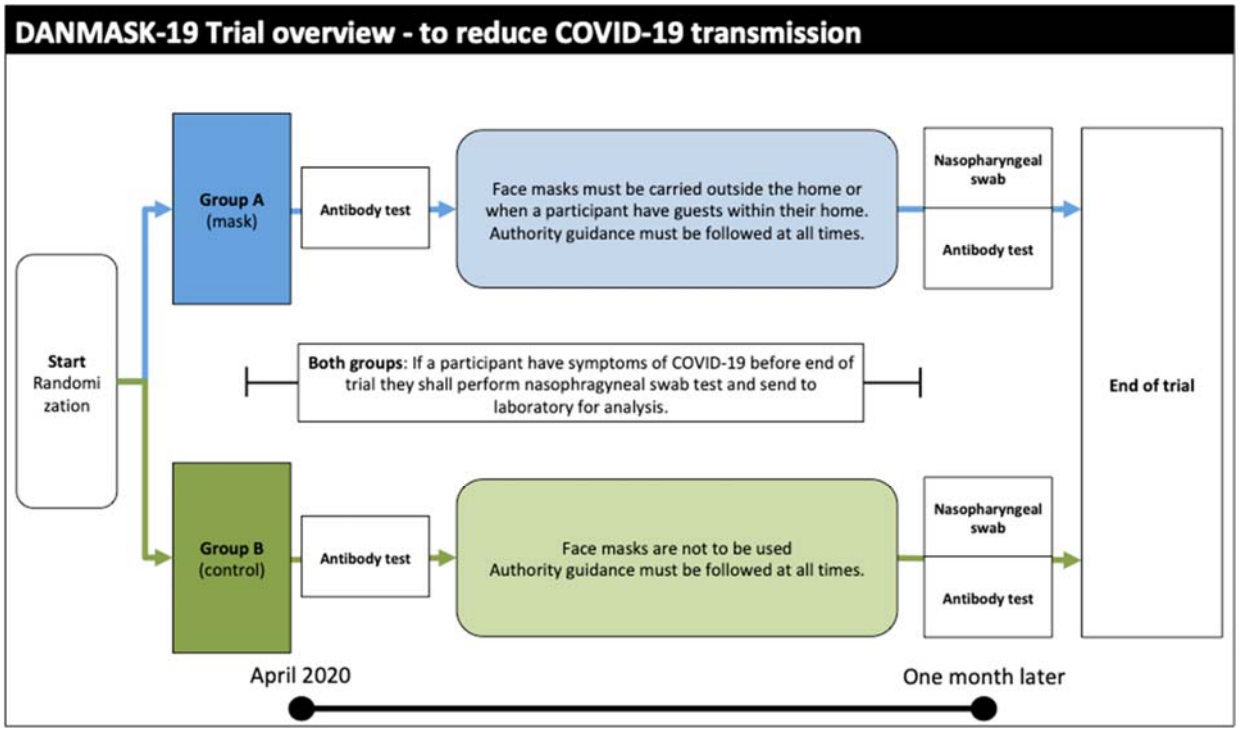
Data collection and management

All data will be collected through questionnaires and through analysis of the nasopharyngeal swaps and will be managed in REDCap.

Data management

Data will be handled in accordance with The Act on Processing of Personal Data. Data will be stored for a minimum of 10 years or 5 years after results are published.

Participant timeline



Confidentiality

Information about study subjects will be kept confidential according to Danish law.

Statistical methods

Baseline categorical variables will be presented as numbers and percentages for categorical variables and mean (SD) or median (IQR) for continuous variables, as appropriate. Differences in baseline characteristics will be compared with chi-square test for categorical variables and 2-sided t-test or Mann-Whitney test for continuous variables, as appropriate. Cumulative incident figures for outcome will be compared by the face mask group and the control group. The level of statistical significance is $p<0,05$.

Dissemination plans

Study results will be published in international peer-reviewed journals regardless of whether the trial leads to positive, negative or inconclusive results.

Trial status

Recruitment was initiated mid April and the 6.000 participants will be enrolled by late April 2020. After the last participant is enrolled a total of 30 days will pass according to the study duration.

Perspectives

The study is expected to provide evidence on whether authorities worldwide should recommend the use of face masks in the general community as a tool to impede transmission of COVID-19. If proven effective, the use of face masks has the potential to significantly contribute to reducing the spread of COVID-19 and open societies earlier. Oppositely, if proven ineffective, the current use of face masks in the general public in multiple countries is not justified. The findings from this research should contribute to the evidence of protection of face masks during this pandemic as well as future pandemics and thereby guide authorities across the world.

Declarations

The study was registered with the Danish Data Protection Authorities (P-2020-311). The study was presented to the regional scientific ethics committee of the Capital Region. The committee concluded that the study did not require a scientific ethics approval.

Availability of data and materials

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Funding

This study was funded by Salling Fondene.

Acknowledgements

Not applicable.

Literature

1. Q Wang, C Yu, Letter to editor: Role of masks/respirator protection against 2019-novel coronavirus (COVID-19). Infect. Control. & Hosp. Epidemiol., 1–7 (year?)

2. Babak Javid, Michael P Weekes and Nicholas J Matheson, Covid-19: should the public wear face masks? BMJ 2920;369:m1442 | doi: 10.1136/bmj.m1442

3. Centers for Disease Control and Prevention. How to Protect Yourself & Others, 2020 https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html

4. World Health Organization Guidelines, Advice on the use of masks in the context of COVID-19, 6 April 2020 https://www.who.int/publications-detail/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak

5. Shou Feng et al. Rational use of face masks in the COVID-19 pandemic. The Lancet Respiratory Medicine 2020 https://doi.org/10.1016/S2213-2600(20)30134-X

6. Doremalen Nv, et al. Aerosol and Surface Stability of SARS-CoV-2 as Compared With SARS-CoV-1 NEJM 2020 PMID: **32182409** DOI: 10.1056/NEJMc2004973

7. Kwok YLA et al. Face Touching: A Frequent Habit That Has Implications for Hand Hygiene Am J Infect Control 2015 PMID: **25637115** DOI: 10.1016/j.ajic.2014.10.015

8. Uchida M et al. Effectiveness of vaccination and wearing masks on seasonal influenza in Matsumoto City, Japan, in the 2014/2015 season: An observational study among all elementary schoolchildren Prev Med Rep. 2017 Mar; 5: 86–91. doi: 10.1016/j.pmedr.2016.12.002 PMCID: PMC5153448 PMID: 27981021

9. Brosseau, N95 Respirators and Surgical Masks | | Blogs | CDC (2009).

10. Davies A[1], Thompson KA, Giri K, Kafatos G, Walker J, Bennett A., Testing the efficacy of homemade masks: would they protect in an influenza pandemic?, Disaster Med Public Health Prep. 2013 Aug;7(4):413-8. doi: 10.1017/dmp.2013.43.

11. Gralton J, McLaws ML. Protecting healthcare workers from pandemic influenza: N95 or surgical masks? Crit Care Med. 2010 Feb;38(2):657-67.

12. Long Y[1], Hu T[2], Liu L[2], Chen R[3], Guo Q[1], Yang L[1], Cheng Y[1], Huang J[4], Du L[1].Effectiveness of N95 respirators versus surgical masks against influenza: A systematic review and meta-analysis. J Evid Based Med. 2020 Mar 13. doi: 10.1111/jebm.12381

13. Johnson DF[1], Druce JD, Birch C, Grayson ML. A quantitative assessment of the efficacy of surgical and N95 masks to filter influenza virus in patients with acute influenza infection. Clin Infect Dis. 2009 Jul 15;49(2):275-7. doi: 10.1086/600041.

14. Radonovich et al. N95 Respirators vs Medical Masks for Preventing Influenza Among Health Care Personnel A Randomized Clinical Trial JAMA. 2019;322(9):824-833. doi:10.1001/jama.2019.11645

15. Leung et al. Respiratory virus shedding in exhaled breath and efficacy of face masks, Nature Medicine, 2020, Brief Communication, doi.org/10.1038/s41591-020-0843-2

16. Colin J. Worby and Hsiao-Han Chang, Face mask use in the general population and optimal resource allocation during the COVID-19 pandemic, Preprint, April 2020 DOI: 10.1101/2020.04.04.20052696

17. Howard et al, Face Masks Against COVID-19: An Evidence Review. *Preprints* **2020**, 2020040203 (doi: 10.20944/preprints202004.0203.v1).

Part 11: Letter from the Ethics Committee – in Danish

Region Hovedstaden

Center for Regional Udvikling

De Videnskabsetiske Komiteer
for Region Hovedstaden
Regionsgården
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Journal-nr.: H-20023709

Dato: 26-03-2020

Reduktion af COVID-19 smitte ved brug af kirurgisk ansigtsmaske uden-for sundhedsvæsenet

Du har ved mail af 25. marts 2020 spurgt, om ovennævnte projekt skal anmeldes til det videnskabsetiske komitesystem.

I vil bede nogle af forsøgspersonerne om at bære ansigtsmasker, og I tester for Covid-19, hvis forsøgspersonerne vil. Forsøgspersonerne tager selv testen, der så indsendes til analyse.

At tage en kendt test for en kendt sygdom er ikke en sundhedsvidenskabelig intervention – det må betragtes som ren afklaring af, om man har sygdommen. Interventionen i dette projekt er derfor alene det, at nogle af forsøgspersonerne bærer ansigtsmaske. Det mener jeg er en så ubetydelig intervention, at projektet ikke er anmeldelsespligtigt, jf. komitélovens § 1, stk. 4 og kan iværksættes uden tilladelse fra De Videnskabsetiske Komiteer for Region Hovedstaden.

Der ligger således ikke i afvisningen af at bedømme projektet nogen etisk stillingtagen eller negativ vurdering af dets indhold.

Behandling af personhenførbare oplysninger er omfattet af databeskyttelsesloven/persondataforordningen. Nærmere oplysning herom findes på Datatilsynets hjemmeside.

Klagevejledning:

Afgørelsen kan, jf. komitélovens § 26, stk. 1, indbringes for National Videnskabsetisk Komité, senest 30 dage efter afgørelsen er modtaget. National Videnskabsetisk Komité kan, af hensyn til sikring af forsøgspersonernes rettigheder, behandle elementer af projektet, som ikke er omfattet af selve klagen.

Klagen skal indbringes elektronisk og ved brug af digital signatur og kryptering, hvis protokollen indeholder fortrolige oplysninger. Dette kan ske på adressen: dketik@dketik.dk.

Klagen skal begrundes og være vedlagt kopi af Den Regionale Videnskabsetiske Komités afgørelse samt de sagsakter, som Den Regionale Videnskabsetiske Komité har truffet afgørelse på grundlag af.

NB: Der må ikke foretages ændringer i dokumenterne, som har været til behandling i komiteen, da sagen ellers vil blive sendt retur til komiteen.

Med venlig hilsen

Mikael Bitsch

Formand for Komite B

Part 12: Letter from the Ethics Committee – translated into English

Reduction of COVID-19 infection by using a surgical face mask outside of healthcare

By email of 25 March 2020, you have asked whether the above project should be notified to the scientific ethics committee system.

You will ask some of the subjects to wear face masks, and you are testing for Covid-19, if the subjects are willing to participate. The subjects take the test themselves, which is then submitted for analysis.

Taking a known test for a known disease is not a health science intervention - it must be regarded as pure clarification of whether one has the disease. The intervention in this project is therefore only that some of the subjects wear face mask. I mean that is such an insignificant intervention that the project is not subject to notification, cf. section of the Committee Act 1 piece. 4 and may be initiated without the permission of the Science Ethics Committees for the Capital Region.

Thus, there is no ethical stance in the refusal to assess the project or negative assessment of its content.

Processing of personally identifiable information is covered by the Data Protection Act / Personal Data Ordinance. Further information on this can be found on the Danish Data Protection Agency's website.

Signed by the Chairman for Ethics Committee B (see above).

Supplement Table 1. Danish HealthCare Regions and Number of Participants Completing the Study per Region

The study was a nationwide randomized trial and all five Danish regions were included.

List of Regions and Number of Randomized per Site

Region	Face mask (N = 2392)	Control group (N = 2470)
Capital Region of Denmark – n. (%)	1220 (51)	1288 (52)
Region Zealand – n. (%)	300 (13)	305 (12)
Central Denmark Region – n. (%)	471 (20)	464 (19)
North Denmark Region – n. (%)	112 (5)	111 (4)
Region of Southern Denmark – n. (%)	289 (12)	302 (12)

Supplement Table 2. Other respiratory virus - secondary outcomes

Secondary Outcome between Study Groups

Virus	Face mask (N = 1934)	Control group (N = 1995)
SARS-CoV-2 – (%)	0 (0)	5 (0.25)
Para-influenza-virus type 1 – (%)	0 (0)	0 (0)
Para-influenza-virus type 2 – (%)	0 (0)	0 (0)
Human coronavirus 229E – (%)	0 (0)	0 (0)
Human coronavirus OC43 – (%)	8 (0.41)	7 (0.35)
Human coronavirus NL63 – (%)	1 (0.05)	0 (0)
Human coronavirus HKU1 – (%)	2 (0.10)	2 (0.10)
Respiratory Syncytial-Virus A – (%)	3 (0.16)	0 (0)
Respiratory Syncytial-Virus B – (%)	0 (0)	0 (0)
Influenza A virus – (%)	1 (0.05)	2 (0.10)
Influenza B virus – (%)	0 (0)	0 (0)
Secondary outcome I* – (%)	9 (0.5)	16 (0.8)
Secondary outcome II** – (%)	9 (0.5)	11 (0.6)

* Secondary outcome I - Positive oropharyngeal/nasal swab (PCR); **SARS-COV-2**, Para-influenza-virus type 1, Para-influenza-virus type 2, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Human coronavirus HKU1, Respiratory Syncytial-Virus A, Respiratory Syncytial-Virus B, Influenza A virus or Influenza B virus

** Secondary outcome II - Positive oropharyngeal/nasal swab (PCR); Para-influenza-virus type 1, Para-influenza-virus type 2, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Human coronavirus HKU1, Respiratory Syncytial-Virus A, Respiratory Syncytial-Virus B, Influenza A virus or Influenza B virus

Supplement Table 3. Symptoms During Follow-up

Symptoms During Follow-up

Symptoms	Face mask (N = 2392)	Control group (N = 2470)
Cough – n. (%)	335 (14)	404 (16)
Fever – n. (%)	53 (2)	84 (3)
Headache – n. (%)	571 (24)	687 (28)
Dyspnea – n. (%)	131 (5)	116 (5)
Muscle joint pain – n. (%)	273 (11)	322 (13)
Taste disturbance – n. (%)	50 (2)	49 (2)

Symptoms are presented as worst reported at any time point for each symptom respectively.

Supplement Table 4. Compliance, Psychological and Other Factors

Compliance, Psychological and Other Factors

Variable	Face mask (N = 2392)	Control group (N = 2470)
Face mask compliance		
Adhere – no. (%)	1098 (46)	-
Partial – no. (%)	1126 (47)	-
No – no. (%)	168 (7)	-
Worry		
Increased – no. (%)	38 (2)	96 (4)
Less – no. (%)	1016 (44)	738 (30)
Unchanged – no. (%)	1244 (54)	1588 (66)
Face mask provides assurance		
Yes – no. (%)	1141 (50)	-
No – no. (%)	955 (42)	-
Unclear – no. (%)	179 (8)	-
Reactions from other citizens regarding your wearing a face mask		
Sensible reactions from others– no. (%)	870 (38)	-
Ignore reactions from others – no. (%)	1085 (48)	-
Adverse reactions from others – no. (%)	320 (14)	-
Performed physical activity		
Less – no. (%)	887 (40)	-
Unchanged – no. (%)	1241 (57)	-
Unclear – no. (%)	69 (3)	-
Face masks used per day during weekday (mean)	1.7	-
Face masks used per day during weekend (mean)	1.3	-

Reasons for not reporting complete face mask compliance at all times during the full study period were due to wet masks (50%), work (32%) and unknown (18%). Calculated as total.

Supplement Table 5. Participants Opinion on Future Behaviour

Participants Opinion on Future Behaviour

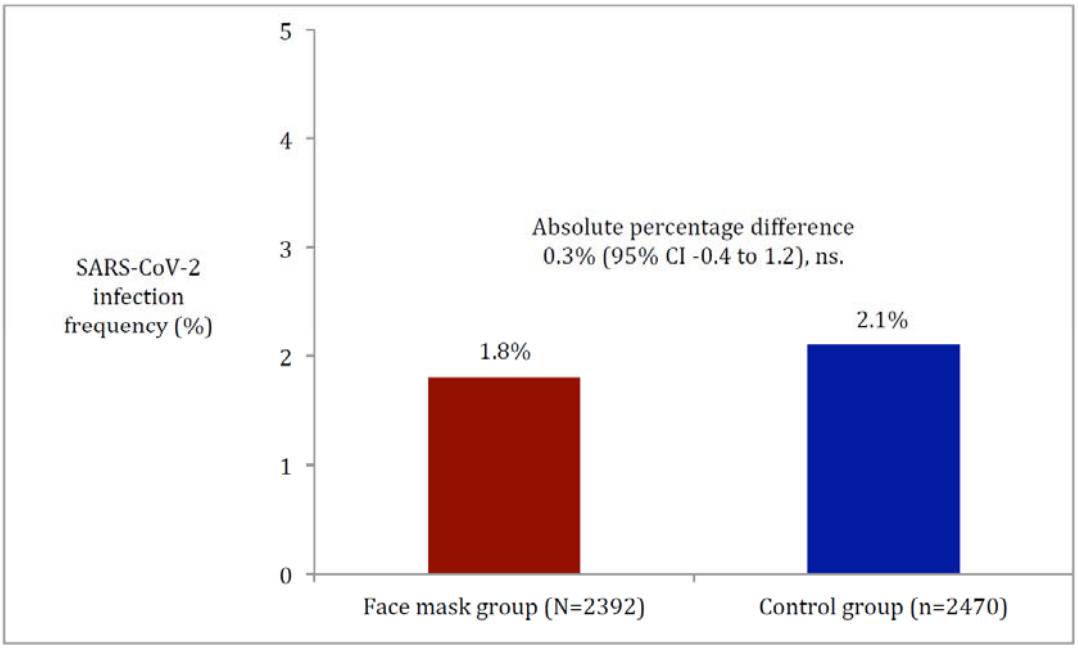
Opinion	Face mask (N = 2392)	Control group (N = 2470)
Opinion on the future use of face masks		
Yes, COVID-19	301 (14)	194 (9)
Yes, future epidemic	766 (37)	459 (21)
No	678 (32)	1117 (50)
Don´t know	350 (17)	465 (21)
Opinion on preferred setting of swab procedure		
Home (if easy with video)	901 (43)	983 (44)
Home (even though difficult)	391 (19)	397 (18)
Hospital	798 (38)	850 (38)

Supplement Table 6. Characteristics of the participants who did not finalize participation due to missing outcome by randomized group.

Characteristic	Control (N=459)	Face mask (N=569)	P Value
Mean age – yr. (SD)	42 (14.5)	42.3 (14.1)	0.68
Female sex – no. (%)	265 (57.7)	362 (63.6)	0.063
Smoking – no. (%)	123 (26.8)	155 (27.2)	0.93
Wearing eyeglasses daily – no. (%)	138 (30.1)	159 (27.9)	0.50
Capital region residents - no. (%)	222 (48.4)	305 (53.6)	0.108
Occupation			0.52
Shop employee	21 (4.6)	40 (7.0)	
Cashier	17 (3.7)	24 (4.2)	
Craftsman	29 (6.3)	29 (5.1)	
Office	52 (11.3)	59 (10.4)	
Manager	20 (4.4)	36 (6.3)	
Transport	112 (24.4)	130 (22.8)	
Service employee	20 (4.4)	35 (6.2)	
Home care / nursing home	38 (8.3)	48 (8.4)	
Kindergarten	15 (3.3)	23 (4.0)	
Sale	13 (2.8)	14 (2.5)	
Other	122 (26.6)	131 (23.0)	

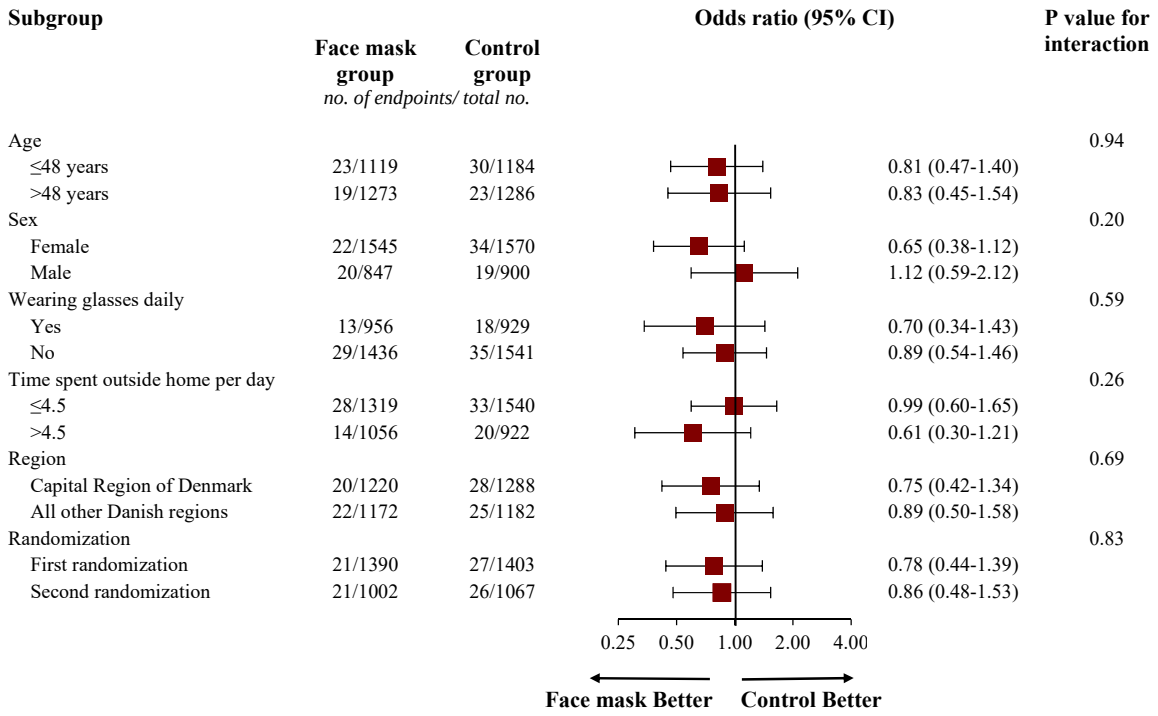
A total of 6024 participants were randomized. The multiple imputation analysis investigated imputed patients due to missing outcome. 134 patients were excluded evenly between the two groups due to study kit distribution error and not due to missing outcome.

Supplement Figure 1. Primary composite outcome



The primary composite outcome was; 1) a positive oropharyngeal/nasal swab for SARS-CoV-2, 2) SARS-CoV-2 antibody seroconversion (positive IgM and/or IgG) and/or 3) hospital-based diagnosed COVID-19 and/or identification of SARS-CoV-2, during the study period of one month during the COVID-19 pandemic. Abbreviations: SARS-CoV-2= Severe Acute Respiratory Syndrome Coronavirus 2, ns.=not significant, CI=confidence interval and n=number.

Supplement Figure 2. Rates of the Primary Outcome in Prespecified Subgroups



The primary composite outcome was; 1) a positive oropharyngeal/nasal swab for SARS-CoV-2, 2) SARS-CoV-2 antibody seroconversion (positive IgM and/or IgG) and/or 3) hospital-based diagnosed COVID-19 and/or identification of SARS-CoV-2, during the study period of one month during the COVID-19 pandemic.