Review Article

Wearing masks to reduce the spread of respiratory viruses: a systematic evidence mapping

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Abstract: Since the outbreak of coronavirus disease in 2019, the controversy over the effectiveness, safety, and enforceability of masks used by the public has been prominent. This study aims to identify, describe, and organize the currently available high-quality design evidence concerning mask use during the spread of respiratory viruses and find evidence gaps. Databases including PubMed, Cochrane Library, Web of Science, EMBASE, WHO International Clinical Trials Registry Platform (ICTRP), clinical trial registry, gray literature database, and reference lists of articles were searched for relevant randomized controlled trials (RCTs) and systematic reviews (SRs) in April 2020. The quality of the studies was assessed using the risk of bias tool recommended by the Cochrane Handbook Version 5.1.0 and the Assessment of Multiple Systematic Reviews (AMSTAR 2) tool. A bubble plot was designed to display information in four dimensions. Finally, twenty-one RCTs and nine SRs met our inclusion criteria. Most studies were of "Low quality" and focused on healthcare workers. Six RCTs reported adverse effects, with one implying that the cloth masks reuse may increase the infection risk. When comparing masks with usual practice, over 70% RCTs and also SRs showed that masks were "beneficial" or "probably beneficial"; however, when comparing N95 respirators with medical masks, 75% of SRs showed "no effect", whereas 50% of RCTs showed "beneficial effect". Overall, the current evidence provided by high-quality designs may be insufficient to deal with a second impact of the pandemic. Masks may be effective in interrupting or reducing the spread of respiratory viruses; however, the effect of an N95 respirator or cloth masks versus medical masks is unclear. Additional high-quality studies determining the impact of prolonged mask use on vulnerable populations (such as children and pregnant women), the possible adverse effects (such as skin allergies and shortness of breath) and optimal settings and exposure circumstances for populations to use masks are needed.

Keywords: COVID-19; cloth mask; evidence mapping; gap maps; mask

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Introduction

On December 31, 2019, a novel coronavirus was reported for the first time in Wuhan, China. The virus is now named by the World Health Organization (WHO) as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). On March 11, 2020, WHO characterized the coronavirus disease 2019 (COVID-19) outbreak as a pandemic (1). There is a lack of specific antiviral treatment or available vaccines that have proven to be effective for this new viral disease (2). The infected people primarily rely on symptomatic treatment and supportive care (3,4). Authorities of most countries have recommended measures such as maintaining social distancing and washing hands, which are considered extremely important measures to reduce the risk of infection (5-7). However, given the cultural differences or absence of high-quality evidence, controversies over the effectiveness, safety, and enforceability of masks worn by the public were prominent in the early stages of this global epidemic.

Most of the available research on masks focused on healthcare workers and household contacts (individuals living in a household with patients with a respiratory virus infection) (8), and data on other populations are scarce (9,10). Furthermore, there are contradictions in the research results between different study settings (such as hospitals, community, and laboratory), which prevents the decision makers from making appropriate judgments (11). Therefore, our study focused on randomized controlled trials (RCTs) of non-laboratory research or systematic reviews (SRs) including RCTs (which met our inclusion criteria of RCTs). This is because non-laboratory studies might generalize to a wider population, and RCTs and SRs, as high-quality study designs, have the highest possible quality of evidence and are an important reference value for decision makers in general (12,13). In addition, the outcomes that we mainly focused on included influenza-like illness (ILI), laboratory-confirmed respiratory infection, and self-reported infection symptoms, which are the most common judgment indicators with regard to the spread of respiratory viruses (11). The ILI was usually defined as fever >38 ℃ and one or more of the following symptoms: nasal discharge/congestion, cough, conjunctivitis, respiratory distress (tachypnea, retractions), sore throat, and new seizure (8).

In addition, medical and public health professionals are concerned that the improper mask use may cause other unfavorable effects (14), policymakers also urgently need relevant high-quality evidence to support policy making. In a previous study, it was suggested that many COVID-19-related studies are poorly designed, merely adding to the COVID-19 noise (13). Therefore, it is necessary to comprehensively and systematically collect, present, and analyze current high-quality design studies. Evidence mapping (EM) is a type of comprehensive evidence-based research method that systematically and rapidly collects, evaluates, organizes, and presents existing evidence (15,16). EM presents a visual overview of existing evidence in a certain research field, and clarifies the characteristics of the studies in this field from multiple dimensions (such as the types of interventions, the research population, conclusions of the research, etc.), thereby providing systematic evidence support for decision makers (17). Furthermore, EM can also help identify evidence gaps (18). Therefore, EM can be the first step to conduct SRs or the framework to inform policy development (19). However, EM does not provide details on the generation of research results or incorporate meta-analytic techniques for pooling effect estimates, which is currently perhaps the most controversial point in EM methodology (20). Currently, no EM study, based on related RCTs and SRs, exists that presents and assesses the effectiveness and adverse effects of wearing masks to control the spread of respiratory viruses. Thus, in this study, we aimed to identify, describe, and organize currently available high-quality design evidence for mask use during the spread of respiratory viruses through an EM approach and identify gaps in evidence.

We present the following article in accordance with the PRISMA reporting checklist (available at http://dx.doi.org/10.21037/atm-20-6745).

Methods

Literature search

We searched four databases (Web of Science, Cochrane Library, EMBASE, and PubMed) on April 9, 2020. Major search terms and strategies (Appendix 1) were as follows: ("Mask"[Mesh] OR mask OR facemask OR masks OR respirator OR N95 OR FFP2 OR "personal protective equipment" OR protective devices) AND ("Respiratory Tract Infections"[Mesh] OR ILI OR infect OR influenza OR MERS OR “Middle East respiratory syndrome” OR pandemic OR parainfluenza OR “respiratory disease” OR “respiratory illness” OR “respiratory infection” OR “respiratory hygiene” OR “respiratory virus” OR SARS OR

SARS-CoV-2 OR COVID-19 OR "severe acute respiratory syndrome" OR virus) AND ("random*" OR "blind*" OR "singleblind*" OR "doubleblind*" OR "trebleblind*" OR "tripleblind*"). Moreover, the WHO International Clinical Trials Registry Platform (ICTRP) Search Portal, clinical trial registry, reference lists of articles, and gray literature were searched on April 27, 2020.

Inclusion and exclusion criteria

RCTs and SRs including RCTs that evaluated the mask use as an intervention against the spread of respiratory viruses were included in the study. The inclusion criteria were as follows: (I) no restriction for participants; (II) inclusion of mask intervention the treatment or intervention group (e.g., face mask, N95 respirator, and/or medical/surgical masks); and (III) inclusion of usual practice (e.g., education without the face mask use) or medical/surgical masks in the control groups. Furthermore, when several SRs published by the same team were identified, the most recent publication was considered. The following studies were excluded: (I) duplicate reports of a study; (II) studies with insufficient data (e.g., conference abstracts); (III) non-human studies; and (IV) laboratory studies.

Study selection and data extraction

Literature screening and data extraction were performed by two independent reviewers. Different views between the two reviewers were discussed and resolved by a third independent reviewer. EndNote X9 software was used to remove duplicates. Subsequently, the title and abstract of preliminary included studies were screened by two independent reviewers. For studies that according by both reviewers should be excluded, further screening was not conducted. For studies that according to at least one reviewer should be included or if a definitive decision could not be made, the full text was further screened and the suitability for final inclusion was determined. A predesigned table was designed to conduct data extraction, and general information was extracted about the study, including publication year, the first author, and country. We also included details concerning the type of intervention, population, result, conclusion, study design, and sample size.

Quality assessment

The tool recommended by the Cochrane Handbook Version 5.1.0 (21) was used to analyze the risk of bias of the included trials based on the following factors: random sequence generation, incomplete outcome data, allocation concealment, blinding of outcome assessment, selective reporting, blinding of participants and personnel, and other bias. Each item was classified as "Yes" ("low risk of bias"), "No" ("high risk of bias"), or "Unclear" ("moderate risk of bias"). When the risk of bias for all seven factors was assessed as "low risk of bias," the trial was assessed to have an overall "low risk of bias." Accordingly, when one or more of the seven bias factors were assessed as high risk, the trial was assessed to have a "high risk of bias." For other cases, the trial was assessed to have an "unclear risk." Differences in bias assessment were resolved through discussion by two independent reviewers. Furthermore, in some cases, a third reviewer participated in the resolution of differences.

The Assessment of Multiple Systematic Reviews (AMSTAR-2) tool (22) was used to assess the methodological quality of all SRs. AMSTAR 2 consists of 16 items and each item was evaluated using "Yes", "Partial Yes", or "No". The assessment process was conducted online (https://amstar.ca/Amstar_Checklist.php), the overall quality assessment results ("Critically low quality," "Low quality," "Moderate quality", or "High quality") was automatically generated. Two independent reviewers evaluated these items, and differences were resolved by discussion with a third reviewer.

Data synthesis and analysis

Currently, there is a lack of reporting guidelines or methodological guidance with regard to EM. We are, therefore, based our study on the methodology of Global Evidence Mapping (23), Campbell evidence and gap maps (24), and our previous findings (17) concerning EM and evidence and gap map methodology, and made necessary expansion on this basis (25,26). All authors have fully discussed the extension of each methodology and the construction of the framework of this article. A bubble plot was designed to display information in four dimensions as follows (27,28): (I) each bubble represents one RCT/SR and different colors represent various research populations; (II) the bubble size represents the sample size/number of RCTs included in this mapping; (III) the rating of authors' conclusions are represented on the X-axis as "beneficial," "probably beneficial," "harmful," "no effect," and "inconclusive"; and (IV) quality assessment is represented on the Y-axis. We observed that some studies (15,27) have made meaningful explorations especially in terms of rating of

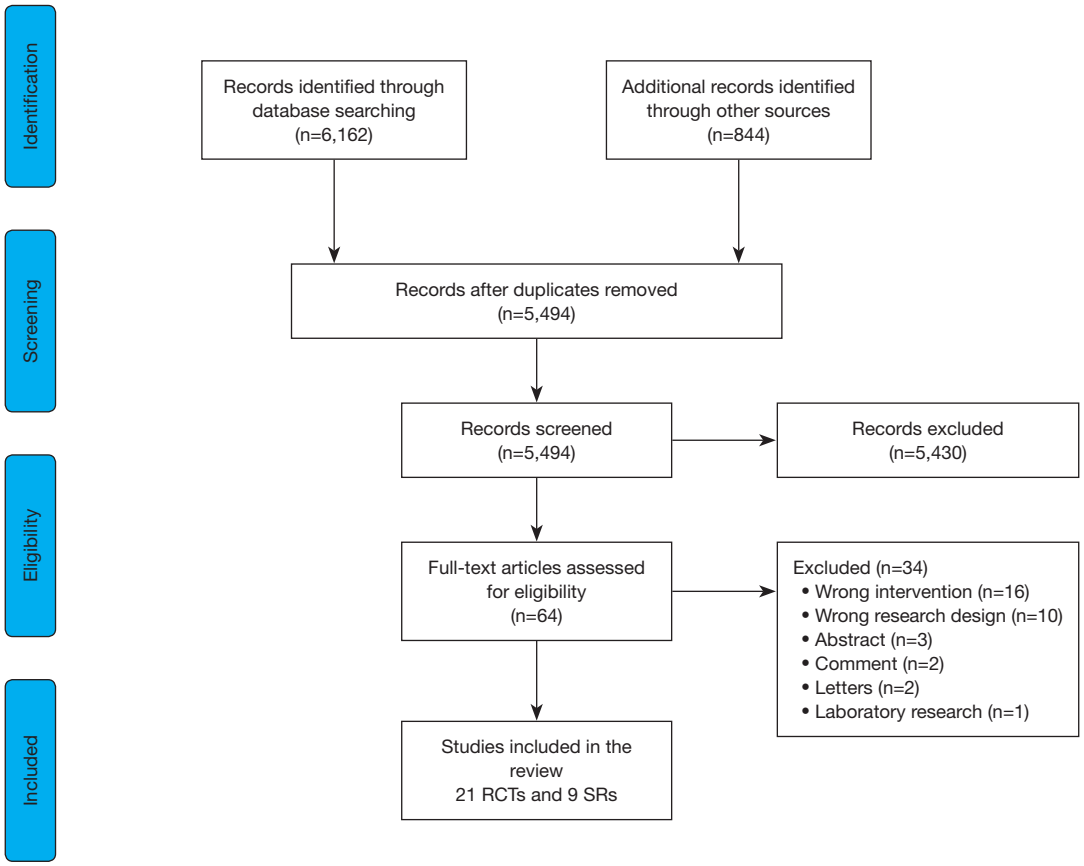

Figure 1 Flow diagram of the literature screening process and results.

the authors' conclusions. Based on these studies, we conducted in-depth discussions and divided the conclusions into five categories considering the descriptions of both the results and conclusions of the included study, in which "beneficial" indicated that the conclusions and results reported a clear beneficial effect without major concerns regarding supporting evidence, "probably beneficial" suggested that the conclusions did not claim firm benefits despite the reported positive treatment effect or the conclusions reported a potential benefits despite the result showing no significant difference, "harmful" suggested that the conclusions and results were reported to be clearly indicative of a harmful effect, "no effect" suggested that the conclusions and results provided evidence of no differences between intervention and comparator, and "inconclusive" suggested that the results of the study were insufficient for the authors to conclude whether the intervention has a definitive or potential effect. Moreover, the judgment indicators mainly were ILI, laboratory-confirmed respiratory infection, or self-reported infection symptoms. In addition, narrative synthesis was conducted for expanding upon mapping to provide more details about the included studies. These included descriptions of the evidence gaps and adverse events.

Results

Study selection

As shown in *Figure 1*, a total of 7,006 studies were initially included; however, of these, 1,512 duplicates were excluded. The titles and abstracts of the remaining 5,494 studies were screened, following which 5,430 studies were deemed unsuitable for inclusion. The full texts of the remaining 64 studies were screened and another 34 articles were excluded (Table S1). Finally, 21 RCTs and nine SRs were included and analyzed.

Study characteristics

The essential information of the included studies has been shown in *Table 1* (Table S2 for a more detailed summary

Table 1 The essential information of the included studies

Study	Country	Study design	Simple size/ number of RCTs*	Population and setting	Experimental	Control	The rating of conclusions	Quality assessment
Aiello AE, 2010 (29)	USA	RCT	1,297	1,437 students living in university residence halls; 1,297 residents further analyzed	Hand sanitizer, medical masks and education; face masks and education	Received the same education but no additional interventions	Probably beneficial	High ROB
Aiello AE, 2012 (30)	USA	RCT	1,111	1,178 students living in university residence halls; 1,111 residents further analyzed	Hand sanitizer and medical masks and education; medical masks and education	Received the same education but no additional interventions	Probably beneficial	High ROB
Atrie D, 2012 (31)	Canada	RCT	446	446 HCWs recruited from eight hospitals	N95 respirator	surgical mask	No effect	Unclear ROB
Barasheed O, 2014 (32)	Saudi Arabia	RCT	164	164 Australian pilgrims recruited from 2011 Hajj	Surgical masks	No facemasks provided	Probably beneficial	Unclear ROB
Canini L, 2010 (33)	France	RCT	306	372 households recruited from general practitioner clinics; 105 households which included 306 household contacts further analyzed	Surgical masks	No facemasks provided	Inconclusive	High ROB
Cowling BJ, 2008 (34)	China	RCT	350	350 household contacts	Hand sanitizer and education; surgical face masks and education	Healthy diet and lifestyle education	No effect	Unclear ROB
Cowling BJ, 2009 (35)	China	RCT	794	794 household contacts	Hand hygiene; surgical face masks plus hand hygiene	Healthy diet and lifestyle education	Probably beneficial	Unclear ROB
Jacobs JL, 2009 (36)	Japan	RCT	32	32 HCWs recruited from a tertiary care hospital in Japan	Surgical mask	No facemasks provided	No effect	High ROB
Larson EL, 2010 (37)	USA	RCT	1,842	617 households recruited; 509 households with 1,842 household contacts further analyzed	Hand sanitizer and surgical masks and education; hand sanitizer and education	Education	Probably beneficial	Unclear ROB
Leung NHL, 2020 (38)	China	RCT	246	246 exposed participants recruited from a general outpatient clinic of a private hospital in Hong Kong, China	Surgical masks	No facemasks provided	Beneficial	Unclear ROB
Loeb M, 2009 (39)	Canada	RCT	446	446 HCWs recruited from 8 hospitals	Fit-tested N95 respirator	Surgical mask	No effect	Unclear ROB

Table 1 (*continued*)

Table 1 (*continued*)

Study	Country	Study design	Simple size/ number of RCTs*	Population and setting	Experimental	Control	The rating of conclusions	Quality assessment
MacIntyre CR, 2009 (40)	Australia	RCT	286	286 exposed participants from 143 households recruited from a pediatric health service	Surgical masks; P2 masks	No facemasks provided	Probably beneficial	Low ROB
MacIntyre CR, 2011 (41)	China	RCT	1,441	1,441 HCWs recruited from 15 Beijing hospitals	Fit-tested N95 respirator; non-fit-tested N95 respirator	Medical masks	Beneficial	Unclear ROB
MacIntyre CR, 2013 (42)	China	RCT	1,669	1,669 HCWs recruited from 19 Beijing hospitals	N95 respirators; targeted use of N95 respirators	Medical masks	Beneficial	Unclear ROB
MacIntyre CR, 2014 (43)	China	RCT	1,441	1,441 HCWs recruited from 15 Beijing hospitals	N95 respirator	Medical masks	Beneficial	High ROB
MacIntyre CR, 2015 (44)	Vietnam	RCT	1,607	1,607 HCWs recruited from 14 hospitals	Medical masks; cloth masks	Usual practice	Probably beneficial	High ROB
MacIntyre CR, 2016 (45)	China	RCT	597	597 household contacts	Medical masks	No facemasks provided	Beneficial	Low ROB
Radonovich LJJr, 2019 (46)	USA	RCT	2,371	2,862 HCWs recruited from 7 medical centers, 2,371 completed the study	Fit-tested N95 respirator	Medical masks	No effect	Low ROB
Simmerman JM, 2011 (47)	Thailand	RCT	1,147	1,147 household contacts	Hand sanitizer; surgical masks	No facemasks provided	No effect	Unclear ROB
Suess T, 2012 (8)	Germany	RCT	218	218 household contacts	Hand sanitizer and surgical masks; surgical masks	No facemasks provided	Probably beneficial	Low ROB
Thomas F, 20115 (48)	USA	RCT	407	407 crew members	Surgical masks or N95-respirator	No facemasks provided	..	Unclear ROB
Bartoszko JJ, 2020 (49)	Canada	SR	4	5,927 HCWs from Canada, China, and USA	N95 respirators	Medical masks	No effect	Moderate quality
bin-Reza F, 2012 (50)	Sweden	SR	8	4,723 participants from Australia, USA, China, Canada, and Japan	N95 respirators; surgical masks	Surgical masks; no face masks provided	Probably beneficial	Critically Low quality
Jefferson T, 2011 (51)	UK	SR	7	5,047 individuals from university, household, and hospital	Face masks plus hand hygiene; surgical masks; P2 masks; N95 respirators	No facemasks provided; Medical masks	Probably beneficial	Moderate quality

Table 1 (*continued*)

Table 1 (*continued*)

Study	Country	Study design	Simple size/ number of RCTs*	Population and setting	Experimental	Control	The rating of conclusions	Quality assessment
Long Y, 2020 (52)	China	SR	6	286 exposed adults from 143 households recruited from a pediatric healthcare service in Australia and 7,814 HCWs from hospitals in China, Canada, and the US	N95 respirators; P2 masks	Surgical masks; Lifestyle measures	No effect	Moderate quality
Offeddu V, 2017 (53)	Singapore	SR	6 (4)[&]	5,195 HCWs in hospitals from China, Japan, Vietnam, and Canada	Fit-tested N95 respirator; non-fit-tested N95 respirator; medical masks	No facemasks provided; surgical masks	Probably beneficial	Moderate quality
Saunders-Hastings P, 2017 (10)	Canada	SR	1	218 household contacts	Hand sanitizer and face mask; face mask	No facemasks provided	Probably beneficial	High quality
Smith JD, 2016 (54)	Canada	SR	3	3,556 HCWs in hospitals from Canada and China	N95 respirators	Surgical masks	No effect	Moderate quality
Wong VWY, 2014 (55)	China	SR	6	5,612 participants come from university, hospital, clinics, households in developed and developing countries	Hand sanitizer and education; surgical masks and education; hand sanitizer and face masks and education	No facemasks provided; healthy diet and lifestyle education	Probably beneficial	Critically low quality
Xiao J, 2020 (9)	China	SR	10	7,806 participants from Australia and other countries.	Facemask plus hand Hygiene; surgical masks; P2 masks; N95 respirators	No facemasks provided; education	No effect	Critically low quality

*Sample size for RCT/Number of RCTs for SRs; HCWs, healthcare workers; ILI, Influenza-like illness; [&]number of RCTs: masks *vs.* usual practice (N95 respirators *vs.* medical masks); ROB, risk of bias.

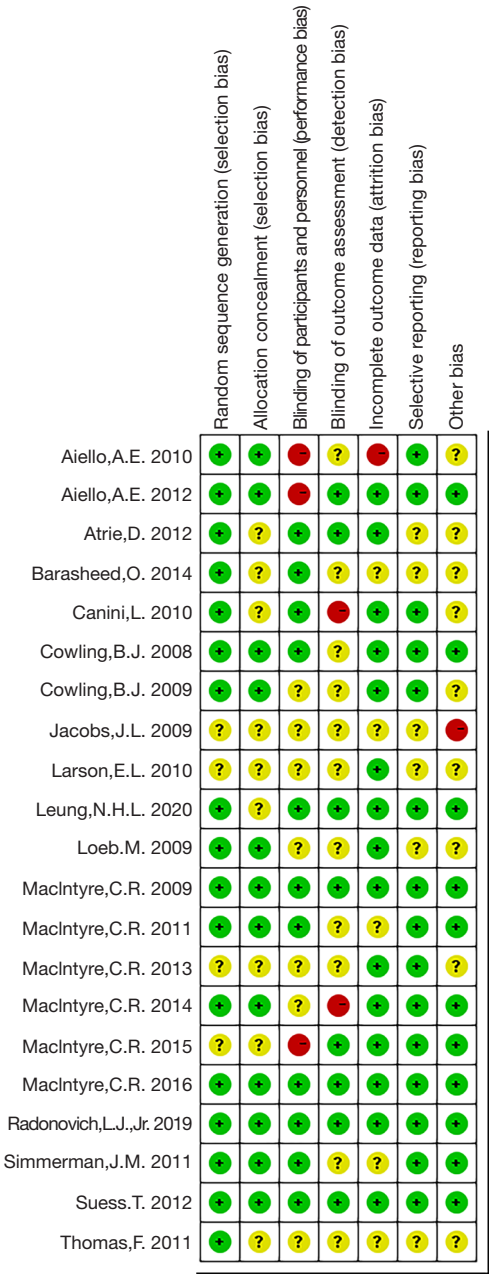

Figure 2 Quality assessment for the 21 included randomized controlled trials.

by PICO). In total, 21 trials evaluating 18,709 individuals were included in our study. Of the selected studies, the highest proportion were conducted in China (>30%, 7/21), followed by USA (23.81%, 5/21), Canada (9.52%, 2/21), Australia (4.76%, 1/21), France (4.76%, 1/22), Germany (4.76%, 1/21), Japan (4.76%, 1/21), Saudi Arabia (4.76%, 1/21), Thailand (4.76%, 1/21), and Vietnam (4.76%, 1/21). The populations in eight trials included healthcare workers (38.10%, 8/21); seven trials, household contacts (33.33%, 7/21); two trials, students (9.52%, 2/21); two trials, exposed participants (9.52%, 2/21); one trial, crewmembers (4.76%, 1/21); and one trial, Australian pilgrims (4.76%, 1/21). Furthermore, nine SRs were included in our study; of these, three were conducted in China (33.33%) and Canada (33.33%), one in Sweden (11.11%), the UK (11.11%), Australia (11.11%), and Singapore (11.11%). The populations in three of these studies included healthcare workers (33.33%); one, household contacts (11.11%), and five, mix populations (55.56%).

Quality assessment

A summary of the risk of bias for each included trial is shown in *Figure 2*. In the random-sequence generation analysis, over 80% (17/21) of trials described an adequate random-sequence generation process. Over 50% (12/21) trials described the use of sealed, opaque envelopes for allocation concealment. No one trial was selective in their data reporting. Eight trials had a "low risk of bias" regarding the blinding of outcome assessment and three trials had a "high risk of bias" in terms of blinding of participants. In addition, over 70% (15/21) of trials were found to have a "low risk of bias" in terms of incomplete outcome data. Other bias was detected in one trial.

As shown in *Figure 3*, according to the evaluation criteria of the latest version of AMSTAR-2, all SRs reported the components of PICO, duplicated coding for study selection and data extraction, and on comprehensive literature search, eight of the remaining items (items 2, 3, 8, 9, 11, 12, 13, and 16) were reported by over 50% SRs. Only less than 40% SRs reported Items 7, 10, 14, and 15. In particular, item 7 (provide a list of excluded studies and justify the exclusions) was reported in only one SR. In addition, only one SR (1/9) was assessed to be of "High quality", five SRs (5/9) were assessed to be of "Moderate quality", and three (3/9) SRs were assessed to be of "Critically Low" (Table S3).

Mapping

As shown in *Figure 4*, a bubble plot was designed for mapping, and four dimensions were used to visualize the RCTs and SRs (research populations, sample size/number of RCTs, the rating of conclusions, and quality assessment).

Masks *vs.* usual practice

As shown in *Figure 4A*, six SRs (9,10,50,51,53,55) evaluated

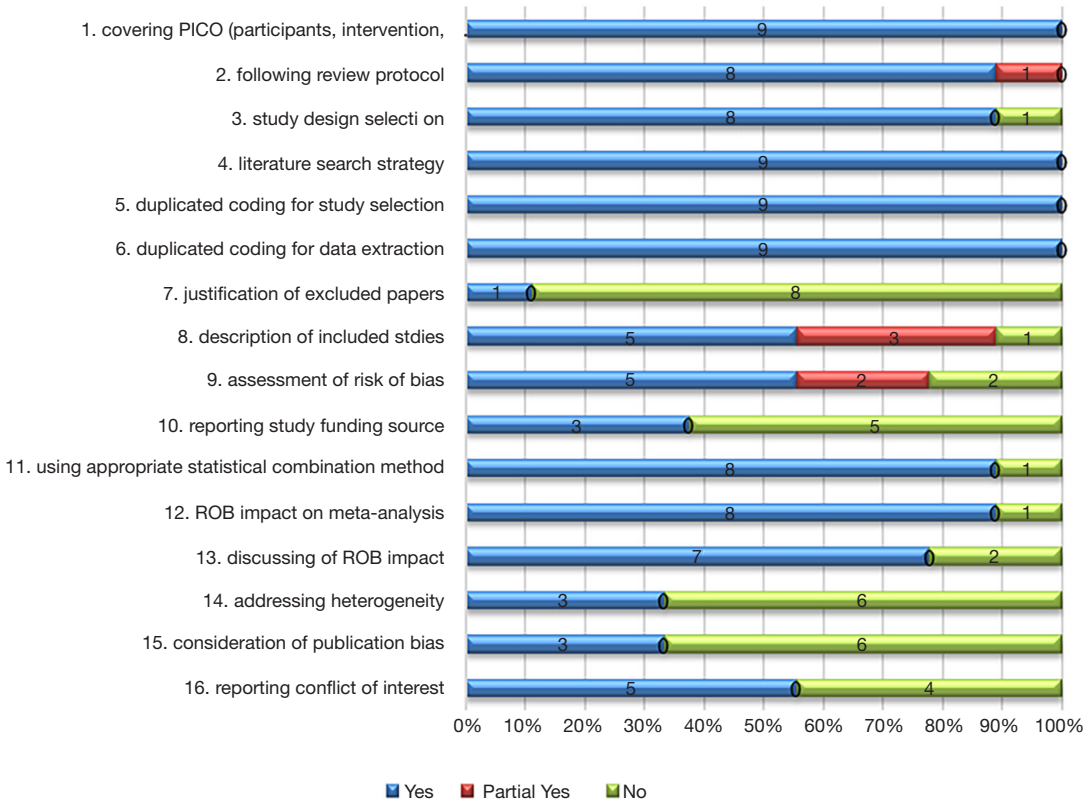

Figure 3 Quality assessment for the nine included systematic reviews.

the effects of wearing masks on the interruption or reduction in the spread of respiratory viruses compared with control groups (i.e., with only education and no face masks). Among them, five SRs (10,50,51,53,55) were selected as "probably beneficial" on the map suggestive of the probable effectiveness of regular masks in limiting transmission during pandemics; the effectiveness of masks and respirators in these studies was likely linked to early, consistent, and correct usage. The remaining study (9) showed "no effect" indicative of limited evidence to support the effectiveness of masks. Moreover, three SRs (9,50,55) were classified to be of "critically low quality", two (51,53) of "moderate quality", and one (10) of "high quality". Overall, 83.33% SRs (5/6, involving 28 RCTs) were included in "beneficial" or "probably beneficial" categories.

As shown in *Figure 4B*, 14 RCTs (8,29,30,32-38,40,44,45,47) including 9,997 participants researched the effects of wearing masks on the interruption or reduction in the spread of respiratory viruses when compared to the control groups. Among these, two RCTs (38,45) with 843 participants were categorized as "beneficial" indicating that masks were effective in interrupting or reducing the spread of respiratory viruses. Eight RCTs (8,29,30,32,35,37,40,44), including 7,319 participants were categorized as "probably beneficial", thereby indicating that masks may be helpful, and recommended wearing masks to interrupt the spread of respiratory viruses. Furthermore, three RCTs (34,36,37), including 1,529 participants were categorized as "no effect". The remaining RCT (33) including 306 participants was found to be "inconclusive", indicating that there was no sufficient evidence to draw a conclusion based on the research. Moreover, according to the risk of bias tool, three (8,40,45), five (29,30,33,36,44), and six (32,34,35,37,38,47) RCTs were assessed as "low risk of bias," "high risk of bias," and "unclear risk of bias," respectively. In all, 71.43% RCTs (10/14, including 8162 participants) were classified into "beneficial" or "probably beneficial" categories.

N95 respirators *vs*. medical masks

As shown in *Figure 4A*, four SRs (49,52-54) evaluated the effect of N95 respirators on the interruption or reduction of the spread of respiratory viruses compared that with the

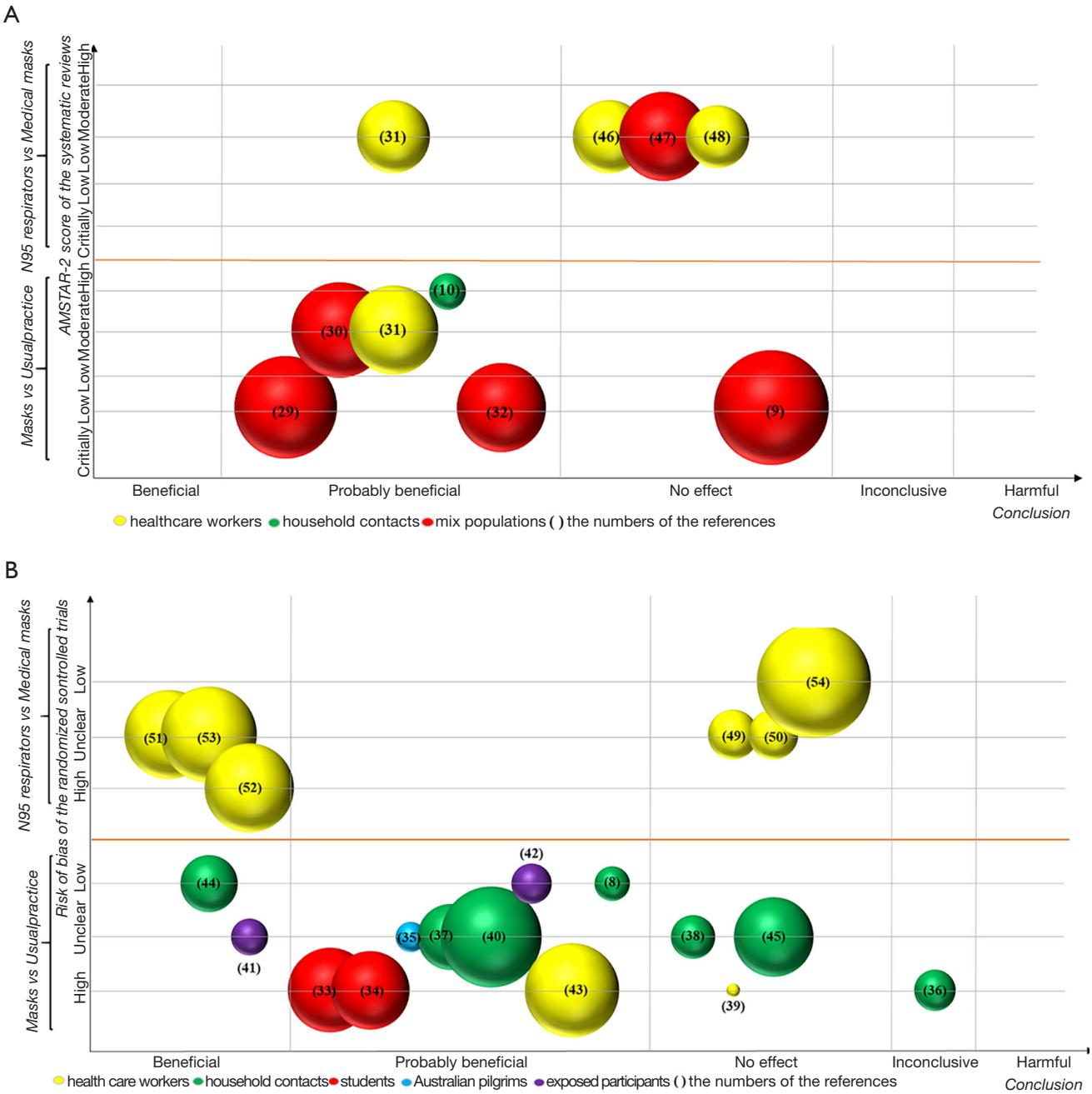

Figure 4 Evidence mapping for mask use during the spread of respiratory viruses.

effect of medical masks. Three SRs were categorized as "no effect," thereby indicating that N95 respirators did not have a better effect compared with medical masks. Furthermore, all four SRs (49,52-54) were assessed as "moderate quality". In all, only 25% (1/4, involving 4 RCTs) SRs was categorized under "beneficial" or "probably beneficial" categories.

As shown in *Figure 4B*, six RCTs (31,39,41-43,46) including 7814 participants evaluated the effect of N95 respirator on the interruption or reduction of the spread of respiratory viruses and compared that with the effect of medical masks. Among these, three RCTs (41-43), including 4,551 participants were categorized as "beneficial", thereby suggesting that N95 respirators may be effective for

interrupting or reducing the spread of respiratory viruses compared with medical masks. Furthermore, three RCTs (31,39,46) including 3,263 participants showed "no effect," indicating similar effects between N95 respirators and medical masks. In addition, one RCT (46) was assessed as "low risk of bias;" one (43), as "high risk of bias;" and four (31,39,41,42), as "unclear risk of bias". Overall, 50% RCTs (3/6, including 4,551 participants) were classified into "beneficial" or "probably beneficial" categories.

Adverse effects

Six trials (8,33,36,44,46,48) partially reported possible adverse effects of wearing masks, and showed that the mask groups were more likely to experience headaches during the study period, skin irritation, worsening acne, shortness of breath, and respiratory difficulties. In addition, since masks seem to affect the precise and clear transmission and reception of some aviation terms or instructions (i.e., helipad, fuel, weather) by pilots, flight nurses, layperson, dispatcher, etc., especially when the aircraft's engine is turned on, mask use may adversely affect radio communication (48). Notably, MacIntyre *et al.* (44) compared the efficacy of cloth masks to that of medical masks in hospital healthcare workers, and showed that participants using cloth masks (cotton, or gauze masks) showed a significantly higher rate of ILI compared with controls and suggested caution against cloth mask use.

Discussion

Summary of findings

In this EM study, concerning mask use for the prevention of the spread of respiratory viruses, we systematically searched for relevant published RCTs and SRs before April 2020. In all, 21 RCTs and nine SRs were included in this study. Among the 21 RCTs, most studies were conducted in China and the USA, and focused on the healthcare workers and household contacts. Overall, masks versus usual practice, 10 of 14 RCTs and 5 of 6 SRs were classified as "beneficial" or "probably beneficial". Furthermore, regarding N95 respirators versus medical masks, 3 of 6 RCTs were classified as "beneficial"; however, 75% of SRs showed that there was no significant difference between groups. In addition, six RCTs reported adverse effects of wearing masks, with one RCT implying that the cloth mask reuse may increase the risk of infection.

In terms of conclusion ratings, when comparing data between with and without masks, most included RCTs, as well as SRs, showed "beneficial" or "probably beneficial" effects of masks, with a higher number of participants wearing masks grouped in "beneficial" and "probably beneficial" categories compared to any other category (8,162 *vs.* 1,835), thereby suggesting that masks may have a positive effect on interrupting or reducing the spread of respiratory viruses, especially for healthcare workers, all relevant studies included show "probably beneficial" effects of masks. However, when comparing the outcomes with N95 respirators and those with medical masks, over 70% of SRs showed "no effect," whereas 50% of RCTs showed "beneficial" effects. Therefore, we were unable to draw a definitive conclusion on whether the N95 respirator is a better or worse choice than medical masks based on the current evidence. Thus, more relevant high-quality studies are needed for making this conclusion. In addition, among the 10 studies included, the subjects of nine studies were healthcare workers. Combined, the results of these studies largely showed that there were conflicting results regarding whether healthcare workers should wear N95 respirators or medical masks. Moreover, the reasons for this inconformity may be as follows. First, we ascertained the rating of conclusions ("beneficial", "probably beneficial", "harmful", "no effect" and "inconclusive") based on the descriptions of both the results and conclusions of the study; the conclusions of most RCTs considered the study design, intervention compliance, and sample size. Thus, the conclusions may be inconsistent with the statistical results. However, the conclusions of SRs depended more on the statistical effect (56-60). Second, the sample sizes of RCTs categorized into "beneficial" or "probably beneficial" categories and those of RCTs categorized into the "no effect" category were similar (4,551 *vs.* 3,263) (60).

Regarding the adverse effects of wearing masks, many experts and studies have indicated that given that complete elimination of COVID-19 does not seem likely in the near future, protective measures, such as maintaining social distancing and wearing masks may be necessary for a prolonged time. Furthermore, according to searched studies, insufficient high-quality design research was available that reported on the adverse effects of prolonged mask use. Among the 21 included RCTs, six reported possible adverse effects of prolonged mask use, such as headaches, skin irritation, and respiratory difficulties. In particular, one RCT implied that cloth mask reuse may increase the risk of an infection (61). It is noteworthy that cloth masks are commonly used in developing countries,

although many non-standard practices around cleaning and cloth mask reuse have evolved. Furthermore, given the COVID-19 situation, many developed countries are widely using cloth masks (44,62). This should draw the attention of the researchers and decision makers. Moreover, there is a lack of RCTs that systematically evaluate the adverse effects of the prolonged wear of masks. This may be because historically, the need to study this has been limited, given that very few pandemics requiring the mask use have been reported. Accordingly, there is limited literature on prolonged mask use, making it difficult to implement RCTs (63-66). A non-RCT reported that masks, especially N95 respirators, affected air intake, thereby decreasing the respiratory efficiency and increasing the respiratory burden (61), and this may affect normal life and even be life threatening for vulnerable populations, such as children, pregnant women, the elderly population, and individuals with chronic diseases or those performing high-intensity exercise. Thus, related RCTs should focus on developing a high-quality study design for evaluating this. In addition, for individuals with poor hearing or those who rely on lip reading, whether masks will significantly affect work efficiency and daily communication is worth further research.

The conclusion of this mapping study should be interpreted with caution because of the quality of the included studies. Combined, the quality of the included RCTs was relatively low as only four (4/21, 19.05%) were assessed to have a "low risk of bias". Furthermore, allocation concealment and outcome assessment blinding were weak links in the design and reporting of the included RCTs, which may affect the authenticity of the reported observations. Moreover, three SRs (3/9, 33.33%) assessed were of "critically low quality". Particularly, only one SR included "list of excluded studies and justification for exclusion", which needs the attention of researchers in the future.

Evidence gaps and future directions

Current evidence of high-quality design research concerning the mask use may be insufficient to deal with a second impact of such a pandemic in the future. First, in our study, EM showed that most studies focused on the effectiveness of masks compared with usual practice than that of N95 respirators compared with medical masks. Accordingly, further research is required for differential ratings of conclusions between SRs and RCTs in terms of effectiveness of N95 respirators compared with medical masks, especially for healthcare workers. Second, over 70% of RCTs focused on healthcare workers and household contacts, and the study of populations in places of gathering, such as students and company staff, was limited. Third, high-quality studies evaluating the adverse events of the prolonged wear of masks are of utmost importance, especially in special populations (such as children, pregnant women, the elderly population, and individuals with chronic diseases, poor hearing, patients who rely on lip reading, or those performing high-intensity exercise), and cases of special reactions (such as the obstruction of vision, skin allergy and sudden death). Fourth, given difficulty in accessing medical masks for many individuals during the pandemic, cloth masks were used as a substitute. However, there is currently only one RCT evaluating the effects of using a cloth mask, which reported that the cloth mask reuse showed a "harmful effect" and may increase the risk of an infection. Accordingly, additional high-quality studies are needed in the future. Fifth, optimal settings and exposure circumstances for populations to use masks should be investigated. For example, high-quality research is needed to explore the effects of wearing masks outdoors as well as indoors.

Strengths and limitations

Compared with other studies (9,11), our research systematically searched and included relevant high-quality study designs (RCTs and SRs), and used bubble charts to visually present the existing research from multiple important dimensions. Moreover, we ascertained the rating of conclusions based on the descriptions of both the results and conclusions of the studies, which may avoid the uncertainty caused by policy recommendations determined based on only the result or conclusion of studies in a sense (56,58,63). In addition, we found evidence gaps, which not only are instructive for future research and for avoiding the wastage of academic resources but are also of great significance to policy makers. Some limitations of this study should be mentioned. First, we did not include other study designs (such as cohort studies, and case analysis); however, RCTs and SRs usually provide the highest quality evidence for decision-making. Second, our findings are only based on publications before the search date (April 9, 2020). With the emergence of newly related studies, regular updates of the existing results will be done in two years. Third, we did not perform sensitivity analysis, heterogeneity analysis, etc.,

because unlike SRs, these are not performed in EMs.

Conclusions

The current evidence of high-quality design research concerning mask use may be insufficient to deal with a second impact of such a pandemic in the future. Overall, masks may be effective in interrupting or reducing the spread of respiratory viruses. However, the study conclusions on the effectiveness of N95 respirators over medical masks are contradictory, especially for healthcare workers, and high-quality design evidence for mask use by a special population (such as students and company employees) is rare, and this requires further research. In addition, it is noteworthy that a few adverse effects of wearing masks have been systematically reported in existing high-quality design evidence. Accordingly, many high-quality studies are of utmost importance to assess the impact of the prolonged wear of masks on vulnerable populations and to assess the possible adverse events. Finally, in view of the current research, cloth mask reuse may aggravate the spread of respiratory infection, which needs to be further evaluated.

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Footnote

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Ethical statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Supplementary

Contents

Table S1 Electronic search strategies

Databases [Platform] Searches run April 2020	Results
PubMed	1253
Cochrane Library	517
Embase	1781
WOS	2611
Other sources (ClinicalTrials.gov, gray literature, and reference lists of articles)	844
TOTAL	7006
Duplicate	1512

Database: PubMed <April 9th 2020> 1253
Search Strategy:

#	Searches	Results
#1	"Masks"[Mesh]	9270
#2	Search Terms: (mask OR facemask OR FFP2 OR respirators OR masks OR N95 OR respirator OR "personal protection equipment" OR "personal protective equipment" OR protective devices OR respiratory protective devices) Search Fields: Title/Abstract	43723
#3	#1 OR #2	46102
#4	Search Terms: ("particulate matter" OR respiratory OR ARI OR chickenpox OR CRI OR droplet OR particle OR pathogen OR epidemic OR flu OR H1N1 OR coronavirus OR haemophilus OR aerosol OR "health care acquired" OR "health care associated" OR "healthcare acquired" OR "healthcare associated" OR "chicken pox" OR "hospital acquired" OR adenovirus OR "hospital associated" OR communicable OR HiB OR ILI OR bioaerosol OR infect OR cross infect OR influenza OR airborne OR measles OR MERS OR metapneumovirus OR bacteri OR "Middle East respiratory syndrome" OR pandemic OR orthomyxoviridae OR parainfluenza OR particle OR paramyxoviridae OR pathogen OR "respiratory disease" OR pneumonia OR "respiratory illness" OR "respiratory hygiene" OR "respiratory tract" OR "respiratory infection" OR rhinovirus OR virus OR "respiratory virus" OR RSV OR SARS-CoV-2 OR COVID-19 OR SARS OR virion OR "severe acute respiratory syndrome" OR viral OR pertussis OR varicella OR "whooping cough") Search Fields: Title/Abstract	1859227
#5	"Respiratory Tract Infections"[Mesh]	353327
#6	#4 OR #5	2047316
#7	"Clinical Trials, Phase II as Topic"[Mesh] OR "Clinical Trials, Phase III as Topic"[Mesh] OR "Clinical Trials, Phase IV as Topic"[Mesh] OR "Controlled Clinical Trials as Topic"[Mesh] OR "Randomized Controlled Trials as Topic"[Mesh] OR "Intention to Treat Analysis"[Mesh] OR "Pragmatic Clinical Trials as Topic"[Mesh] OR "Clinical Trials, Phase II"[Publication Type] OR "Clinical Trials, Phase III"[Publication Type] OR "Clinical Trials, Phase IV"[Publication Type] OR "Controlled Clinical Trials"[Publication Type] OR "Randomized Controlled Trials"[Publication Type] OR "Pragmatic Clinical Trials as Topic"[Publication Type] OR "Single-Blind Method"[Mesh] OR "Double-Blind Method"[Mesh]	325776
#8	Search Terms: (random* OR singleblind* OR blind* OR doubleblind* OR tripleblind* OR trebleblind*) Search Fields: Title/Abstract	1255768
#9	#7 OR #8	1352738
#10	#3 AND #6 AND #9	1253

http://dx.doi.org/10.21037/atm-20-6745

Database: Cochrane Library <April 9th 2020> 517
Search Strategy:

#	Searches	Results
#1	[Masks] explode all trees	1513
#2	(mask or facemask or FFP2 or respirators or masks or N95 or respirator or "personal protection equipment" or "personal protective equipment" or protective devices or respiratory protective devices):ti	4941
#3	#1 OR #2	5396
#4	[Respiratory Tract Infections] explode all trees	14230
#5	("particulate matter" or respiratory or ARI or chickenpox or CRI or droplet or particle or pathogen or epidemic or flu or H1N1 or coronavirus or haemophilus or aerosol or "health care acquired" or "health care associated" or "healthcare acquired" or "healthcare associated" or "chicken pox" or "hospital acquired" or adenovirus or "hospital associated" or communicable or HiB or ILI or bioaerosol or infect or cross infect or influenza or airborne or measles or MERS or metapneumovirus or bacteri or "Middle East respiratory syndrome" or pandemic or orthomyxoviridae or parainfluenza or particle or paramyxoviridae or pathogen or "respiratory disease" or pneumonia or "respiratory illness" or "respiratory hygiene" or "respiratory tract" or "respiratory infection" or rhinovirus or virus or "respiratory virus" or RSV or SARS-CoV-2 or COVID-19 or SARS or virion or "severe acute respiratory syndrome" or viral or pertussis or varicella or "whooping cough"):ti	63755
#6	#4 OR #5	71118
#7	#3 AND #6	517

Database: Embase <April 9th 2020> 1781
Search Strategy:

#	Searches	Results
#1	'mask'/exp	34117
#2	Search Terms: (mask OR facemask OR FFP2 OR respirators OR masks OR N95 OR respirator OR "personal protection equipment" OR "personal protective equipment" OR protective devices OR respiratory protective devices) Search Fields: Title/Abstract	55540
#3	#1 OR #2	75059
#4	'respiratory tract infection'/exp	453102
#5	Search Terms: ("particulate matter" OR respiratory OR ARI OR chickenpox OR CRI OR droplet OR particle OR pathogen OR epidemic OR flu OR H1N1 OR coronavirus OR haemophilus OR aerosol OR "health care acquired" OR "health care associated" OR "healthcare acquired" OR "healthcare associated" OR "chicken pox" OR "hospital acquired" OR adenovirus OR "hospital associated" OR communicable OR HiB OR ILI OR bioaerosol OR infect OR cross infect OR influenza OR airborne OR measles OR MERS OR metapneumovirus OR bacteri OR "Middle East respiratory syndrome" OR pandemic OR orthomyxoviridae OR parainfluenza OR particle OR paramyxoviridae OR pathogen OR "respiratory disease" OR pneumonia OR "respiratory illness" OR "respiratory hygiene" OR "respiratory tract" OR "respiratory infection" OR rhinovirus OR virus OR "respiratory virus" OR RSV OR SARS-CoV-2 OR COVID-19 OR SARS OR virion OR "severe acute respiratory syndrome" OR viral OR pertussis OR varicella OR "whooping cough") Search Fields: Title/Abstract	2283350
#6	#4 OR #5	2507169
#7	'phase 2 clinical trial (topic)'/exp OR 'multicenter study (topic)'/exp OR 'phase 3 clinical trial (topic)'/exp OR 'controlled clinical trial (topic)'/exp OR 'phase 4 clinical trial (topic)'/exp OR 'randomized controlled trial (topic)'/exp OR 'double blind procedure'/exp' OR single blind procedure'/exp	427430
#8	Search Terms: (random* OR singleblind* OR blind* OR doubleblind* OR tripleblind* OR trebleblind*) Search Fields: Title/Abstract	1707345
#9	#7 OR #8	1865091
#10	#3 AND #6 AND #9	1781

http://dx.doi.org/10.21037/atm-20-6745

Database: WoS<April 9th 2020> 2611
Search Strategy:

#	Searches	Results
#1	TOPIC: (mask or facemask or FFP2 or respirators or masks or N95 or respirator or "personal protection equipment" or "personal protective equipment" or protective devices or respiratory protective devices)	155777
#2	TOPIC: ("particulate matter" or respiratory or ARI or chickenpox or CRI or droplet or particle or pathogen or epidemic or flu or H1N1 or coronavirus or haemophilus or aerosol or "health care acquired" or "health care associated" or "healthcare acquired" or "healthcare associated" or "chicken pox" or "hospital acquired" or adenovirus or "hospital associated" or communicable or HiB or ILI or bioaerosol or infect or cross infect or influenza or airborne or measles or MERS or metapneumovirus or bacteri or "Middle East respiratory syndrome" or pandemic or orthomyxoviridae or parainfluenza or particle or paramyxoviridae or pathogen or "respiratory disease" or pneumonia or "respiratory illness" or "respiratory hygiene" or "respiratory tract" or "respiratory infection" or rhinovirus or virus or "respiratory virus" or RSV or SARS-CoV-2 or COVID-19 or SARS or virion or "severe acute respiratory syndrome" or viral or pertussis or varicella or "whooping cough")	3570063
#3	TOPIC: (randomized controlled trial OR Clinical trial OR Controlled Clinical trial OR random* OR singleblind* OR blind* OR doubleblind* OR tripleblind* OR trebleblind*)	2305918
#4	#3 AND #2 AND #1	2611

Database: WHO International Clinical Trials Registry Platform (ICTRP) Search Portal <April 27th 2020> 86
Search terms: "mask"; applied filters: "With Results" and "Interventional"

Database: Clinical trial registry <April 27th 2020> 351
Search terms: "mask"; applied filters: "With Results" and "Interventional"

Database: Gray literature <April 27th 2020> 402
Search term: "mask": 402

http://dx.doi.org/10.21037/atm-20-6745

Table S2 Excluded studies: 34

Title	Author, year	Reason for Exclude
Results of the respiratory protection effectiveness clinical trial (respect)	Radonovich, L, 2018	Abstract
The First Randomized, Controlled Clinical Trial of Mask Use in Households to Prevent Respiratory Virus Transmission	MacIntyre, C. R, 2018	Abstract
A randomized intervention trial of mask use and hand hygiene to reduce seasonal influenza-like illness and influenza infections among young adults in a university setting	Aiello, A. E, 2010	Abstract
Influence of household contacts on the effectiveness of face masks for preventing influenza in a healthcare setting: a comment on Cowling *et al.*	Williams, C. J, 2010	Comment
Health care worker use of N95 respirators vs medical masks did not differ for workplace-acquired influenza	Glatt, A. E, 2020	Comment
A randomised controlled pilot study to compare filtration factor of a novel non-fit-tested high-efficiency particulate air (HEPA) filtering facemask with a fit-tested N95 mask	Au, S. S, 2010	Laboratory research
Efficacy of face masks and respirators in preventing upper respiratory tract bacterial colonization and co-infection in hospital healthcare workers - Comment on the article by MacIntyre et al	Soerokromo, N. S, 2014	Letters
Surgical masks vs N95 respirators for preventing influenza	Clynes, N, 2010	Letters
The efficacy and safety of laryngeal mask versus endotracheal tubes for laparoscopic surgery: A meta-analysis	Yasen, Y, 2017	Wrong intervention
Airway Complications during and after General Anesthesia: A Comparison, Systematic Review and Meta-Analysis of Using Flexible Laryngeal Mask Airways and Endotracheal Tubes	Xu, R, 2016	Wrong intervention
Effect of reduction in household air pollution on childhood pneumonia in Guatemala (RESPIRE): a randomised controlled trial	Smith, K. R, 2011	Wrong intervention
The use of gowns and masks to control respiratory illness in pediatric hospital personnel	Murphy, D, 1981	Wrong intervention: multiple interventions
Comparison of laryngeal mask airway Supreme and laryngeal mask airway Pro-Seal for controlled ventilation during general anaesthesia in adult patients: Systematic review with meta-analysis	Maitra, S, 2014	Wrong intervention
Optimal dose of succinylcholine for laryngeal mask airway insertion: systematic review, meta-analysis and metaregression of randomised control trials	Liao, A. H, 2017	Wrong intervention
The impact of laryngeal mask versus other airways on perioperative respiratory adverse events in children: A systematic review and meta-analysis of randomized controlled trials	Li, L, 2019	Wrong intervention
Effect of airway clearance techniques in patients experiencing an acute exacerbation of chronic obstructive pulmonary disease: A systematic review	Hill, K, 2010	Wrong intervention
The effect of sevoflurane versus desflurane on the incidence of upper respiratory morbidity in patients undergoing general anesthesia with a Laryngeal Mask Airway: A meta-analysis of randomized controlled trials	De Oliveira Jr, G. S, 2013	Wrong intervention
A systematic review and meta-analysis of the i-gel((R)) vs laryngeal mask airway in adults	de Montblanc, J, 2014	Wrong intervention
Laryngeal Mask Airway Versus Other Airway Devices for Anesthesia in Children With an Upper Respiratory Tract Infection: A Systematic Review and Meta-analysis of Respiratory Complications	de Carvalho, A. L. R, 2018	Wrong intervention
Non-invasive ventilation improves respiratory distress in children with acute viral bronchiolitis: A systematic review	Combret, Y, 2017	Wrong intervention
Comparison of the effectiveness of inhaler devices in asthma and chronic obstructive airways disease: a systematic review of the literature	Brocklebank, D. Ram, F, 2001	Wrong intervention
The advantages of the LMA over the tracheal tube or facemask: a meta-analysis	Brimacombe, J, 1995	Wrong intervention
Comparative efficacy and safety of the Ambu((R)) AuraOnce() laryngeal mask airway during general anaesthesia in adults: a systematic review and meta-analysis	Baidya, D. K, 2014	Wrong intervention
Household transmission of influenza A and B in a school-based study of non-pharmaceutical interventions	Azman, A. S, 2013	Wrong intervention
Protection by Face Masks against Influenza A(H1N1)pdm09 Virus on Trans-Pacific Passenger Aircraft, 2009	Zhang, L. J, 2013	Wrong research design
Respiratory consequences of N95-type Mask usage in pregnant healthcare workers-a controlled clinical study	Tong, P. S. Y, 2015	Wrong research design: CCT
Public perceptions of non-pharmaceutical interventions for reducing transmission of respiratory infection: systematic review and synthesis of qualitative studies	Teasdale, E, 2014	Wrong research design
Facemasks and intensified hand hygiene in a German household trial during the 2009/2010 influenza A(H1N1) pandemic: adherence and tolerability in children and adults	Suess, T, 2011	Wrong research design
Who should wear mask against airborne infections? Altering the contact network for controlling the spread of contagious diseases	Schimit, P. H. T, 2010	Wrong research design
The efficacy of medical masks and respirators against respiratory infection in healthcare workers	MacIntyre, C. R, 2017	Wrong research design
Prevalence of preventive behaviors and associated factors during early phase of the H1N1 influenza epidemic	Lau, J. T. F, 2010	Wrong research design
Impact of the flu mask regulation on health care personnel influenza vaccine acceptance rates	Edwards, F, 2016	Wrong research design
Aerosol transmission is an important mode of influenza A virus spread	Cowling, B. J, 2013	Wrong research design
Facemasks for the prevention of infection in healthcare and community settings	MacIntyre, C. R,2015	Wrong research design

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Table S3 Summary of studies included by PICO framework

Study	Country	Objectiveness	Population and Setting	Experimental	Control	Result	Conclusion
Aiello AE,2010	USA	To examine the role of masks and hand hygiene in preventing ILI	1437 students living in university residence halls;1297 residents further analyzed	Hand sanitizer and medical masks and education; medical mask and education	Only education intervention	Compared with the control group, the incidence of ILI in the mask and hand hygiene group decreased significantly, but the incidence of ILI does not seem to be statistically different between the mask group, hand hygiene group, and control group	Hand hygiene and mask intervention may be effective in reducing the occurrence of respiratory diseases and reducing the adverse effects of the pandemic.
Aiello AE,2012	USA	To explore the effects of using masks and hand hygiene in the natural setting to prevent influenza	1178 students living in university residence halls; 1111 residents further analyzed	Hand sanitizer and medical masks and education; medical masks and education	Received the same education but no additional interventions	Compared with the control group, the incidence of influenza in the intervention group (mask group) did not significantly decrease	In the community environment, the combined use of masks and hand hygiene can reduce the occurrence of influenza
Atrie D,2012	Canada	To evaluate the effectiveness of N95 respirators compared to standard surgical masks in reducing influenza infection in health care workers	446 HCWs recruited from eight hospitals	N95 respirator	surgical mask	Compared with the surgical mask group, the laboratory-confirmed influenza cases in the N95 mask group did not decrease significantly	The protection provided by an N95 respirator is not superior to that provided by a standard surgical mask
Barasheed O,2014	Saudi Arabia	To determine the effectiveness of facemasks in preventing influenza	164 Australian pilgrims recruited from 2011 Hajj	Surgical mask	No facemasks provided	Compared with the control group, mask intervention has no significant effect in laboratory-confirmed influenza, but the incidence of ILI has dropped significantly	This was a pilot study with small sample, which has shown the feasibility of a future full-scale study
Canini L,2010	France	To evaluate the effectiveness of facemask use for preventing influenza in households	372 households recruited from general practitioner clinics; 105 households which included 306 household contacts further analyzed	Surgical mask	No facemasks provided	No significant difference in preventing transmission of influenza in households between control and mask-only group	Due to the lack of corresponding evidence, we cannot draw a definite conclusion
Cowling BJ,2008	China	To evaluate the feasibility and efficacy of face masks and hand hygiene to reduce influenza transmission among Hong Kong household members	944 participants recruited from outpatient clinics; 122 households with 350 household contacts further analyzed	Hand sanitizer and education; surgical face masks and education	Healthy diet and lifestyle education	No significant reduction in the secondary influenza attack rate in control, mask or hand group	The secondary attack ratios were lower than anticipated, and lower than reported in other countries, perhaps due to differing patterns of susceptibility
Cowling BJ,2009	China	To investigate whether hand hygiene and use of face-masks prevents household transmission of influenza	407 laboratory-confirmed influenza cases recruited from outpatient clinics; 259 households which included 794 household contacts further analyzed	Hand hygiene; surgical facemasks plus hand hygiene	Healthy diet and lifestyle education	No significant difference in rates of laboratory-confirmed influenza in control, hand-only or mask and hand group	Hand hygiene and facemasks seemed to prevent household transmission of influenza virus when implemented within 36 hours of index patient symptom onset
Jacobs JL,2009	Japan	To evaluate the effectiveness of face masks in reducing influenza infection in HCWs	32 HCWs recruited from a tertiary care hospital in Japan	Surgical mask	No facemasks provided	No difference in self-reported cold symptoms between control and face mask	For health care workers' cold incidence, the benefits of using masks have not been proven
Larson EL,2010	USA	To explore the effectiveness of hand sanitizer and masks in reducing the incidence of upper respiratory infections and influenza	617 households recruited; 509 households with 1842 household contacts further analyzed	Hand sanitizer and surgical mask and education; hand sanitizer and education	Education	No significant reduction in rates of laboratory-confirmed influenza in control, hand-only, mask or hand group	Wearing a mask seems to reduce the spread of influenza
Leung NHL,2020	China	To explore the importance of respiratory droplet and aerosol routes of transmission and determining the potential efficacy of surgical face masks to prevent respiratory virus transmission	246 exposed participants recruited from a general outpatient clinic of a private hospital in Hong Kong, China	Surgical face masks	No facemasks provided	Surgical face masks significantly reduced detection of influenza virus RNA in respiratory droplets and coronavirus RNA in aerosols, with a trend toward reduced detection of coronavirus RNA in respiratory droplets	Surgical face masks could prevent transmission of human coronaviruses and influenza viruses from symptomatic individuals
Loeb M,2009	Canada	To compare the surgical mask with the N95 respirator in protecting HCWs against influenza	446 HCWs recruited from emergency departments, medical units, and pediatric units of 8 tertiary care Ontario hospitals	Fit-tested N95 respirator	Surgical mask	No significant difference in preventing Influenza infection between surgical mask group and N95 respirator group	Among nurses in Ontario tertiary care hospitals, compared with N95 respirator, using surgical mask resulted in noninferior rates of laboratory-confirmed influenza
MacIntyre CR,2009	Australia	To compare the efficacy of surgical masks, non-fit-tested P2 masks, and no masks in prevention of ILI in households	286 exposed participants from 143 households recruited from a pediatric health service	Surgical mask; P2 mask	No facemasks provided	No significant difference in rate of laboratory confirmed influenza in control, face mask-only or P2 mask-only group	Face masks is ineffective for controlling seasonal respiratory disease. However, the use of masks may block the spread of the virus during severe epidemic
MacIntyre CR,2011	China	To study the effectiveness and differences of medical masks and N95 respirators for protecting medical staff in the hospital setting	1441 HCWs recruited from 15 Beijing hospitals	Fit-tested N95 respirator; non-Fit-tested N95 respirator	Medical masks	Compared with the N95 respirator group, the incidence of infection in the medical mask group was higher	N95 respirators seem to be more effective than medical masks
MacIntyre CR,2013	China	To study the effectiveness and differences of medical masks and N95 respirators for protecting medical staff in the hospital setting	1669 HCWs recruited from 19 Beijing hospitals	N95 respirators; targeted use of N95 respirators	Medical masks	Compared with the medical mask group, the incidence of CRI is lower in the N95 respirators	N95 respirators are more effective than medical masks for the prevention of CRI, especially continuous use of them
MacIntyre CR,2014	China	To study the effectiveness and differences of medical masks and N95 respirators for protecting medical staff in the hospital setting	1441 HCWs recruited from 15 Beijing hospitals	N95 respirator	Medical masks	N95 respirators were significantly protective against bacterial colonization.	N95 masks have a significant effect on preventing infections of healthcare workers
MacIntyre CR,2015	Vietnam	To study the effectiveness and differences of medical masks and cloth masks for protecting medical staff in the hospital setting	1607 HCWs recruited from 14 hospitals	Medical mask; cloth masks	Usual practice	Compared with the medical mask group, the infection rate in the cloth mask group was significantly higher	The cloth mask group has a higher infection rate and should be used with caution
MacIntyre CR,2016	China	To study the effectiveness of medical masks in preventing infections	245 ILI^ cases and 597 household contacts recruited from fever clinics	Medical mask	No facemasks provided	Clinical respiratory illness, ILI and laboratory-confirmed viral infections were lower in the mask-only group	Medical masks have a potential role in infection control
Radonovich LJJr,2019	USA	To study the effectiveness and differences of medical masks and N95 respirators for protecting medical staff in the hospital setting	2862 HCWs recruited from 7 medical centers, 2371 completed the study	Fit-tested N95 respirator	Medical masks	Compared with the medical mask group, the infection rate of the N95 respirator group did not change significantly	N95 respirators and medical masks are not significantly different in protecting outpatient medical staff from influenza
Simmerman JM,2011	Thailand	To examine the effectiveness of non-pharmaceutical interventions to reduce influenza transmission	1147 household contacts	Hand sanitizer; surgical face mask;	No facemasks provided	Compared with the control group, there was no significant difference in the incidence of influenza in the mask group	Hand hygiene and masks do not seem to reduce the spread of influenza
Suess T,2012	Germany	To investigate efficacy, acceptability, and tolerability of non-pharmaceutical interventions in households with influenza index patients	218 household contacts	Hand sanitizer and surgical face mask; surgical face mask	No facemasks provided	Compared with the control group, there was no significant difference in the incidence of influenza in the mask group	Some interventions, such as mask interventions, may reduce the spread of influenza in the family
Thomas F,2011	USA	To study the impact of wearing masks on radio reception	407 crew members	Surgical facemask or N95-Respirator	No facemasks provided	When the aircraft engine starts, the mask will affect the accurate transmission and reception of some flight terms	the mask maybe affect the accurate transmission and reception of some flight terms
Bartoszko, J. J,2020	Canada	To study the effectiveness and differences of medical masks and N95 respirators for protecting medical staff in the hospital setting	5927 HCWs from Canada, China, and USA	N95 respirators	Medical masks	Compared with the medical mask group, the infection rate of the N95 respirator group did not change significantly	N95 respirators are similar to medical masks in improving protection, however, the quality of evidence currently available is lower
bin-Reza, F,2012	Sweden	To seek evidence to stop the spread of the pandemic	4723 participants from Australia, USA, China, Canada, and Japan	N95 respirators; surgical masks	Surgical masks; no facemasks provided	Compared with the N95 respirator group, the incidence of respiratory disease in the medical mask group was higher	Long-term, continuous use of masks or hand hygiene may be effective for pandemic control
Jefferson T,2011	UK	To study the effect of physical intervention in blocking the respiratory virus transmission	5047 individuals from university, household, and hospital	Facemask Plus Hand Hygiene; surgical mask group; P2 mask; N95 respirators	No facemasks provided; Medical masks	Masks are useful for virus transmission	Masks are useful for virus transmission, and N95 respirators are better than medical masks
Long YL, 2020	China	To study the effectiveness and differences of medical masks and N95 respirators for protecting medical staff and households	286 exposed adults from 143 households recruited from a pediatric healthcare service in Australia and 7814 HCWs from hospitals in China, Canada, and the US	N95 respirators; P2 mask	Surgical masks; Lifestyle measures	Compared with the medical mask group, the infection rate of the N95 respirator group did not change significantly	N95 respirators are similar to medical masks in improving protection
Offeddu V, 2017	Singapore	To study the effectiveness and differences of medical masks and N95 respirators for protecting medical staff in the hospital setting	5195 HCWs in hospitals from China, Japan, Vietnam, and Canada	N95 respirators; medical masks	No facemasks provided; surgical masks	Compared with the N95 respirator group, the incidence of respiratory disease in the medical mask group was higher	Masks have a beneficial effect on the spread of respiratory viruses. N95 respirators are better than medical masks, but the currently available evidence is of low quality and quantity
Saunders-Hastings P, 2017	Canada	To examine the effectiveness of personal protective measures in preventing pandemic influenza transmission in human populations.	84 laboratory-confirmed influenza cases and 218 household contacts recruited by general practitioners or pediatricians in Germany	Hand sanitizer and face mask; face mask	No facemasks provided	Facemask use provided a non-significant protective effect against 2009 pandemic influenza infection	Regular hand hygiene and facemask may be effective at limiting transmission during future pandemics
Smith, J. D,2016	Canada	To study the effectiveness and differences of medical masks and N95 respirators for protecting medical staff in the hospital setting	3556 HCWs in hospitals from Canada and China	N95 respirators	Surgical masks	Compared with the medical mask group, the infection rate of the N95 respirator group did not change significantly	N95 respirators are similar to medical masks in improving protection
Wong, V. W. Y,2014	China	To study the effectiveness of non-pharmacological interventions such as masks and hand hygiene in blocking the spread of influenza in the community	5612 participants come from university, hospital, clinics, households in developed and developing countries	Hand sanitizer and education; surgical face masks and education; hand sanitizer and face mask and education	No facemasks provided; healthy diet and lifestyle education	Combined hand hygiene and facemask showed significant reduction in both laboratory confirmed inflluenza outcomes	Personal interventions such as masks and hand hygiene are important to stop the influenza virus
Xiao, J,2020	China	To study the effectiveness of personal non-pharmacological interventions such as masks and hand hygiene in blocking influenza viruses	7806 participants from Australia and other countries.	Facemask Plus Hand Hygiene; surgical mask group; P2 mask; N95 respirators	No facemasks provided; education	No significant reduction in influenza transmission with the use of face masks	Limited evidence on the effectiveness of improved hygiene and environmental cleaning

ILI, Influenza-like illness; HCWs, healthcare workers; CRI, clinical respiratory illness

Table S4 Quality assessment results for SRs (AMSTAR-2)

Author	Items 1	Items 2	Items 3	Items 4	Items 5	Items 6	Items 7	Items 8	Items 9	Items 10	Items 11	Items 12	Items 13	Items 14	Items 15	Items 16	Total
Bartoszk 2020	1	1	3	1	1	1	3	1	1	1	1	1	1	3	3	3	Moderate quality
bin-Reza, 2012	1	1	1	1	1	1	3	1	3	3	4	4	3	3	4	1	Critically Low
Jefferson 2011	1	1	1	1	1	1	3	1	2	3	1	1	1	1	1	1	Moderate quality
Long, 2020	1	1	1	1	1	1	1	2	1	3	1	1	1	3	3	1	Moderate quality
Offeddu, 2017	1	1	1	1	1	1	3	1	2	3	1	1	1	3	1	1	Moderate quality
Saunders 2017	1	1	1	1	1	1	3	2	1	1	1	1	1	1	1	1	High quality
Smith 2016	1	1	1	1	1	1	3	2	1	3	1	1	1	3	3	3	Moderate quality
Wong 2014	1	1	1	1	1	1	3	3	1	1	1	1	3	3	3	3	Critically Low
Xiao 2020	1	2	1	1	1	1	3	1	3	3	1	1	1	1	3	3	Critically Low

SRs, systematic reviews; AMSTAR-2, Assessment of Multiple Systematic Reviews-2; 1, Yes; 2, Partial Yes; 3, No; 4, No meta-analysis conducted.

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