Journal of Infection 91 (2025) 106557

Contents lists available at ScienceDirect

Journal of Infection

journal homepage: www.elsevier.com/locate/jinf

Infectious Disease Practice

Impact of distribution of facemasks on community incidence and outcomes of COVID-19: A cluster randomised trial in India

Poppy A.C. Mallinson [a,*,1], Teena Dasi [b,1], Santosh Kumar Banjara [b], Judith Lieber [c], Santhi Bhogadi [d], Srivalli Addanki [d], Prasad Undrajavarapu [b], Subhash Masapeta [b], Hemant Mahajan [b], Bharati Kulkarni [b,e], Sanjay Kinra [a]

[a] Department of Non-Communicable Disease Epidemiology, London School of Hygiene & Tropical Medicine, UK
[b] Clinical Division, Indian Council of Medical Research-National Institute of Nutrition, India
[c] Department of Medical Statistics, London School of Hygiene & Tropical Medicine, UK
[d] Indian Institute of Public Health Hyderabad, India
[e] Reproductive and Child Health and Nutrition, Indian Council of Medical Research, India

ARTICLE INFO

Article history:
Accepted 18 July 2025
Available online 23 July 2025

Keywords:
COVID-19
Randomised controlled trial
Facemasks
India
Respiratory viruses
Infection prevention and control

SUMMARY

Background: Randomised evidence on the effectiveness of delivering facemasks for reducing the health impact of COVID-19 remains limited.
Methods: We conducted a cluster randomised trial in Telangana, India, in August–November 2020 to investigate whether distribution and promotion of facemasks in villages reduces the incidence and adverse outcomes of COVID-19. We randomised 20 villages from the ongoing APCAPS surveillance study (1:1 ratio) to village-wide distribution of 3-layer cloth facemasks along with promotional messaging, or no intervention. Outcomes were incidence of notified COVID-19 (primary), hospitalised COVID-19 and all-cause mortality (secondary), collected through household surveillance by village health workers. Mask wearing was assessed through standardised observations in village centres. Data were analysed by multilevel Poisson regression.
Findings: Use of the study facemasks and any face coverings in public spaces was higher in intervention villages (19% and 59%, respectively) than control villages (0% and 38%). In the 10 intervention (N=16,741 adults) and 10 control villages (N=15,278 adults), respectively, the crude incidence per thousand person months (number of events) of notified COVID-19 was 2.15 (n=144) and 2.45 (n=150), of hospitalised COVID-19 was 0.07 (n=5) and 0.21 (n=13), and of all-cause mortality was 0.91 (n=61) and 1.10 (n=67). In models accounting for age, sex and pre-intervention COVID-19 rate, rate ratios in intervention versus control villages were 0.96 (95% confidence interval 0.57–1.63) for COVID-19 cases, 0.36 (0.12–1.05) for COVID-19 hospitalisations, and 0.84 (0.55–1.29) for all-cause mortality. No adverse effects were reported.
Interpretation: We are unable to draw firm conclusions about the effect of village-wide distribution and promotion of facemasks on COVID-19 incidence from these data due to a low number of events leading to imprecise effect estimates. Nonetheless, our findings are consistent with the modest protective effect on incident cases seen in previous randomised trials, extending these to adverse outcomes for the first time.
Registration: The trial was pre-registered on the Clinical Trials Registry of India on 25/07/2020 (CTRI/2020/07/026796).

Introduction

Use of facemasks in public spaces was widely adopted as an infection prevention and control measure in response to the global COVID-19 pandemic of 2020–2023. More than 80% of countries enforced a mandate to wear facemasks in public spaces during this period.[1] The World Health Organisation's (WHO) COVID-19 guidelines strongly recommended use of facemasks by the general public in public

* Correspondence to: Department of Non-Communicable Disease Epidemiology, London School of Hygiene & Tropical Medicine, Keppel Street, London WC1E 7HT, UK.
E-mail address: poppy.mallinson1@lshtm.ac.uk (P.C. Mallinson).
[1] Contributed equally.

https://doi.org/10.1016/j.jinf.2025.106557

spaces that were crowded, enclosed or poorly ventilated, and tentatively recommended them in public spaces if COVID-19 cases were increasing or population susceptibility was high (e.g. low vaccination coverage).[2] Facemasks are believed to prevent the spread of respiratory illnesses by forming a physical and electrostatic barrier that blocks the transfer of droplets containing infectious particles via two routes – from the nose or mouth of an infectious person, and into the nose or mouth of a susceptible person.[3] They may also act through behavioural mechanisms, for example by providing visual cues to maintain physical distancing or respiratory etiquette.[4] These mechanisms, coupled with the fact that COVID-19 can be spread by asymptomatic carriers,[5] suggest that facemasks could be most effective when adopted at a community-wide scale.[3]

Despite near universal adoption into policy and plausible mode of action, evidence from randomised trials that facemasks can reduce incidence of COVID-19 remains limited.[6] A large cluster randomised trial in Bangladesh found that communities allocated to a facemask distribution programme had lower incidence of symptomatic COVID-19 than control communities, noting a modest ~9% reduction in incidence (rate ratio 0.91, 95% confidence interval 0.82–1.00).[7] A cluster randomised trial in Guinea Bissau found that distributing cloth facemasks to urban clusters was associated with a ~19% reduction in self-reported symptomatic COVID-19, although this difference was not statistically robust (odds ratio 0.81, 95% confidence interval 0.57–1.15), and overall facemask usage hardly differed between trial arms.[8] Two trials randomised individuals, rather than communities, to receive surgical masks to wear in public; the DANMASK-19 trial reported a non-significant 18% reduction in SARS-CoV-2 antibodies at one month (odds ratio 0.82, 95% confidence interval 0.54–1.23), while a trial in Norway reported very uncertain evidence for self-reported COVID-19 due to few cases, but a statistically robust decrease in self-reported respiratory symptoms (odds ratio 0.71, 95% confidence interval 0.58–0.87).[9,10] A 2023 Cochrane review of community-based trials of surgical masks for preventing viral respiratory illnesses (from any virus) reported a pooled risk ratio of 0.95 (95% confidence interval 0.84–1.09), but found no studies of adverse outcomes such as hospitalisation or death.[11] Given this uncertainty in the trial evidence, further data from randomised trials are needed to inform policymaking in future outbreaks of COVID-19 variants and potentially other viral infections.

We report the results of a cluster randomised trial examining whether community-wide distribution and promotion of facemasks reduced the community incidence and outcomes of COVID-19 in a rural population in Telangana state, India.

Methods

Study design

This was a parallel-arm cluster randomised trial in which 20 villages in Telangana State, India, were allocated to receive community-wide distribution of three-layer cotton facemask along with promotional messaging to wear facemasks, or no intervention, in a 1:1 ratio. The trial took place between 1st August 2020 and 30th November 2020, which encompassed much of the first wave of COVID-19 in this region. The trial was pre-registered on 25/07/2020 on the Clinical Trials Registry of India (CTRI/2020/07/026796), which is part of the World Health Organization's International Clinical Trials Registry Platform (URL: https://trialsearch.who.int/Trial2.aspx?TrialID=CTRI/2020/07/026796). This study is reported in accordance with the Consort 2010 Statement extension to cluster randomised trials.

Protocol amendments

We made the following changes to the methods of the trial after recruitment started, but before trial data was compiled and analysed: Amended the follow-up duration from 6 months to 4 months based on absence of new COVID-19 cases in the study area from late November 2020; and dropped initial plans to do more detailed follow-up including serological testing on a sub-sample of ~10,000 participants (members of an ongoing cohort study), because of being unable to re-start in-person clinical data collection until over a year later than anticipated.

Participants

The study setting was a geographically contiguous area of Ranga Reddy district in Telangana state, India, comprising 28 villages near to Hyderabad city. These villages are the site of the ongoing APCAPS Cohort (described in detail previously[12,13]) with whom the research team have close existing relationships, allowing us to rapidly implement this research study. The villages are close-knit social and administrative units which provided a natural cluster at which to deliver the facemask distribution intervention. Eligibility criteria for villages included: a population of < 8000 people (as it would not be feasible to make enough facemasks for the two largest APCAPS villages), no ongoing mask distribution programme (as this could make it difficult to estimate the effect of our intervention), and village leaders consenting to being part of the study (including to being randomised which meant that they may not receive any intervention). Eligibility criteria for participants was that they were adults (aged 20 years or over). We used an intention-to-treat approach, meaning that all adult resident of the included villages were considered part of the trial, with no specific exclusions. Written informed consent to participate was provided by village leaders of each village prior to randomisation, and from community health workers who were contacted to provide village-level outcome information.

Interventions

The trial intervention consisted of distribution of cotton facemasks to village residents along with promotional messaging around their use displayed in village centres. The study facemasks were purpose-made, reusable, 3-layer cotton facemasks with recognisable colours/designs. We opted for 3-layer cotton facemasks as they are re-useable and comfortable, could be rapidly made locally, and according to laboratory studies have similar effectiveness to surgical masks in blocking the expulsion of particles during simulated coughing or breathing.[2,14,15] Much higher levels of filtration efficacy can be achieved by medical grade fitted respirators, such as KN95 respirators, however these require training and fit testing to be worn correctly and are prioritised for healthcare settings, so are generally not promoted for widespread use by the public.

We delivered the study facemasks (1–2 per adult resident) to village leaders, who were asked to distribute them at central village locations and door-to-door with the help of community health workers, until all households had received their allocation of masks. They were asked to inform village residents of the importance of wearing facemasks in public places. We also provided posters to be displayed in village centres with reminders to wear the masks and information on how to correctly wear and wash the facemasks. Facemasks (n=29,400) were delivered to the intervention villages between 1st August 2020 and 3rd September 2020. Posters were put up at the same time as facemasks delivery and remained in place throughout the trial period. Villages in the control arm received no intervention.

To monitor distribution of facemasks, the study team contacted village leaders regularly until they reported that all masks had been distributed to village residents. Distribution status reported by village leaders was cross-checked through phone calls to selected residents and health workers. To monitor the usage of facemasks in

public spaces, we conducted standardised observations monthly in all study villages. Members of the research team sat in a parked car in view of the village market (a central congregation point for each village), and for 30 min counted the number of people leaving the market area wearing: i) no mask, ii) improvised face covering of scarf/flannel, iii) the study's cotton facemasks (distinguished by a unique recognisable design), iv) other reusable facemasks, v) surgical/disposable masks, and vi) other face coverings. At the start, middle and end of each observation, they took a standardised set of photographs for coding by an independent reviewer (blinded to village intervention status), to check the quality of the fieldworker observations.

The context surrounding delivery of our intervention was that there were no lockdown orders in place over this period, but public messaging and awareness about COVID-19 prevention measures were widespread, with face coverings recommended in crowded spaces.

Outcomes

The primary outcome was incidence of notified COVID-19 as confirmed by a positive COVID-19 test result at Primary Health Centres. Secondary outcomes were incidence of hospitalised COVID-19 (defined as any notified COVID-19 case admitted to hospital for at least one night), all-cause mortality (defined as any death reported in study villages by village health workers), and a composite outcome of either hospitalised COVID-19 or all-cause mortality.

The source of outcome data for the trial was surveillance information collected by village health officials as part of their ongoing COVID-19 surveillance. During the study period, the Telangana state Department of Public Health and Family Welfare was implementing a surveillance system of active community case-finding by village health workers. This involved village health workers making regular visits to all households in study villages to identify symptomatic cases, who were asked to attend Primary Healthcare Centres (along with any known contacts) for follow-up testing (by polymerase chain reaction or rapid antigen tests). To gather this data, we telephoned village health workers from each study village on a weekly basis between 1st August and 30th November 2020 (obtaining information retrospectively for June/July 2020), recording for each positive COVID-19 test, the date, age and sex of the person, and whether they were hospitalised because of COVID-19. We collected similar information on the deaths occurring in the village each week, which the village health workers were also responsible for reporting to local health authorities. To confirm the completeness of this data, we were also granted access to consolidated records from the Primary Healthcare Centres serving the study villages on a monthly basis. We continuously monitored agreement between these two data sources and resolved any discrepancies by following-up with Primary Healthcare Centres and cross-checking patient demographic information.

Denominator data used to calculate incidence rates of the outcomes in the study villages was estimated from a household survey conducted by research team in 2011–13 in which we visited every household in the villages and recorded demographic information on all residents. Using this data as our base population, we used the cohort component method to project population size and age/sex distribution to 2020,[16] assuming age-specific fertility and mortality rates and sex-ratio at birth for the state of Telangana (available from https://censusindia.gov.in/census.website/data/).

Randomisation and blinding

Randomisation was done using a simple web-based randomisation tool to generate a random ordering of ten 1 s and ten 0 s which was applied to the list of study villages, resulting in 10 intervention and 10 control villages. Randomisation was done after leaders from each study village had consented, ensuring concealment of allocation. The random allocation sequence was generated and assigned to clusters by a statistician on the trial team who was not involved with trial implementation, and then handed to the local field team coordinator to deliver the intervention accordingly.

Village leaders, healthcare officials and residents who received the intervention were not blinded to their allocation status, as this was not possible. The field team implementing the intervention and conducting standardised observations were also not blinded for the same reason (although quality checking of photographs by an independent reviewer was blinded). We used a system of anonymised village identification numbers to ensure that all other research staff were blinded, including the local research team responsible for collecting the outcome data from village healthcare officials, the senior research staff responsible for decision making for the trial, and the statistical analysts, up until the point when the final analysis models had been run.

Statistical methods

Incidence rate of each study outcome from August to November 2020 were compared between intervention and control villages using multilevel Poisson regression with random intercept at the village level. The data were structured at village level, further disaggregated by gender (male or female) and age categories (5-year age bands), with number of cases modelled as the outcome and person-months included as an offset term (assuming each resident contributed four months of person-time). Rate ratios were obtained by exponentiating the model coefficients for the fixed effect of trial arm, while predictive margins were used to obtain rate differences. In addition to crude models which contained only trial arm as a fixed effect, we estimated adjusted models including gender, age (as a cubic spline), and pre-intervention rate of notified COVID-19 (June to July 2020), (except for hospitalised COVID-19 where we could only adjust for age (as a linear term) due to the small number of events). Standard errors were clustered at the village level in all models.

As a sensitivity analysis, analyses were repeated with data collapsed to the village level, with village-level rates compared by Poisson regression with robust standard errors (an alternative to linear regression which avoids estimation of negative bounds for estimated incidence rates). We fitted crude and adjusted models, adjusting for pre-intervention COVID-19 incidence rate, proportion of village residents who were female, and proportion who were aged over 65 years (except for hospitalised COVID-19 where again we could only adjust for age).

All analyses were conducted on an intention-to-treat basis, that is, intervention status was determined based on randomisation rather than whether they actually received or used the facemasks.

Analyses were conducted using Stata SE (Version 17.0).

Sample size

At the time of planning of the study, in the very early stages of the COVID-19 pandemic, we did not have reliable data to estimate the incidence rate of COVID-19 in this population during the study period. We calculated that, based on being able to procure enough facemasks for 10 intervention villages (~25,000 facemasks), randomising a total of 20 villages would give us 80% power at 5% significance level to detect an effect size of 0.33 (from the latest systematic review of medical or cotton facemasks for preventing coronaviruses versus no facemask[17]) if there was a cumulative incidence of 15% in the control villages. We felt this scenario was plausible given that the Indian population was facing its first widespread exposure to COVID-19 following the lifting of severe lockdown restrictions from April 2020 onwards, and rates of

seropositivity as high as 28% had been observed in Northern Italy early in the pandemic.[18] This calculation assumed an intra-cluster correlation coefficient (ICC) of 0.068, the most conservative ICC reported in a previous cluster trial of facemasks to prevent respiratory illness.[19]

Ethical approval

Ethical approval for this trial was granted by the Indian Council of Medical Research-National Institute of Nutrition Institutional Ethics Committee on 17/07/2020 (reference 05/I/2020, approved protocol p1–4 and consent forms p8–22 in trial supporting information). Written informed consent to participate was provided by village leaders of each village prior to randomisation, and from community health workers who were contacted to provide village-level outcome information.

Role of the funding source

The facemasks for the study intervention were manufactured and delivered to study sites by a local non-governmental organisation, who had no role in the study design, analysis, or decision to publish the manuscript. In-kind support in the form of overhead resources was provided by the Indian Council of Medical Research-National Institute of Nutrition.

Results

Ten villages were randomised to the intervention arm and ten to the control arm, with a total estimated population of 32,019 adults (16,741 in intervention and 15,278 in control, Fig. 1). The mean age of adults in the study population was 42 years (standard deviation 15 years). Baseline characteristics were comparable between intervention and control villages, with a mean size of 1674 and 1528 adult residents in each village, 9.9% and 10.9% aged over 65 years, 49% and 49% female, and 40 km and 44 km from Hyderabad city, respectively (Table 1). The incidence rate of notified COVID-19 in June and July 2020 (before the intervention) was 1.14 per 1000 person months in intervention villages, and 1.07 per 1000 person-months in control villages.

Our standardised observations at four timepoints during the follow-up period suggest that up to 26% of the intervention village residents visiting public spaces at any one time were using the study's facemasks (compared to 0% in the control villages) (Table 2). Wearing of any sort of mask or face-covering (including study facemasks) averaged 59% in the intervention villages compared with 38% in control villages ($p < 0.001$). We noted that most of the non-study face coverings were improvised cloths tied around the face rather than medical or surgical masks. The proportion observed wearing any face covering was similar between trial arms towards the start of the intervention period (~55% at week 3). Across the 4-month study period, mask-wearing increased slightly in the intervention arm while decreasing substantially in the control arm.

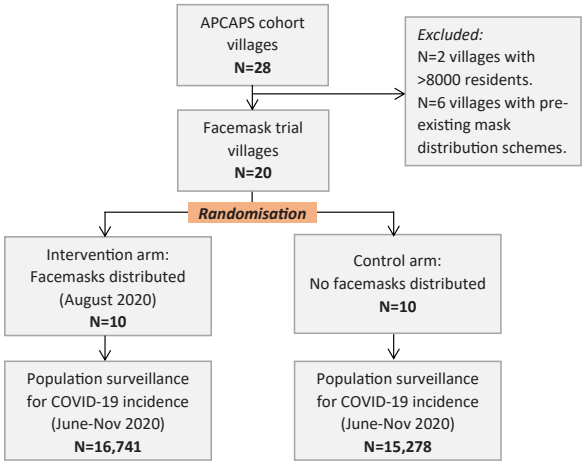

Fig. 1. Flow diagram of trial participation, APCAPS facemask trial June–November 2020.

Table 1
Baseline description of intervention and control villages, APCAPS facemask trial June–November 2020.

Characteristic	Mean (standard deviation)	
	Intervention villages (N=10)	Control villages (N=10)
Population size[a]	1674 (451)	1528 (941)
Proportion aged >65[a]	9.9 (1.6)	10.9 (2.6)
Proportion female[a]	48.8 (0.51)	49.0 (0.80)
Distance from Hyderabad	39.7 (9.6)	44.2 (10.7)
Number of community health (ASHA) workers	1.9 (0.88)	1.8 (0.79)
Pre-intervention notified COVID-19 rate per 1000 person months (June/July 2020)	1.14 (0.89)	1.07 (1.19)

[a] Based on demographic projections.

Notified COVID-19 case rates per week in the 4 months (August–November 2020) following facemask distribution are shown in Fig. 2. The rate of notified COVID-19 cases was 2.15 per 1000 person months (number of events=144) in the intervention villages and 2.45 (n=150) in the control villages, corresponding to a model-based crude rate ratio of 0.97 (95% confidence interval (CI) 0.53 to 1.80) (Table 3). In the primary outcome model accounting for age, sex and pre-intervention COVID-19 rate, the adjusted rate ratio and rate difference per thousand person months (respectively) in intervention compared with control villages were 0.96 (95% confidence interval 0.57–1.63) and −0.09 (−1.33–1.16). We note that the observed cumulative incidence of notified COVID-19 cases (~1%) was substantially lower than we had assumed in our power calculation (15%) indicating that the primary analysis was underpowered.

The incidence rates of the secondary outcomes, in intervention versus control villages, were 0.07 per 1000 person months (number of events=5) versus 0.21 (n=13) for COVID-19 hospitalisations, 0.91 (n=61) versus 1.10 (n=67) for all-cause mortality, and 0.97 (n=65) versus 1.23 (n=75) for the composite outcome of COVID-19 hospitalisation or all-cause mortality. In models accounting for age, sex and pre-intervention COVID-19 rate, the adjusted rate ratio and rate difference per thousand person months (respectively) in intervention compared with control villages were 0.36 (0.12–1.05) and −0.14 (−0.29–0.02) for COVID-19 hospitalisations, 0.84 (0.55–1.29) and −0.18 (−0.60–0.25) for all-cause mortality, and 0.80 (0.54–1.17) and −0.25 (−0.67–0.16) for the composite outcome.

Results were very similar in sensitivity analyses aggregated to the village-level (Appendix Table 1).

We did not collect data on harms from individual participants receiving the facemask intervention, although there were no perceived harms reported by village leaders or health care officials when asked at the end of the intervention period.

Discussion

In this cluster randomised trial conducted during the first COVID-19 pandemic wave in India, we found that distribution and promotion of cotton facemasks to all adults in a community resulted in moderate increases (~20% points) in mask wearing in public places. We observed a similar incidence of notified COVID-19 in intervention compared with control villages, with high uncertainty around

Table 2
Adherence to allocated intervention, based on standardised observations in village centres, APCAPS facemask trial August–November 2020.

Observation week (post-mask distribution)	Intervention villages (N=10)			Control villages (N=10)			P-value difference (any face mask)
	Mean (SD) N observed	Mean (SD) % wearing study facemasks	Mean (SD) % wearing any facemask	Mean (SD) N people observed	Mean (SD) % wearing study facemasks	Mean (SD) % wearing any facemask	
Week 3[a]	33.9 (7.0)	8.4 (11.8)	53.7 (17.6)	28.2 (11.6)	0 (0)	57.1 (13.0)	0.63
Week 6[b]	46.1 (11.7)	26.4 (13.4)	68.5 (9.6)	39.8 (17.0)	0 (0)	59.8 (7.2)	0.04
Week 9	101.4 (26.2)	23.5 (8.4)	65.1 (17.2)	105.8 (44.1)	0 (0)	35.8 (10.2)	0.002
Week 15	47.6 (17.2)	12.3 (4.2)	41.6 (11.2)	60.7 (16.9)	0 (0)	17.6 (5.7)	<0.0001
All	229.0 (42.2)	19.3 (4.0)	59.2 (8.6)	230.5 (83.2)	0 (0)	37.6 (6.8)	<0.0001

[a] Mask distribution in intervention villages was ongoing at this time.
[b] One control village not surveyed due to sudden lockdown.

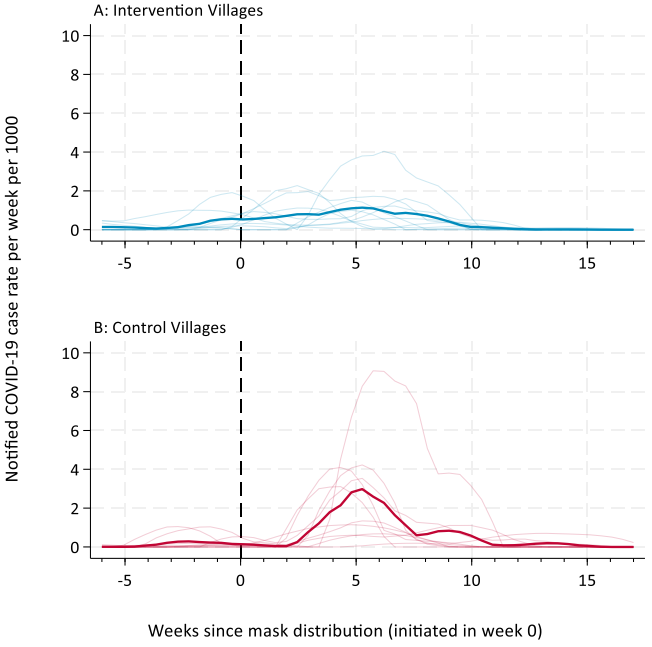

Fig. 2. Epidemic curves by village and trial arm during the study period, APCAPS facemask trial June–November 2020. Dark lines show the village-level mean incidence, faint lines show the incidence in each village.

the effect estimate. We observed a lower incidence of COVID-19 hospitalisations and all-cause mortality in the intervention villages compared with control villages, although low absolute numbers meant that these effect estimates were not statistically robust.

Impact on COVID-19 incidence

Although our results were imprecise, our central estimate for the effect of distributing and promoting facemasks on COVID-19 incidence is similar to a previous cluster randomised trial in Bangladesh in 2020–2021, which randomised 600 villages (N=342,183 adults) to either surgical facemasks (200 villages), mixed material cloth facemasks (100 villages) or no intervention (300 villages).[7] Over an 8-week intervention period, mask usage in public was 29% higher in intervention villages than control villages, and the proportion of participants who had symptoms of COVID-19-like-illness and tested seropositive for SARS-CoV-2 was 9% lower (prevalence ratio 0.91 (95% CI 0.82, 1.00) for any facemask, and 0.93 (0.77, 1.08) for cloth facemasks). The three other published trials of facemasks for reducing the incidence of COVID-19 are difficult to compare with ours; two were individual-level trials (thus not capturing the community-level effect of mask-wearing),[9,10] while one was a cluster trial but with little difference in facemask wearing between trial arms.[8]

There are several contextual factors that may have limited the potential impact of delivering facemasks on COVID-19 incidence in our trial and in Bangladesh. Firstly, in many rural and semi-rural communities in South Asia, a high proportion of the social contacts taking place in public spaces (such as shopping, transport, restaurants, workplaces) occur in open-air or well-ventilated spaces, which would have limited the potential benefit of mask-wearing in public. This could also explain the greater effect sizes seen in some natural experiments of facemask mandates in US schools, which are indoor settings shared for prolonged periods of time.[20] Secondly, these trials took place amid a real-world pandemic, with participants inevitably exposed to broader policy and behavioural contexts around facemask use. Mask use was recommended locally at the time of both trials, with mask-wearing ranging from 13% to 38% in the control arms, and only 22%–29% of participants changing their mask-wearing behaviour as a result of these interventions. This limits the potential effect observable in intention-to-treat analyses, and could partly account for the smaller effect sizes seen in trials than in observational studies.[21] Furthermore, an individuals' likelihood of wearing a facemask may be dynamic based on perceived risk, for example being higher at times of high community prevalence, and lower when community prevalence is low, further underestimating the effect of the facemask interventions. Thirdly, by examining symptomatic or notified COVID-19, these trials are not able to capture the true effects of facemask distribution on SARS-CoV-2 transmission (up to 40% of which may be asymptomatic), potentially attenuating the observed effects.[5]

Impact on adverse outcomes of COVID-19

There are no comparable randomised studies to our knowledge examining the effect of delivering facemasks on COVID-19 hospitalisation or mortality. Ecological studies of US states or counties found that implementation of mask mandates was associated with reduced COVID-19 hospitalisations[22,23] and mortality,[24,25] while globally, countries that implemented mask mandates for longer had slower increases in COVID-19 mortality up to May 2020.[26] One study that reported effects on both incidence and hospitalisation[22] reported similar effects of mask mandates (~60% reduction) on both outcomes. It is interesting therefore that we observed a greater magnitude of reduction in COVID-19 hospitalisations and mortality than on incidence. This could be due to sampling error (confidence intervals were wide and overlapping), or because our estimates for hospitalisation and mortality were more robust than for incidence, which relied on case finding of symptomatic cases and their contacts. Alternatively, facemasks may have reduced but not entirely eliminated the infectious dose transmitted, resulting in a similar number of infections, but fewer severe infections, in intervention villages.[4] The potential impact of infectious dose reduction may be more prominent in vulnerable populations, fitting with the observation in the Bangladesh trial and our trial (data not shown due to

Table 3
Effect of facemask distribution on notified COVID-19 cases, COVID-19 hospitalisation, all-cause mortality, and composite of COVID-19 hospitalisation or all-cause death, APCAPS facemask trial June–November 2020.

Outcome	Overall rate per 1000 person month (n of cases)		Rate ratio (95% CI)		Rate difference per 1000 person months (95% CI)	
	Intervention villages (total 66,963 p-months)	Control villages (total 61,114 p-months)	Crude	Adjusted	Crude	Adjusted
Notified COVID-19 cases	2.15 (144)	2.45 (150)	0.97 (0.53, 1.80)	0.96 (0.57, 1.63)	−0.06 (−1.52, 1.40)	−0.09 (−1.33, 1.16)
Hospitalised COVID-19 cases	0.07 (5)	0.21 (13)	0.35 (0.12, 1.00)	0.36 (0.12, 1.05)	−0.14 (−0.29, 0.01)	−0.14 (−0.29, 0.02)
All-cause mortality	0.91 (61)	1.10 (67)	0.81 (0.53, 1.24)	0.84 (0.55, 1.29)	−0.22 (−0.66, 0.22)	−0.18 (−0.60, 0.25)
Composite of hospitalised COVID-19 and mortality	0.97 (65)	1.23 (75)	0.77 (0.52, 1.14)	0.80 (0.54, 1.17)	−0.29 (−0.72, 0.14)	−0.25 (−0.67, 0.16)

Rate ratios and differences are from multilevel Poisson regression models (random intercept for village, clustered standard errors). Adjusted models are adjusted for age, sex and village-level pre-intervention COVID-19 incidence rate, except for hospitalised COVID-19 cases which are only adjusted for linear age due to low number of events. Estimated variance of random effects (adjusted model) for notified COVID-19, hospitalised COVID-19, all-cause mortality and composite outcome, respectively, are: 0.24 (0.11, 0.53), 0.17 (0.01, 2.11), 0.06 (0.01, 0.38), 0.03 (0.00, 0.50).

low numbers) of greater effectiveness of facemasks on COVID-19 incidence in older age groups.[7]

Strengths and limitations

Our cluster randomised trial of community-wide facemask distribution for preventing incidence and adverse outcomes of COVID-19 adds valuable data to the limited body of randomised evidence on this question. We used objective standardised methods to confirm intervention uptake and collected data on COVID-19 hospitalisation and all-cause deaths over a large population, providing some of the first insights on these policy-relevant outcomes. However, several limitations make it difficult to draw firm conclusions from our trial. The trial took place at the time of a relatively small increase in COVID-19 cases at the study site, which coupled with the relatively young age of the study participants (for adverse outcomes), resulted in less statistical power than anticipated. Because the trial was underpowered, our effect estimates are imprecise meaning strong conclusions cannot be drawn from these data alone. Nevertheless, given the scarcity of trials addressing this important question, they have the potential to make a valuable contribution to any future meta-analyses. As noted earlier, our analysis of notified COVID-19 relied on active surveillance by local health workers which may have underestimated the incidence. Finally, as in previous facemask trials, uptake of masks was incomplete; only around 20% of people in the intervention villages wore the study facemasks on average, while a further ~40% wore other face coverings (predominantly improvised coverings such as scarfs wrapped around the face), which would have attenuated the intervention effect, although this also reflects a realistic scenario in which not all individuals comply to facemask policies. Over a third of people in the control villages also wore some form of face covering in public, predominantly scarfs wrapped around the face. Although the efficacy of these is unknown, they may confer some benefit (for example by reducing droplet transmission), which could have further attenuated our effect estimates.[14]

Policy implications

Whilst the combined evidence from our trial and previous trials is too limited to directly support actionable conclusions around community-wide distribution and promotion of facemasks for COVID-19 prevention, it is widely acknowledged that policy decisions should be made on the balance of a range of sources of evidence, from biological to observational, alongside consideration of the risks and costs.[6] This is especially pertinent for the question of facemasks for COVID-19, as all trials to date have suffered from insufficient number of events, low uptake of facemasks, or both, systematically diluting effect sizes and interpretability.[27] With a wider view of the evidence in mind, it has been argued that facemasks represent a low-risk and affordable public health measure that could potentially save lives and avert healthcare expenditure, although externalities such as waste and supply chain impact may need consideration when implementing at scale.[6,28] The findings from our trial are consistent with this policy approach. The potential effect of delivering facemasks is likely to vary between settings (notably due to differences in adherence behaviours, population density and time spent indoors) indicating that evidence may need to be contextualised when applying to new situations; still, further trials and high-quality observational studies from a range of contexts will help to shed light on this question.

Conclusion

This cluster randomised trial in a rural setting in India adds to the very limited data on the community-wide effects of distribution and promotion of facemasks for reducing incidence and impacts of

COVID-19. Although firm conclusions cannot be drawn from our trial alone due to low number of events and imprecise effect estimates, our results will make a valuable addition to any future meta-analyses on this important topic. Our overall findings are consistent with the modest protective effect on incident COVID-19 cases seen in previous randomised trials, extending these to adverse outcomes for the first time. Further evidence from a range of settings, particularly on COVID-19 hospitalisations and mortality, are needed to confirm these observations.

Author contributions

BK, SK, SKB, TD, SB, PACM, and JL were involved in conception of the study. BK, SK, SKB, TD, SB, PACM, JL and SA were involved in the design of the study. BK was responsible for funding acquisition and institutional support. BK, TW, SKB, SB, SA, PU, SM and HM were involved in data collection and validation. PACM and JL conducted the analysis. PACM wrote the first draft. All authors read and commented on the manuscript and approved the final version.

Funding

There was no allocated funding for this study apart from the manufacture and distribution of facemasks for the intervention, which was provided directly by Synergy India Foundation, a Non-Governmental Organisation involved in delivery of healthcare and education services in the study area. Synergy India Foundation has no financial interests in the intervention product and was not involved in trial design, analysis, or decision to publish the manuscript. In-kind support in the form of overhead resources was provided by the Indian Council of Medical Research-National Institute of Nutrition.

Data availability

Data cannot be shared publicly because of stipulations in the study consent forms. Data can be made available to collaborating researchers who meet the criteria for data access, in accordance with the APCAPS data sharing policies. Requests should be made to the APCAPS study team. Details on how to apply to collaborate are available here: https://www.lshtm.ac.uk/research/centres-projects-groups/apcaps#collaborate.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

We are hugely grateful to the participants, village leaders, village health workers and field team who facilitated this study despite the adverse conditions presented by the COVID-19 pandemic in India. Particular thanks to Ms Sandhya, Mr Kiran Kumar, and their teams, at Synergy India Foundation, for supporting the manufacture and delivery the facemasks and thus making this study possible.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.jinf.2025.106557.

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