Personal protective effect of wearing surgical face masks in public spaces on self-reported respiratory symptoms in adults: pragmatic randomised superiority trial

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ABSTRACT

OBJECTIVE

To evaluate the personal protective effects of wearing versus not wearing surgical face masks in public spaces on self-reported respiratory symptoms over a 14 day period.

DESIGN

Pragmatic randomised superiority trial.

SETTING

Norway.

PARTICIPANTS

4647 adults aged ≥18 years: 2371 were assigned to the intervention arm and 2276 to the control arm.

INTERVENTIONS

Participants in the intervention arm were assigned to wear a surgical face mask in public spaces (eg, shopping centres, streets, public transport) over a 14 day period (mask wearing at home or work was not mentioned). Participants in the control arm were assigned to not wear a surgical face mask in public places.

MAIN OUTCOME MEASURES

The primary outcome was self-reported respiratory symptoms consistent with a respiratory infection. Secondary outcomes included self-reported and registered covid-19 infection.

RESULTS

Between 10 February 2023 and 27 April 2023, 4647 participants were randomised of whom 4575 (2788 women (60.9%); mean age 51.0 (standard deviation 15.0) years) were included in the intention-to-treat analysis: 2313 (50.6%) in the intervention arm and 2262 (49.4%) in the control arm. 163 events (8.9%) of self-reported symptoms consistent with respiratory infection were reported in the intervention arm and 239 (12.2%) in the control arm. The marginal odds ratio was 0.71 (95% confidence interval (CI) 0.58 to 0.87; P=0.001) favouring the face mask intervention. The absolute risk difference was −3.2% (95% CI −5.2% to −1.3%; P<0.001). No statistically significant effect was found on self- reported (marginal odds ratio 1.07, 95% CI 0.58 to 1.98; P=0.82) or registered covid-19 infection (effect estimate and 95% CI not estimable owing to lack of events in the intervention arm).

CONCLUSION

Wearing a surgical face mask in public spaces over 14 days reduces the risk of self-reported symptoms consistent with a respiratory infection, compared with not wearing a surgical face mask.

TRIAL REGISTRATION

ClinicalTrials.gov NCT05690516.

WHAT IS ALREADY KNOWN ON THIS TOPIC

The effectiveness of face masks as a protective measure against infection is uncertain

Observational studies suggest that face masks reduce the risk of respiratory tract infections

Findings from randomised trials are, however, highly uncertain owing to methodological limitations such as insufficient statistical power

WHAT THIS STUDY ADDS

Our pragmatic trial provides evidence that wearing surgical face masks in public spaces reduces the incidence of self-reported respiratory symptoms consistent with respiratory infections in real world settings

Unlike most earlier trials of face mask, our study was sufficiently powered

Similar trials can and should be conducted for other public health and social measures

Introduction

As of 3 November 2023, more than 76.9 million confirmed SARS-CoV-2 infections and more than 6.9 million deaths with covid-19 have been recorded worldwide.[1] Although public health and social measures, such as wearing face masks and school closures, were widely implemented to limit the spread of the virus,[2] evidence on the effectiveness and unintended consequences of these measures is limited.[3 4]

Systematic reviews of observational studies have reported an association between wearing face masks and lower risk of respiratory infections.[5 6] On the basis of findings from 10 randomised trials, however, the authors of a recent Cochrane review concluded that use of a face mask in the community had little or no effect on risk of developing a respiratory viral infection.[7] They also noted that adverse effects were rarely measured and poorly reported.[7] Several factors could explain the seemingly discrepant findings from observational studies and randomised trials, including the higher risk of bias inherent to observational studies, insufficient power of the randomised controlled trials, or low adherence to the intervention.[7]

We carried out a pragmatic randomised trial to evaluate the personal protective effect of wearing surgical face masks in public spaces over 14 days on self-reported symptoms consistent with respiratory infection, compared with not wearing face masks.

Methods

Study design and participants

We conducted a pragmatic parallel two arm individually 1:1 randomised superiority trial. Details on the rationale, design, and statistical analysis plan can be

found elsewhere.[8 9] The trial was performed according to a published protocol, with exceptions (see Protocol Amendments section), and the principles outlined in the Declaration of Helsinki. We followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines (see supplementary material, table 1).

The trial took place in Norway between 10 February 2023 and 27 April 2023. This was after the most acute phase of the covid-19 pandemic, but during the normal influenza season in the Nordic countries.[10] No public health or social measures were enforced by Norwegian authorities on the general population during the trial.

To be eligible for inclusion, individuals had to be aged at least 18 years, be willing to be randomly assigned to either wear face masks (intervention) or not wear face masks (control) in public spaces when near to other people for a period of 14 days, and provide written informed consent (online consent form). No exclusion criteria were applied.

Participants were recruited from multiple locations across Norway, using a diverse range of methods, with participant entry occurring predominantly in three phases. The initial phase was triggered by publicity through Norwegian national TV, radio, and various media channels, including paid print advertisements. The two following phases commenced after engaging two data collection firms that invited members of their survey panels to take part in our study.

Protocol amendments

One amendment was made to the protocol before the start of the trial. In the original protocol, we proposed evaluating the effectiveness of wearing either FFP3 respirators or surgical face masks, or not wearing a mask. We revised this design in a protocol update published on 6 December 2022, narrowing the scope of the study to investigate the effectiveness of surgical face masks only. This modification was done based on sample size considerations and to simplify the procedure for trial participants and pharmacy staff. After the 14 day trial period, but before unblinding, we introduced four modifications: two sensitivity analyses were added to deal with missing data; no exploratory analysis of immune status and covid-19 was to be carried out owing to low numbers of reported covid-19 infections; the main analysis was unadjusted rather than adjusted; and we decided to primarily report the main results as odds ratios rather than risks ratios. The supplementary material provides details of the adjusted analyses and risk ratios.

Intervention

Participants in the intervention arm were assigned to wear a surgical face mask when close to people in public spaces (eg, shopping centres, streets, and public transport) over a 14 day period (mask wearing at home or work was not mentioned). These participants collected a pack of 50 three ply, disposable, surgical face masks (type II/IIR, compliant with the EN 14683 standard) from their nearest pharmacy, provided at no cost using a unique verification email. The email also contained instructions on the proper use of face masks in line with Word Health Organization (WHO) recommendations.[11] Participants assigned to the control arm were to remain mask-free when close to people in public spaces.

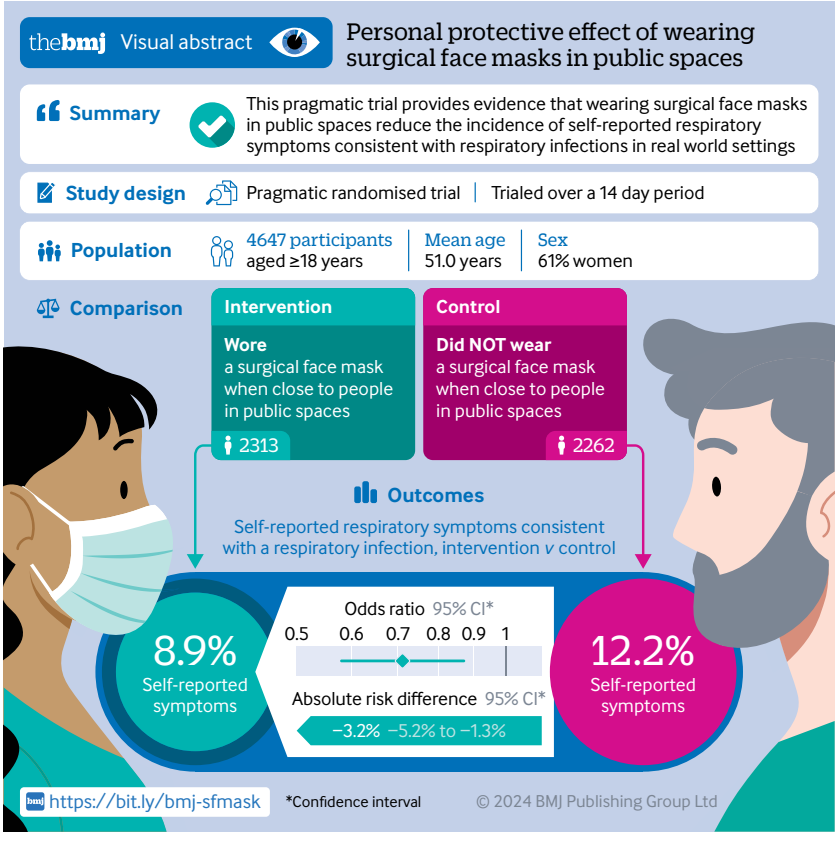
Randomisation and blinding

Eligible participants were randomised 1:1 to the intervention or control arm. We used Nettskjema, an independent web based survey tool, to randomise participants using a computer generated pseudorandom sequence over which we had no influence.[12] Randomisation occurred after consent had been obtained and the baseline survey completed.

It was not possible to blind participants owing to the nature of the intervention. The researchers and study statistician were blinded to intervention allocation throughout the trial, and all main analyses were performed blinded. After analysis but before unblinding, we agreed how we would interpret the results, including possible explanations for the degree and direction of imbalance of missing outcome data.[13]

Procedures

After consent had been obtained, trial participants immediately completed an online questionnaire about sociodemographic and lifestyle factors, beliefs about face masks and risk of infection, and face mask use in the two weeks before the study period. On completion of the questionnaire, the participants were randomised and notified of the arm to which they had been assigned both in Nettskjema and by email (see supplementary material, table 2). The email encouraged participants



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to see their doctor for a covid-19 polymerase chain reaction (PCR) test if they experienced symptoms of respiratory symptoms or covid-19. In Norway, covid-19 PCR tests were analysed by laboratories that directly notified a national registry, the Norwegian Surveillance System for Communicable Diseases. We sent a follow-up questionnaire (see supplementary material, table 3) on day 17, three days after the 14 day intervention, asking participants about outcomes, use of public transport, testing behaviours, adherence to the face mask intervention, and any adverse events. Participants identified themselves using their national identification number and therefore could be linked to the Norwegian Surveillance System for Communicable Diseases, the National Population Register, and the Norwegian Immunisation Registry.

Outcomes

Nettskjema was used to record baseline and outcome data. The primary outcome was self-reported respiratory symptoms consistent with a respiratory infection. This outcome is a composite that required participants to give a positive response to having experienced symptoms of a cold or covid-19, and having experienced fever and one respiratory symptom (stuffy or runny nose, sore throat, coughing, sneezing, heavy breathing); or one respiratory symptom and at least two other symptoms (body ache, muscular pain, fatigue, reduced appetite, stomach pain, headache, loss of smell).

Secondary outcomes were self-reported positive covid-19 test results (confirmed by either PCR or rapid antigen self-test), positive covid-19 test result registered with the Norwegian Surveillance System for Communicable Diseases, self-reported sick leave, self-reported healthcare use for respiratory symptoms (eg, visit to the family doctor), and self-reported healthcare use for any injury. All outcomes from the follow-up questionnaire, Norwegian Surveillance System for Communicable Diseases, and Norwegian Immunisation Registry were binary and assessed over a 17 day period after randomisation (days 1-17 of the trial).

Statistical analysis

We calculated that a minimum of 2692 participants (1346 in each arm) would be required to detect a risk reduction of 30% from an assumed 10% risk of infection in the control arm to a 7% risk in the intervention arm, with a two sided α of 0.05 (significance criterion) and 80% power. The power calculation is described in detail elsewhere.[8]

We estimated marginal odds ratios[14] using unadjusted logistic regression for all outcomes following the intention-to-treat principle. The intention-to-treat analysis included all eligible participants who had provided consent. We report point estimates with two sided 95% confidence intervals and P values.

As prespecified, missing primary outcome data was accounted for using multiple imputation via chained equations.[15] We imputed and analysed 50 completed datasets and combined the estimates using Rubin's rules.[16] The prespecified imputation model included intervention and all auxiliary variables collected in the baseline form.

In a non-prespecified sensitivity analysis, we estimated Manski-type bounds: best case and worst case bounds on intervention effect calculated by assuming that missing outcome data either maximally favoured wearing a surgical face mask or maximally favoured no face mask.[17] In another non-prespecified analysis, we also considered three less extreme scenarios using a method similar to the mean score method suggested by White et al (table 1).[18]

Scenario 1 assumes that the incidence of infection in the intervention arm is the same between those who did and did not drop out, but 50% lower for those who dropped out versus did not drop out in the control arm. Scenario 2 assumes that the incidence of infection in the control arm is the same between those who did and did not drop out, but 50% higher for those who dropped out versus did not drop out in the intervention arm. Scenario 3 assumes that the incidence of infection in the control arm is 50% lower for those who dropped out versus did not drop out, but 50% higher for those who dropped out versus did not drop out in the intervention arm.

The non-prespecified sensitivity analyses, including choice of scenarios, were decided on during the blinded assessment of the trial results.[13] We also performed complete case analyses, including participants with complete data at baseline and follow-up. Prespecified subgroup analyses were also performed to explore potential effect modification owing to sex (male or female), age (<30 years, 31-59 years, or ≥60 years), household includes children (yes or no), regular use of face masks (<50% of the time or ≥50% of the time), and beliefs about wearing face masks and risk of infection (reduce risk, no effect, or increase risk). We conducted all analyses using R version 4.2.2. No data monitoring committee was involved in the trial.

Patient and public involvement

Neither patients nor public representatives were involved in the design, implementation, or analysis of this study, largely due to time constraints as the trial was conducted in a window of opportunity during the influenza season. Participation in the trial was open to all adults (≥18 years) residing in Norway.

Table 1 | Three scenarios of missing outcome data on incidence of infection

	Control arm		Intervention arm	
	Did not drop out	Dropped out	Did not drop out	Dropped out
Scenario 1	Reference	50% lower	No difference	No difference
Scenario 2	No difference	No difference	Reference	50% higher
Scenario 3	Reference	50% lower	Reference	50% higher

Results

Between 10 February 2023 and 27 April 2023, 5086 individuals read the consent form. Of these, 4647 (91%) provided consent, completed the baseline form, and were randomised (2371 to the intervention arm and 2276 to the control arm; fig 1). Of those

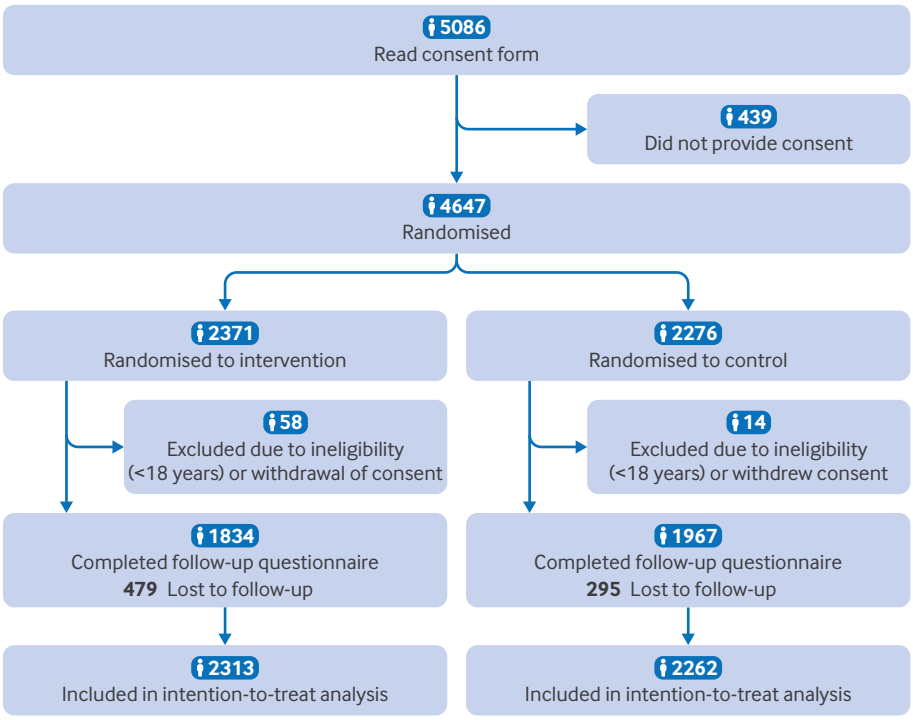

Fig 1 | Flow of participants through trial

randomised, we excluded 72 from the intention-to-treat analysis owing to ineligibility (<18 years; n=20) or withdrawal of consent (n=52). This left 4575 participants for inclusion in the intention-to-treat analysis (fig 1). At follow-up, 479 (20.7%) participants in the intervention arm and 295 (13.1%) in the control arm did not respond to the questionnaire (fig 1). Table 2 shows the baseline characteristics of the participants.

Primary outcome

Overall, 163 (8.9%) participants in the intervention arm and 239 (12.2%) in the control arm self-reported respiratory symptoms. In the intention-to-treat analysis, which used the prespecified multiple imputation via chained equations analysis and included data from 4575 participants, the estimated effect on the primary outcome of self-reported respiratory symptoms was in favour of the face mask intervention (odds ratio 0.71, 95% CI 0.58 to 0.87; P=0.001; absolute risk difference −3.2%, 95% CI −5.2% to −1.3%; P<0.001) (table 3). The complete case analysis (n=3801) supported the findings of the main analysis (odds ratio 0.71, 95% CI 0.57 to 0.87; P<0.001; absolute risk difference −3.3, 95%

Table 2 | Baseline characteristics of participants assigned to either wearing a surgical face mask or not wearing a face mask in public spaces during the day. Values are number (percentage) unless stated otherwise

Characteristics	Intervention arm (n=2313)	Control arm (n=2262)
Female sex	1423 (61.5)	1365 (60.3)
Mean (SD) age (years)	51 (15.2)	51 (16.3)
Norwegian region:		
Northern	201 (8.7)	234 (10.3)
Southern	84 (3.6)	98 (4.3)
Central	211 (9.1)	219 (9.6)
Western	503 (21.8)	578 (25.5)
Eastern	1314 (56.8)	1133 (50.3)
No of covid-19 vaccine doses received:		
0	109 (4.7)	94 (4.1)
1	27 (1.2)	25 (1.1)
2	303 (13.1)	254 (11.3)
≥3	1874 (81.0)	1889 (83.5)
No of covid-19 vaccine doses >14 days before the trial:		
None	109 (4.7)	94 (4.2)
≥1	2204 (95.3)	2168 (95.8)
No of people in household:		
1	591 (25.5)	559 (24.7)
2	907 (39.2)	988 (43.7)

(*Continued*)

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Table 2 | Continued

Characteristics	Intervention arm (n=2313)	Control arm (n=2262)
3	373 (16.2)	292 (12.9)
4	297 (12.8)	283 (12.5)
≥5	132 (5.7)	129 (5.7)
Missing	13 (0.6)	11 (0.5)
No of children in household:		
0	1654 (71.5)	1685 (74.5)
1	308 (13.3)	261 (11.5)
2-3	329 (14.2)	295 (13.2)
≥4	22 (1.0)	21 (0.9)
No of close daily contacts at work:		
0	598 (26.2)	564 (24.9)
1-4	293 (12.6)	306 (13.)
5-9	362 (15.6)	321 (14.2)
≥10	994 (42.7)	1004 (44.4)
Do not know	66 (2.9)	67 (3.0)
Beliefs about face masks and risk of infection:		
Reduce risk	697 (30.1)	655 (28.4)
Reduce risk to some extent	1335 (57.7)	1329 (58.7)
No effect	134 (5.8)	133 (5.9)
Increase risk to some extent	16 (0.7)	17 (0.8)
Increase risk	13 (0.6)	8 (0.4)
Do not know	117 (5.1)	114 (5.8)
Missing	1 (<0.1)	6 (0.3)
Time spent wearing masks two weeks before randomisation (%):		
Always (100)	25 (1.1)	21 (0.9)
Almost always (75)	39 (1.7)	32 (1.4)
Often (50-75)	42 (1.8)	61 (2.7)
Sometimes (25-50)	87 (3.8)	74 (3.3)
A few times (≤25)	217 (9.4)	220 (9.7)
Never	1898 (82.0)	1847 (81.7)
Do not know	5 (0.2)	7 (0.3)
Commute using public transport:		
No	1485 (64.2)	1447 (63.7)
Yes	799 (34.5)	780 (34.8)
Do not know	29 (1.3)	35 (1.5)

All items were answered after consenting to participate in the trial, but before allocation to intervention arm.

CI −5.2 to −1.3; P<0.001). Supplementary material, tables 5 and 6 provide details of the adjusted analysis and relative risks. The results from the adjusted analysis were essentially identical to those of the main unadjusted analysis. The non-prespecified sensitivity analyses comparing different scenarios of the missing outcome data (table 3) suggest that the intervention was effective in scenarios 1 and 2 (odds ratio 0.76, 95% CI 0.62 to 0.92; P=0.006 and 0.79, 0.65 to 0.95; P=0.01, respectively) but not in scenario 3 (0.85, 0.70 to 1.03; P=0.08). The Manski-type bounds (table 3) covered all possible missingness mechanisms and therefore included large beneficial and detrimental effects.

Secondary outcomes

Overall, 42 participants, equally distributed between the two arms, self-reported covid-19 either by PCR or antigen test (odds ratio 1.07, 95% CI 0.58 to 1.98; P=0.82; absolute risk difference 0.1%, 95% CI −6.0% to 8.0%; P=0.82) (table 3).

The Norwegian Surveillance System for Communicable Diseases registered covid-19 test results for 37 participants in the control arm and 32 in the intervention arm (n=69 (1.5%); P=0.06 for difference in proportions). Two tests were positive in the control arm and none in the intervention arm (effect estimate and 95% CI not estimable owing to lack of events in the intervention arm; table 3).

In total, 144 (6.3%) participants in the control arm and 102 (4.5%) in the intervention arm reported needing healthcare during the trial. Of these participants, 29 (20%) in the control and 23 (23%) in the intervention arm reported that this was due to respiratory symptoms, whereas 40 (28%) participants in the control arm and 27 (26%) in the intervention arm reported other reasons.

Adherence

Among participants in the intervention arm, 450 (25%) reported always wearing a face mask, 753 (41%) wearing face masks more than 75% of the time, 265 (14%) wearing face masks 75-50% of the time, and 357 (19%) wearing face masks less than 50% of the time. Among participants in the control arm, 1865 (95%) reported not wearing face masks.

At follow-up, the percentage of participants who reported commuting to work by public transport was comparable between the control and intervention arms (60% and 58%, respectively; P=0.32). Attendance at

Table 3 | Effects of wearing a surgical face mask on primary and secondary outcomes. Values are number (percentage) unless stated otherwise

	Participants		Marginal odds ratio* (95% CI)	P value	Absolute risk difference† (% (95% CI)
	Intervention arm (n=2313)	Control arm (n=2262)			
Prespecified primary outcome					
Self-reported respiratory symptoms	163/1834 (8.9)‡	239/1967 (12.2)‡	0.71 (0.58 to 0.87)§	0.001§	−3.2 (−5.2 to −1.3)§
Prespecified secondary outcomes					
Self-reported covid-19 (complete case analysis)	21/1834 (1.1)	21/1967 (1.1)	1.07 (0.58 to 1.98)	0.82	0.1 (−6.0 to 8.0)
Registered covid-19 (complete case analysis)	0/1834¶ (0)	2/1967¶ (‹0.1)	NE**	›0.99	NE**
Non-prespecified sensitivity analyses					
Self-reported respiratory symptoms (complete case analysis)	163/1834 (8.9)	239/1967 (12.2)	0.71 (0.57 to 0.87)	0.001	−3.3 (−5.2 to −1.3)
Manski-type bounds††	163/2313 (7.1) to 642/2313 (27.8)	239/2262 (10.6) to 534/2262 (23.6)	0.64 to 1.24 (0.52 to 1.42)	NA	NA
Scenario 1‡‡	206/2313 (8.9)	257/2262 (11.4)	0.76 (0.63 to 0.92)	0.006	NA
Scenario 2§§	227/2313 (9.8)	275/2262 (12.2)	0.79 (0.65 to 0.95)	0.01	NA
Scenario 3¶¶	227/2313 (9.8)	257/2262 (11.4)	0.85 (0.70 to 1.03)	0.08	NA

CI=confidence interval; NA=not applicable; NE=not estimable.
*Value ‹1 favours intervention arm (wearing surgical face mask).
†Value ‹0 favours intervention arm (wearing surgical face mask).
‡Events from complete case dataset.
§Intention-to-treat analysis values represent pooled estimates from 50 imputed datasets.
¶Data notified to Norwegian Surveillance System for Communicable Diseases.
**Confidence interval could not be calculated using logistic regression owing to lack of events in intervention arm.
††Best case and worst case bounds on treatment effect were calculated by assuming that missing outcome data either maximally favoured wearing a surgical face mask or maximally favoured no face mask.
‡‡Assumes that incidence of infection in the intervention arm was the same between those who did and did not drop out, but 50% lower for those who dropped out versus did not drop out in the control arm.
§§Assumes that incidence of infection in the control arm was the same between those who did and did not drop out, but 50% higher for those who dropped out versus did not drop out in the intervention arm.
¶¶Assumes that incidence of infection was 50% lower in the control arm for those who dropped out versus did not drop out, but 50% higher for those who dropped out versus did not drop out in the intervention arm.

cultural events was, however, more frequent among participants in the control arm compared with those in the intervention arm (39% and 32%, respectively; P<0.001). Similarly, a larger percentage of participants in the control arm (62%) visited restaurants compared with those in the intervention arm (53%; P<0.001).

Adverse effects

In total, 155 participants (3.4%; 143 in the intervention arm) reported adverse effects, with 128 participants describing these experiences using the free text field in the questionnaire. The most reported adverse event (80 participants) was unpleasant comments from other people when wearing a face mask in public spaces and feeling "silly" being the only one wearing a face mask in public. Some participants (n=40) reported that wearing face masks was uncomfortable or tiring owing to difficulty breathing, fogging of glasses, and poor fit.

Subgroup analyses

Figure 2 shows results for the prespecified subgroup analyses. The only analysis for which significant effect modification was estimated was for participants' beliefs about wearing face masks and risk of infection (P=0.04 for interaction). A beneficial effect was estimated for participants who reported that they believed face masks reduced the risk of infection. Estimates for participants who reported that they believed face masks had no effect or increased risk were consistent with benefit, no effect, and harm. However, owing to the small number of events in these subgroups, the confidence intervals were wide and therefore these estimates lack precision.

Discussion

We found that wearing surgical face masks in public spaces reduced the risk of self-reported respiratory symptoms among Norwegian adults. The results support the claim that face masks may be an effective measure to reduce the incidence of self-reported respiratory symptoms consistent with respiratory tract infections, but the effect size was moderate. With a 12.2% risk of being infected and an absolute risk reduction of −3.2% (95% CI −5.2% to −1.3%), wearing a face mask reduced the risk to 8.9%, equivalent to around 3300 fewer infections per 100 000 people. Wearing face masks in public spaces was safe and generally well tolerated. The most reported adverse effects were unpleasant comments from other people.

Comparison with other studies

Our findings are consistent with the two randomised trials of face masks conducted during the covid-19 pandemic. Although the Danish face mask trial from 2020 was similar in many respects to ours, a major difference was it used a positive covid-19 result based on rapid antigen testing as the main outcome, whereas we relied on self-reporting of respiratory symptoms.[19] The Danish trial reported a point estimate similar to ours, but its findings were uncertain study owing to low statistical power (odds ratio 0.82, 95% CI 0.54 to 1.23). In a trial in Bangladesh, 600 rural villages were randomised to face mask promotion strategies or no intervention at community level.[20] The trial reported a smaller, but statistically significant reduction in symptomatic seroprevalence at nine weeks (adjusted prevalence ratio 0.91, 95% CI 0.82 to 1.00) in favour

Subgroup	No/total No in group: Intervention group	Control group	Odds ratio (95% CI)	Odds ratio (95% CI)	P value
Sex					
Male	52/703	72/783		0.79 (0.54 to 1.14)	
Female	111/1131	167/1185		0.66 (0.51 to 0.86)	0.45
Age group (years)					
<30	33/212	44/218		0.73 (0.44 to 1.20)	
30-60	108/1062	155/1112		0.70 (0.54 to 0.91)	
>60	22/560	40/638		0.61 (0.35 to 1.03)	0.88
Household includes children					
Yes	102/1311	167/1479		0.66 (0.51 to 0.86)	
No	61/523	72/489		0.76 (0.53 to 1.10)	0.53
Regular use of face masks					
<50% of time	9/83	22/86		0.35 (0.15 to 0.80)	
>50% of time	154/1747	216/1875		0.74 (0.60 to 0.92)	0.87
Beliefs about face masks and risk of infection					
Reduce risk	140/1622	222/1735		0.64 (0.51 to 0.80)	
No effect	20/188	14/209		1.66 (0.82 to 3.45)	
Increase risk	3/23	3/22		0.95 (0.16 to 5.69)	0.041

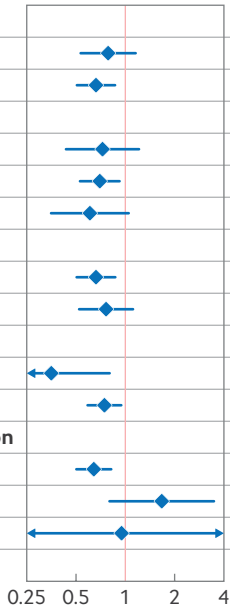

Fig 2 | Prespecified subgroup analysis on the intervention effect of wearing surgical face masks

of face mask promotion.[20] Compared with the earlier face mask trials, our findings provide a more precise estimate of effect. When our study is compared with not only the earlier face masks studies to prevent covid-19, but also the face mask studies for influenza prevention, our findings indicate a somewhat larger effect.[3 7]

The proposed mechanisms of action for face masks include limiting droplet and aerosol transmission.[21] We decided to evaluate the effect of surgical face masks that were recommended by WHO during the covid-19 pandemic.[22] It has been presumed that FFP2 masks (N95 by American standards) protect people better than surgical masks because of their higher filtering rate, but randomised trials[23] and meta-analyses[24 25] suggest that surgical masks offer similar protection to FFP2/N95 masks in healthcare settings. We did not, however, study mechanisms of action or effectiveness in healthcare settings.

Limitations of this study

Our trial has several limitations. Firstly, outcome data were missing for 13.7% and 20.7% of the participants in the control arm and intervention arm, respectively. This is broadly similar to the 19% missing outcome data in the Danish face mask trial.[19] We mitigated the impact of missing outcome data by prespecifying and using multiple imputation. Since it is plausible that the imbalance in missing data was due to outcome (ie, outcome data may be missing not at random), we performed non-prespecified sensitivity analyses to explore whether our main finding was robust to more extreme assumptions about missingness. Only under extreme and arguably implausible assumptions (eg, scenario 3 and the upper end of the Manski-type bounds) do the non-prespecified sensitivity analyses suggest that the intervention is not beneficial.[13] Moreover, the estimate from multiple imputation is similar to the complete case estimate.

Secondly, our primary outcome was self-reported rather than an objective outcome or based on immunological biomarkers. Although an outcome based on a PCR test result would have provided more specific information about infections, our primary outcome assessed symptoms that are important to both individuals and the public in a real world setting. For example, self-reported respiratory symptoms had important consequences during the covid-19 pandemic, such as denial of air travel. We encouraged our participants to take a covid-19 test when they felt unwell, but testing was neither mandatory nor recommended at the time of our trial, and the number of participants taking a test was low.

Thirdly, blinding of participants was not possible owing to the nature of the intervention and it is not intended in a pragmatic trial aiming to provide evidence in a real world setting. However, we cannot deny that awareness of intervention allocation may have introduced bias in reporting of symptoms either way. The group allocation might also have led to additional effects on participants' behaviour. For instance, a higher proportion of participants in the control arm reported attending cultural events and restaurants during the trial period. Furthermore, some participants in the intervention arm reported feeling awkward wearing face masks when there was no official requirement to do so. This finding may imply

that non-participants tended to keep a larger social distance from participants in the intervention arm, which could be seen as an inherent effect of wearing face masks.

Fourthly, our results apply under trial conditions and therefore caution is needed when generalising the findings to other settings. The duration of our trial period was only 14 days, so our findings might not apply to situations where face masks are used for longer periods. The most acute phase of the covid-19 pandemic was over when we conducted our study, but the trial period occurred during a normal influenza season in the Nordic countries.[10]

Fifthly, although we acknowledge environmental concerns associated with face mask usage (eg, manufacture and transport emissions, littering, landfill), these were not measured in our study.

Finally, we focused on evaluating the personal protective effects of wearing surgical face masks, specifically examining how effectively they safeguard wearers against infection. We did not study source control (preventing the spread of infection from the mask wearer to other people). The total effect of wearing face masks, including both personal protection and source control, therefore could be higher than our findings suggest.

Strengths of this study

Study strengths include the pragmatic randomised design, prespecified analyses, and transparent treatment of missing outcome data, which included non-prespecified sensitivity analyses.[17 18] Trial staff were blinded. The outcomes we studied are likely important to individuals as well as from a public health perspective. People could participate regardless of where they lived in Norway, an approach that allowed broad recruitment, and probably increased the wider applicability of our findings. The results from our trial represent real world evidence on the effect of wearing surgical face masks. Similar trials should consider investigating other public health and social measures.

Future research should study face masks for source control. Research should also concentrate on the protective effectiveness of face masks for vulnerable populations, such as elderly people and individuals with pre-existing health conditions. For example, people with lung disease are typically at higher risk of respiratory tract infections, so the benefits of wearing face masks for personal protection need to be weighed against potential adverse effects, such as discomfort and breathing difficulties. It is vital to explore alternatives to single use masks that are sufficiently effective but minimise environmental harm, tackling the ecological problems linked to extensive and long term face mask use, as occurred during the covid-19 pandemic. Finally, future studies should consider including cost-benefit analyses.

Conclusion

Wearing surgical face masks is superior to not wearing surgical face masks in reducing the risk of respiratory symptoms over 14 days. The effect size was moderate, but wearing a face mask is a simple intervention with low burden and of relatively low cost and is one of several public health and social measures that may be worth considering for reducing the spread of respiratory infections.

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Ethical approval: This study was approved by the Regional Ethics Committee South East Norway (reference 36544).

Data sharing: The final anonymised trial dataset and statistical codes will be freely available to the public through GitHub (https://github.com/folkehelseinstituttet/2024-facemask-trial-bmj).

Transparency: The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and if relevant, registered) have been explained.

Dissemination to participants and related patient and public communities: The advisory board of our research centre, which includes representatives from various civil society organisations (eg, Norwegian Pensioners' Association) will be invited to engage in the dissemination of the findings. The research findings will be disseminated via press release through several of the National Institute of Public Health channels. We will also disseminate the findings on social media, in Norwegian and international newspapers, on television, at academic conferences, and to relevant patient and public organisations. Finally, we will inform every trial participant by email of the trial findings.

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Supplementary information: Supplementary material, tables 1-5