

FACE MASKS PREVENT TRANSMISSION OF RESPIRATORY DISEASES: A META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS*

Hanna M. Ollila^{1,2,3}, Markku Partinen^{4,5}, Jukka Koskela^{1,2,6}, Riikka Savolainen⁷, Anna
Rotkirch⁸, and Liisa T. Laine^{9,10}

¹Institute for Molecular Medicine Finland (FIMM), University of Helsinki, Helsinki, Finland

²Broad Institute of MIT and Harvard, Cambridge, MA, USA

³Stanford University School of Medicine, Palo Alto, CA, USA

⁴Helsinki Sleep Clinic, Vitalmed Research Center

⁵Department of Clinical Neurosciences, Clinicum, University of Helsinki, Helsinki, Finland

¹Institute for Molecular Medicine Finland (FIMM), University of Helsinki, Helsinki, Finland

²Broad Institute of MIT and Harvard, Cambridge, MA, USA

⁶Helsinki University and Helsinki University Hospital, Clinic of Gastroenterology Helsinki, Finland

⁷Newcastle University Business School, Newcastle-upon-Tyne, United Kingdom

⁸Population Research Institute, Väestöliitto – The Family Federation of Finland

⁹University of Pennsylvania, The Wharton School, Philadelphia, PA, USA

¹⁰Department of Medical Ethics and Health Policy, The Perelman School of Medicine, Philadelphia, PA,
USA

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SUMMARY

Background. Coronavirus Disease 2019 (COVID-19) is caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and spreads through droplet-mediated transmission on contaminated surfaces and in air. Mounting scientific evidence from observational studies suggests that face masks for the general public may reduce the spread of infections. However, results from randomized control trials (RCT) have been presented as inconclusive, and concerns related to the safety and efficacy of non-surgical face masks in non-clinical settings remain. This controversy calls for a meta-analysis which considers non-compliance in RCTs, the time-lag in benefits of universal masking, and possible adverse effects.

Methods. We performed a meta-analysis of RCTs of non-surgical face masks in preventing viral respiratory infections in non-hospital and non-household settings at cumulative and maximum follow-up as primary endpoints. The search for RCTs yielded five studies published before May 29th, 2020. We pooled estimates from the studies and performed random-effects meta-analysis and mixed-effects meta-regression across studies, accounting for covariates in compliance vs. non-compliance in treatment.

Results. Face masks decreased infections across all studies at maximum follow-up ($p = 0.0318$, $RR = 0.608 [0.387 - 0.956]$), and particularly in studies without non-compliance bias. We found significant between-study heterogeneity in studies with bias ($I^2 = 71.2\%$, $P = 0.0077$). We also used adjusted meta-regression to account for heterogeneity. The results support a significant protective effect of masking ($p = 0.0006$, $\beta = 0.0214$, $SE = 0.0062$). No severe adverse effects were detected.

Interpretation. The meta-analysis of existing randomized control studies found support for the efficacy of face masks among the general public. Our results show that face masks protect populations from infections and do not pose a significant risk to users. Recommendations and clear communication concerning the benefits of face masks should be provided to limit the number of COVID-19 and other respiratory infections.

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1 INTRODUCTION

COVID-19 is caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and spreads through droplet-mediated transmission on contaminated surfaces and in air. COVID-19 has caught the medical community and policymakers off guard through both the pace and initial unpredictability of viral transmission. Minimizing the exposure time of the uninfected to viral particles in droplets and aerosols is central to limit the spread of the disease. Moreover, the role of superspreading events seem to be crucial for the transmission of COVID-19[1], and preventing a single superspreading event can have a large impact on the spread of the virus (Figure 1).¹ Also, viral particles may linger in the air and also after the infected individual has left the shared space [5, 6]. Limiting the time and magnitude of release of droplets and aerosols by those infected is thus emerging as the key factor in reducing COVID-19 transmission.

A combination of different non-pharmaceutical interventions (NPIs) including good hand hygiene, maintaining physical distance, and the use of cloth masks and coverings (masking) are currently seen as the primary interventions to limit future COVID-19 infections. Among these NPIs, face masks have caused most scientific and political debate, leading to conflicting and confusing messages to the general public. Doubts and controversy about the safety and efficacy of face masks worn by the public has been substantial. Even though masks are currently mandated or recommended in several countries [7], the recommendations vary (Figure 2). Also concerns over the potential harms have been voiced, such as possibility that face masks may spread COVID19 or masks may potentially create false sense of security [8].

We examine whether there is an independent protective (in contrast to pure source control), or predisposing, effect of the use of face masks on respiratory infections including COVID-19 by computing a meta-analysis focusing solely on RCTs in community settings. Indeed, the gap in the field is that only a few RCTs in community setting exist. Currently, the largest meta-analysis contains three publications. A larger set of publications have been included in one white paper [9]. However, previous literature does not contain a formal meta-analysis of RCTs in community setting that are currently available.

¹A visualization of possible infection pathways show how when 80% of individuals use any face covering, including cloth mask, the infection rates could be halved [2, 3, 4].

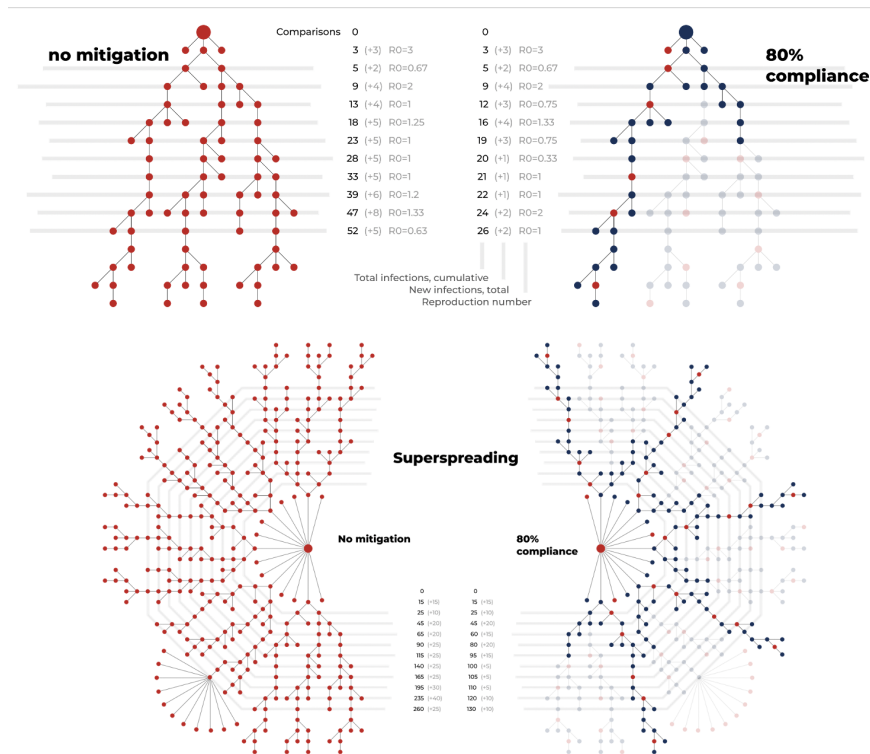


FIGURE 1: Illustration of possible effects of face mask use in preventing infections. Typical chain of infections without masking (top). When 80 percent compliance in mask use (blue) is achieved, half of the infections can be prevented. Visualization of cluster of infections through one super spreading event below. Mitigation through 80 percent compliance in face mask use together with other protective measures can prevent individual infections and infections through super spreading events. Red shows infection without mask, blue indicates use of face mask and infection. Image by Riina Ruppenen.

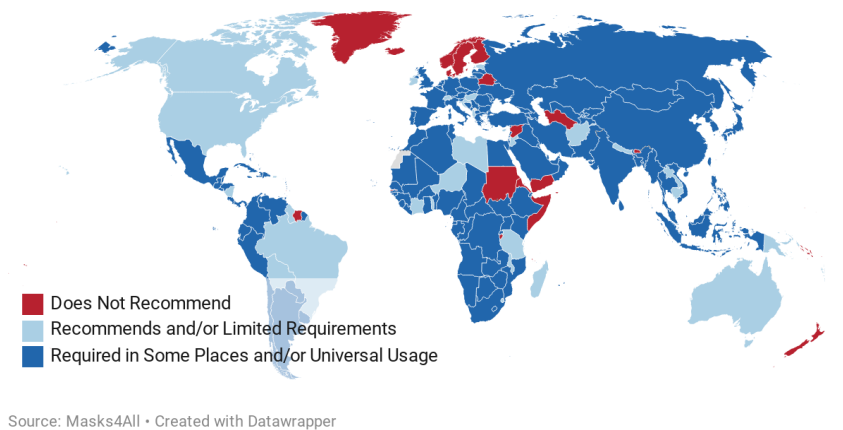


FIGURE 2: Which countries require or recommend public mask usage to help contain COVID-19 infections (date: July 30, 2020)

The current evidence of the efficacy of face masks stems from prediction models showing that universal masking in public can have a substantial impact on spreading and does not require the use of medical masks or 100% compliance [2, 3, 10]. A review assessing masks in source control (in contrast to protection) recommended their use in the general population [11]. Other empirical evidence indicates that countries and regions using masks have lower increases in COVID-19 infection rates and death rates [3] and finally, a pooled meta-analysis of the spread of infectious viral diseases of up to 172 studies showed a consistent effect regarding the efficacy of face masks in preventing infections [4].

However, the epidemiologically most robust type of evidence for the efficacy of face masks use among the general public – that from randomized control trials – has been consistently noted as still lacking, also among scholars favoring mask use [12, 13]. Several studies also note the possibility that non-compliance may have skewed and confused RCT-results, yet no study has statistically corrected for non-compliance in a meta-analysis (ibid). We fill this gap in the literature.

2 SEARCH STRATEGY AND SELECTION CRITERIA

Data collection process. Only a few analyses of RCTs and face masks have been conducted in order to assess the ability of masks to protect the wearer from infection. Barasheed et al. (2011)[14] and Brainard et al. (2020)[15] included three RCTs of face masks in non-hospital settings. They found very weak support for face mask efficacy, and stressed the problem with non-compliance in the few existing RCTs.

A commissioned research by the Ministry of Social Affairs and Health Finland and the consulting group Summaryx Oy did a systematic review (MSAH 2020)[9] in spring 2020 and detected in total five RCTs in non-hospital and non-household settings which were published prior May 29th, 2020. Three of them were used in Baynard et al. (2020): Aiello et al. (2010)[16], Aiello et al. (2012)[17], and Alfelali et al. (2019)[18] and two additional (Barasheed et al. (2014)[14] and Abdin et al.(2005)[19]). None of the five studies addressed heterogeneity and non-compliance of RCTs statistically.

For our analysis, we consulted both Baynard et al. (2020) and MSAH (2020), but also performed the same searches independently and detected the same five RCTs [14, 16, 17, 18, 19].

Search criteria. Selection criteria included face masks that were

1. FFP1, cloth mask or surgical mask. Exclusion; FFP2 or FFP3.

2. Population prone to respiratory infection. Exclusion; health care workers
3. Comparison group; no face mask. Exclusion; different type of face mask
4. Outcome; Relative risk for infection, safety and efficacy, slowing of infection at the population level
5. Sample size and follow up did not have exclusion criteria
6. RCT with either individual or group level (clustered). Exclusion criteria; cohort study, case control study, study without controls
7. Setting. Community setting. Exclusion criteria; home, healthcare environment.
8. Publication format. Whole text available, preprints included. Exclusion criteria; only abstract available
9. Language of original publication; Finnish, English, Spanish, Danish, Swedish, Norwegian, German or French. Exclusion criteria; other language

Data items. We extracted relative risks (RR), number of individuals per RCT group, and baseline study characteristics including type of study; pilgrim, college dorm, household, use of masks in control group, study time points, outcome measures: symptoms for infection, laboratory confirmed infection, compliance in cases, and adverse effects.

Selected studies. We included RCT studies a) based on the search criteria above and b) those reported by MSAH (2020)[9]. We compared those studies also to current meta-analyses and did not discover additional RCTs in community settings that would have been included in other meta-analyses of masks.

Study endpoints. The primary endpoint was relative risk of infection across studies using meta-regression. Sub analyses were calculated in cohorts with similar follow-up time, similar population and no heterogeneity.

Statistical analysis. Analyses were performed using R version 3.5.0 (2018-04-23) and the packages meta, metafor, data.table, dplyr, and visualized with metaviz and forest packages. Key data fields for each study are shown in Table 1.

Heterogeneity. We computed between-study heterogeneity as estimated with I^2 and τ using Random effects meta-analysis and Mixed-model Meta-analysis as implemented in functions meta-gen.

Significance and summary estimates. Summarized effects were computed using Random effects meta-analysis, and meta-regression as implemented in `rma.uni` to account for those parameters that induced significant heterogeneity between studies. For comparable studies with similar settings and no evidence of heterogeneity we used Fixed effects meta-analysis as implemented in `metagen` package in R.

Sensitivity analyses. We calculated effects in using leave-one-out analysis where summary effects were computed for all studies leaving one RCT study out. This analysis was done to ensure that with less than 10 studies in the meta-analysis the effects were not significantly driven by a single RCT study.

ESTIMATION AND ACCOUNTING FOR BIASES IN THE STUDY SETTING

We discovered the following discrepancies and treated them in the analysis as follows.

1) *Use of face masks in controls and accounting for bias caused by non-compliance.* One challenge in RCT studies is the opportunity of controls to opt in treatment groups if the treatment is freely available. Such possibility of failure in randomization of cases and controls for RCT groups exists for face masks as those can be purchased or made at home. Indeed, in the selected present studies analyzed here, face masks were used in the control group in 3 out of the 5 studies.

Amount of use of face masks by controls ranged from 12% to 53% (Table 1). Especially in those studies where use of face masks is high (over 50%) comparisons were made between face mask users vs. face mask users which and induces high uncertainty in the estimates. We controlled for this in meta-regression through adjusting for percentage of face mask use in controls and in sub analyses by dichotomizing the use of face masks.

2) *Non-compliance of face mask use in the intervention group.* Compliance in the facemask group varied substantially, being lowest in the Alfelali study (27% of intervention group used facemask daily) [18], and highest in Barasheed (76%)[14].

3) *Examining potential selective reporting within studies.* We analyzed both the cumulative risk and study endpoints and computed meta-analysis estimates separately for end of study versus the cumulative estimates in these studies.

All studies provided cumulative risk estimates, or numbers to compute these. In addition, two studies had longer follow-up periods of up to 6 weeks from trial start date. We included these study endpoints because the incubation period of respiratory infections ranges between 1-10 days on average depending on infection. This means that protective effects of face masks appear with a

TABLE 1: RCT study characteristics

Publication	Population	Endpoints	RR [CI95%]	N per comparison	Controls use masks (%)
Barasheed 2014	Pilgrims	Mask vs. no mask	0.576 [0.332-1.007]	11/25/28/25	12
Abdin 2005	Pilgrims	Mask and education vs no mask	0.97 [0.79-1.2]	129/381/126/359	33.6
Alfelali preprint	Pilgrims	Mask vs. no mask	1.079 [0.935-1.244]	354/2845/322/2817	53
Aiello 2012	Students	Mask and hand hygiene vs. no mask	0.78 [0.59-1.05]	31/318/51/319	0
Aiello 2010	Students	Mask and hand hygiene vs. no mask	0.88 [0.75-1.03]	92/224/177/310	0

*Relative risk as reported in the original publication. Or computed for publication where RR was not reported.

** N reported as Mask infected/ Mask uninfected / Control infected / Control uninfected. N from original publications.

time lag. Another motivation for including the study endpoints is that the estimates from the first few days when protective measures are used do not account for infections that have been contracted prior to wearing a mask.

4) *Blindedness*. All RCTs were unblinded due to the nature of face mask use.

3 RESULTS

We computed meta-analysis across five RCT studies using log transformed relative risk to estimate the effect of face masks on respiratory infections (Table 1). While Fixed effects meta-analysis was statistically significant both using cumulative risk estimates and using end of study time points ($p = 0.032$, $RR = 0.91$ [0.84 – 0.99], $p = 0.0001$, $RR = 0.81$ [0.73 – 0.90] computing I^2 with Random effects model meta-analysis showed significant statistical heterogeneity between the studies ($I^2 = 71.2\%$ [27.0%; 88.6%], $\tau^2 = 0.0253$ [0.0045; 0.3801], heterogeneity $p = 0.0077$). Furthermore, accounting for heterogeneity using Random effects model meta-analysis showed statistically significant association with end of the study endpoint ($p = 0.0318$, $RR = 0.608$ [0.387 – 0.956]), whereas cumulative risk did not ($p = 0.1$) (Figure 3).

Variance can be induced to the measurement for example through differences in a) study setting b) ethnicity, sex and underlying demographic factors and c) validity of the randomization such as compliance in treatment or blindness. When examining population characteristics within the selected studies, we were thus able to clearly attribute study heterogeneity to at least the following

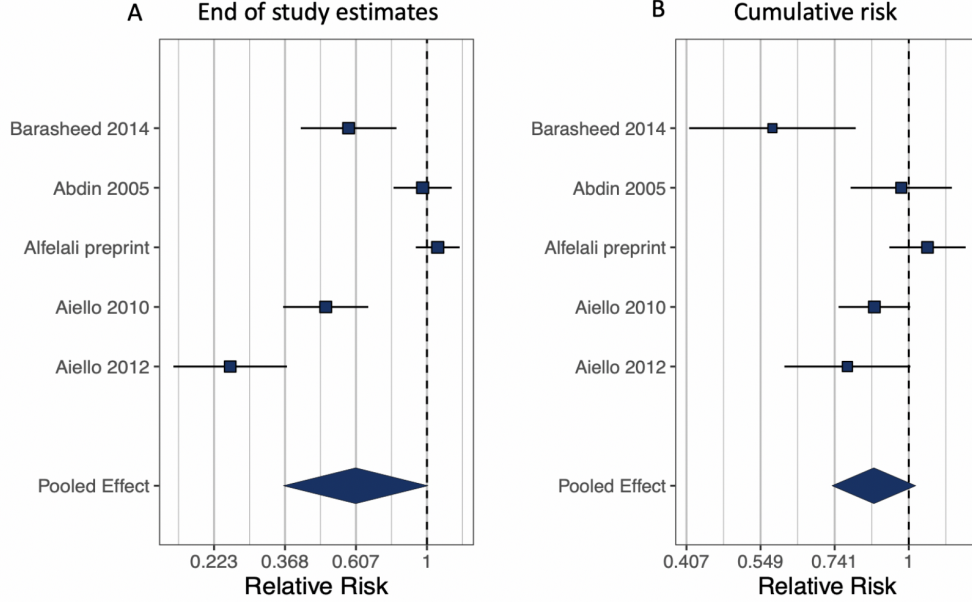


FIGURE 3: Random-effect meta-analysis of five RCT studies. There is significant variance between studies. Statistically significant association was detected with Random effects meta-analysis a) at the end of the study endpoints ($p = 0.0318$), b) but not with cumulative estimates $p = 0.1$).

differences. The predominant differences were type of study population and non-compliance in the control group (outlined in Table 1). Two studies were conducted in a college student community setting in the United States, with primarily White ($> 80\%$) with a subset of Asian (16%) college students [16, 17]. These studies had adjusted for the differences within the study population and for underlying baseline characteristics. By contrast, three studies were conducted within a pilgrim population during Hajj pilgrimage with predominantly Saudi Arabian, Middle Eastern or Asian populations [14, 18, 19], where Alfelali adjusted for baseline measures [18].

The largest differences within the RCTs was due to non-compliance within the control groups in the pilgrim studies: controls used face masks between 12 and 53% of the time. Obviously, if half of the group supposed not to be using face masks is using face masks, such biases will affect the estimates substantially, and reduce power to reliably estimate any effect.

To formally adjust for non-compliance, we computed a meta-regression adjusting for percentages of facemask use in controls. This accounted for a significant proportion of the cumulative heterogeneity (p heterogeneity remaining = 0.08) and showed significant association at cumulative endpoints under Fixed effects model ($p = 0.0067$, $\beta = -0.0051$, $SE = 0.0019$).

While the end of the study was statistically significant ($p < 0.0001$, $\beta = -0.0186$, $SE = 0.0026$), there is also statistically significant heterogeneity at the end of the study endpoint ($p = 0.0078$).

We therefore computed Random effects meta-regression using REML estimates, detecting similarly a significant effect from face masks ($p = 0.0006$, $\beta = -0.0214$, $SE = 0.0062$).

No study findings reported any severe adverse outcomes in the group using face masks. On the contrary, overall, masking did not increase the rate of infections but rather reduced laboratory confirmed infections. Self-reported negative outcomes were assessed in the preprint by Alfelali, in which 26% of those that used face masks in Alfelali study reported difficulty in breathing. Discomfort was assessed in the studies by Aiello and reported by discomfort (22%); in addition, 3% reported feeling hot, sweating, a bad smell, or blurred vision with eyeglasses [14, 16, 17, 18, 19].

To estimate the effect of face masks across similar study settings, we computed conservative stratified analyses in those with face masks only in the treatment group, versus those studies where face masks were also used in the control group. This stratified analysis found a strong protective effect for face masks in studies where controls did not use masks ($p = 0.0344$; $\beta = -0.1653$ $[-0.3184; -0.0122]$ and $p = 0.0024$; $\beta = -0.8343$ $[-1.3741; -0.2946]$), using cumulative risk or end of study, respectively. Effects were the strongest when combined with other protective measures and at the end of study, with maximal time for the protective effect to develop (Figure 4).

Finally, we performed sensitivity analyses using a leave-one-out model under meta-regression. Adjusted effect sizes at the end of study were systematically distributed across the comparisons, suggesting that no single study was responsible for the effect, and adjusted meta-regression estimates were statistically significant independently of which study was left out (Figure 5). These sensitivity analyses supported the protective effect of face masks in preventing respiratory infections.

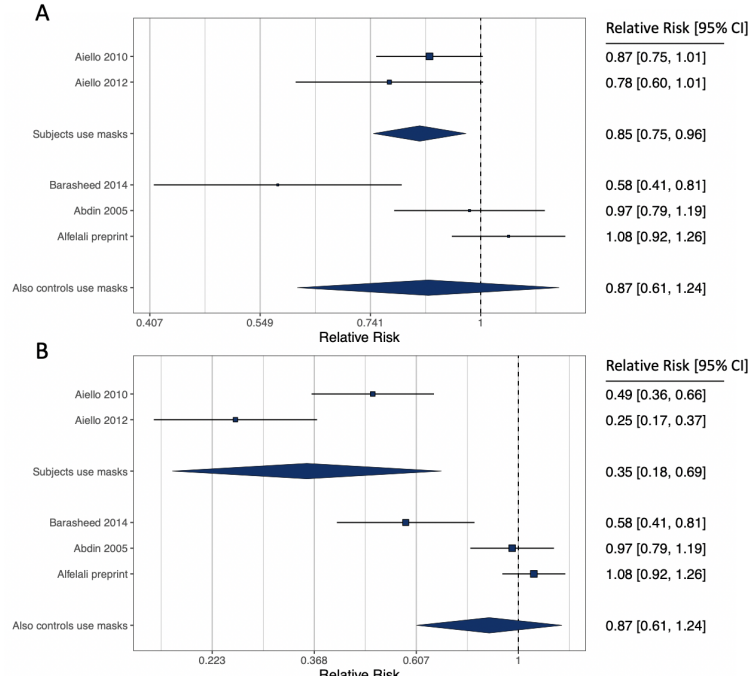


FIGURE 4: Stratified analysis in studies where face masks are used in the study population show significant protective effect. a) Cumulative time point b) end of study time point.

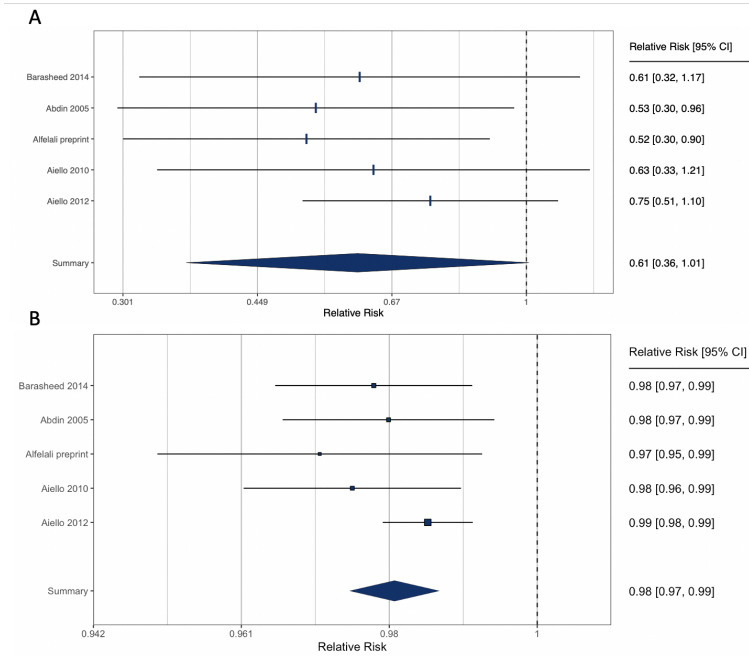


FIGURE 5: Leave one out -analyses under a) unadjusted random effects raw values show directionality of mean under $RR < 1$, and b) after accounting for use in face masks in controls adjusted meta-regressions show a robust, protective effect of face masks independently of which RCT study is omitted, suggesting that no single study drives the raw estimates to significance ($p < 0.05$ for all models).

4 DISCUSSION

While scientific evidence favoring universal masking in public settings to prevent respiratory diseases has increased, only a few randomized-controlled trials exist and these have been referred to as providing weak or no evidence for efficacy and safety of face masks. Through careful statistical meta-analysis of the five RCTs on mask use in non-hospital and non-household settings, we document for the first time a robust effect from face masks preventing respiratory infections using control groups. Four of the analyzed studies evaluated the use of masks on respiratory infections directly, and in one the primary outcome was compliance with mask use. We found a statistically significant protective effect of face masks preventing respiratory infections across these studies. Also sensitivity and subgroup analyses strongly support the claim that masks have a concrete impact on curtailing infections in the general population.

Three out of the five original studies concluded that face masks have an impact in managing the spread of respiratory infections, and two of the original studies concluded that there was no clear evidence for the use of face masks [14, 16, 17, 18, 19]. Our study with formal meta-analysis and meta-regression comes to the conclusion that masks do have an impact for managing spread of COVID-19 also under RCT setting.

We also addressed the limitations of the single RCT studies, notably in relation to compliance with treatment. For example, in one study, over half of the controls which were not supposed to wear masks were actually wearing them at some point [18]. Unsurprisingly, the largest protective effect with face masks was seen in studies where compliance in both treatment and control groups was high. This was especially evident in the college student cohorts but also in the study of pilgrims [14], where 76% of the treatment group used masks but only 12% of individuals in the control arm used masks ($p < 0.05$). We stress that even relatively heterogeneous studies, or studies where RCT has been biased through non-compliance, can be useful when pooled using carefully selected statistical methods, which account for study heterogeneity.

While medical masks have been the gold standard to prevent doctor to patient or patient to doctor transmitted infections, the current discussion in use of face masks has debated whether masks can also protect the wearer, whether individuals who are not formally trained to use masks can wear them safely, and whether masks may represent an infection risk due to contamination effects or masks causing respiratory problems.

Only a few RCT studies outside the hospital setting have been conducted that assess the

efficacy of masks in preventing respiratory infections in the general public. Most studies have been conducted using case control studies and with masks with strong filtering capacity. Furthermore, meta-analyses summarizing these pooled effects are numerous, including by far the largest meta-analysis of face masks [4]. Our study is in alignment with these studies showing similarly a strong protective effect of face masks. The Estimated number needed to mask to prevent one infection has ranged from 3 (N95 masks) to 6 (face masks), to even higher when infection risk is low to start with [20].

While masks have been shown to be effective alone, their impact and therefore efficacy is largest when combined with other protective measures [4]. Also in our study, the effect of masks was further accentuated when combined with complementary measures such as handwashing [16, 17]. Furthermore, other complementary measures for disease control, such as physical distance have a large impact on the spread and number of particles in the air and therefore also add to the effect of face masks.

One possible concern is that masking could cause risk compensation so that wearers become more careless with other mitigation measures, making masks counterproductive. However, the current evidence does not support this concern [21, 22]. Moreover, using data from the U.S., [23] found that mobility decreased in most settings when the policy of masks for employees started in a state. Mask mandates in Germany were associated first with a decreased mobility but had no long-term effect [24]. Finally, a paper using the store-level data from Germany documents that the mask mandate was not associated with a change in the distance keeping around the experimenter [22].

With regard to the findings in this paper and those from earlier studies, it is surprising that policy makers have been reluctant to recommend masks to prevent infections despite the evidence that masks prevent deaths at hospitals, assisted living and nursing home settings, and globally limit the spread of the pandemic. For a long time, the WHO also adhered to this cautious and reluctant view. Future research should address the causes of such caution and inertia in national and international health authorities, protocols for assessing and revising guidelines and admitting mistakes, in order to be better prepared in future health crises.

We show that those studies where hand washing was assessed together with mask use, effects with multiplicative protective measures were the strongest. Our results strongly support the WHO guidelines that recommend the use of face masks together with physical distancing and hand washing as primary measures for controlling the spread of the COVID-19 virus.

5 CONCLUSIONS

Our findings from existing randomized controlled trials support the health policy of public use of face masks to limit the spread of COVID-19 and other infectious diseases. Face masks protect both the wearer and the people around them, and are particularly efficient when used in combination with other non-pharmaceutical interventions, such as physical distance and hand washing.

Our findings also stress the importance of estimating effects of non-compliance in meta-analyses. Recommendations and clear communication of the benefits of face masks should be given by policy makers to limit the number of infections and ultimately deaths, and to ensure sufficient safety measures to control local and global COVID-19 disease clusters providing time for vaccine development.

6 CONFLICT OF INTEREST

The authors declare no conflict of interest.

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