Supplementary material

ECDC technical guidance: Using face masks in the community

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Review team

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Review methods

Review question and selection criteria

The primary review question was:

What is the effectiveness of face masks in preventing COVID-19 in the community??

Population: general public

Intervention: face mask, nose-mouth cover, medical and non-medical, all types and materials

Control: no face mask use

Outcome: COVID-19

Setting: community

Since only very few studies were expected to address specifically the question of face mask use in the community to prevent SARS-CoV-2 transmission, the scope of the review was expanded to assess the effectiveness of face masks in preventing transmission of respiratory infections such as SARS, MERS and influenza in different settings such as healthcare, households, community and mass gatherings.

In addition, information on possible harms/adverse effects of mask use, as well as effectiveness of face mask policies, was extracted when available.

Records were selected according to predefined inclusion and exclusion criteria, tested using a random selection of identified records to ensure a common understanding and high agreement across the review team (Table 1).

Table 1. Predefined inclusion and exclusion criteria

Characteristics	Criteria for inclusion	Criteria for exclusion
Population	Humans (all ages) Any country	In vitro studies
Condition	Use of any type of face covering (mask, cloth mask, medical mask, surgical mask, respirator, scarf etc.), face shields Compared to no mask OR any comparison	
Types of evidence	Comparative studies (preferred) - Randomised studies (preferred) - Observational studies (preferred, such as cohort, case-control, ecological pre-post) - Experimental studies - Modelling studies Reviews were included for reference check	Commentaries, editorials, letters, opinion papers not including original data Surveys, Knowledge, Attitude and Practices (KAP) studies (studies focusing on knowledge of face mask use, attitudes towards face masks use or practice of face mask use), cross-sectional descriptive studies
Outcome measures	1. Mask effectiveness (preferred): Reduction of transmission - source control - personal protection 2. Effectiveness of policies to increase mask use compliance 3. Harms and side effects of using masks	Disinfection and reuse of masks (incl. disposable masks in healthcare settings)

Characteristics	Criteria for inclusion	Criteria for exclusion
Setting	Community (preferred) Households Gatherings Healthcare	
Languages	No limits	

Search strategy

Since only few studies were expected to address the primary review question, the searches were not limited to community and SARS-CoV-2 (Table 2). The search strategies combined the concept of respiratory viruses, in particular, SARS-CoV-2, influenza and SARS-1, with the concept of face masks and face coverings. Controlled vocabulary where available (i.e. MeSH and Emtree terms) and natural vocabulary (i.e. keywords) in multiple field search combinations were used to represent the concepts in the search strategies. No study design or language limits were applied for the search.

PubMed, Embase, Scopus, and CENTRAL were searched from 2002 onwards, with the exception of *influenza,* for which the search was limited to 2019 onwards. An ECDC review of reviews on non-pharmaceutical interventions to prevent influenza was available covering the literature on influenza until the end of 2018 (not published). Hence, the review team decided to limit the search for influenza studies, also for pragmatic reasons to keep the number of records manageable, given the short time available to perform the review.

The ECDC Library ran the searches on 10 November 2020, updated them on 11 December 2020, and established daily email search alerts for the above listed databases to keep the review team informed on any new studies published after 11 December 2020, and until 18 January 2021.

Additional supplementary searches were performed in the in-house COVID-19 database of references and grey literature (including preprints). In addition, more references were collected using the method of backwards and forward citation-chasing for two key references [1,2].

In addition, the reference lists of identified reviews were searched for additional primary studies, including the ECDC review of reviews on non-pharmaceutical interventions to prevent influenza covering the literature on influenza until the end of 2018 (not published).

Table 2. Database searches

This presents the searches run on 10 November 2020, as these are the ones to be used in case the reader would like to reproduce them. Exact searches were re-run on 11 December 2020, but the time limit was adapted to exclude references already retrieved in the previous search.

PubMed (search run 10/11/2020)

No.	Query	Results
#1	"Masks"[Mesh] OR "Respiratory Protective Devices"[Mesh] OR cloth mask*[TW] OR disposable mask*[TW] OR disposable respirator*[TW] OR elastomeric respirator*[TW] OR face mask*[TW] OR facemask*[TW] OR face shield*[TW] OR filtering facepiece respirator*[TW] OR filter mask*[TW] OR filter respirator*[TW] OR medical face mask*[TW] OR medical mask*[TW] OR respiratory protection mask*[TW] OR respiratory mask*[TW] OR reusable mask*[TW] OR reusable respirator*[TW] OR surgical mask*[TW]	15 795
#2	respirator[TIAB] OR respirators[TIAB] OR mask*[TIAB]	86 166
#3	aerosol filtration[TIAB] OR FFP[TIAB] OR FFP1[TIAB] OR FFP2[TIAB] OR FFP3[TIAB] OR filtering face piece[TIAB] OR filtering facepiece[TIAB] OR filtering respiratory[TIAB] OR N95[TIAB] OR N99[TIAB] OR particle filter*[TIAB] OR particulate air filter[TIAB] OR particulate filter*[TIAB]	4 985
#4	#2 AND #3	1 083
#5	"Covering the face"[TW] OR "cover the face"[TW] OR Face cover*[TW] OR face barrier*[TW] OR face protect*[TW] OR facial cover*[TW] OR facial barrier*[TW] OR facial protect*[TW] OR eye cover*[TW] OR eye barrier*[TW] OR eye protect*[TW] OR eye shield*[TW] OR ocular cover*[TW] OR ocular barrier*[TW] OR ocular protect*[TW] OR ocular shield*[TW] OR nose cover*[TW] OR nose barrier*[TW] OR nose protect*[TW] OR nasal cover*[TW] OR nasal barrier*[TW] OR nasal protect*[TW]	20 040
#6	face[TI] OR facial[TI] OR eye[TI] OR ocular[TI] OR nose[TI] OR nasal[TI]	239 178
#7	cover*[TI] OR barrier[TI] OR protect*[TI]	240 841
#8	#6 AND #7	1 749
#9	face[OT] OR facial[OT] OR eye[OT] OR ocular[OT] OR nose[OT] OR nasal[OT]	63 337
#10	cover*[OT] OR barrier[OT] OR protect*[OT]	40 376
#11	#9 AND #10	361
#12	#1 OR #4 OR #5 OR #8 OR #11	36 805
#13	"COVID-19"[Supplementary Concept] OR "severe acute respiratory syndrome coronavirus 2"[Supplementary Concept] OR "COVID-19 vaccine"[Supplementary Concept] OR "COVID-19 serotherapy"[Supplementary Concept] OR "COVID-19 diagnostic testing"[Supplementary Concept] OR "COVID-19 drug treatment"[Supplementary Concept] OR "LAMP assay"[Supplementary Concept] OR "Coronavirus Infections"[Mesh:noexp] OR "Wuhan coronavirus"[TW] OR "Wuhan seafood market pneumonia virus"[TW] OR COVID19[TW] OR "COVID-19"[TW] OR "COVID-2019"[TW] OR "coronavirus disease 2019"[TW] OR "SARS-CoV-2"[TW] OR SARS2[TW] OR "2019-nCoV"[TW] OR "2019 novel coronavirus"[TW] OR "severe acute respiratory syndrome coronavirus 2"[TW] OR "2019 novel coronavirus infection"[TW] OR "coronavirus disease 2019"[TW] OR "coronavirus disease-19"[TW] OR "novel coronavirus"[TW] OR coronavirus[TW] OR "SARS-CoV-19"[TW] OR "SARS-CoV-2019"[TW]	83 955
#14	#12 AND #13	1 535
#15	#14 AND 2020:2021[DP]	1 493
#16	"Influenza, Human"[Mesh] OR "Influenzavirus A"[Mesh] OR "Influenzavirus B"[Mesh] OR "Influenzavirus C"[Mesh] OR Influenza*[TW] OR Flu[TW] OR flus[TW]	139 196
#17	#12 AND #16	669
#18	#17 AND 2019:2021[DP]	113
#19	"SARS Virus"[Mesh] OR "Severe Acute Respiratory Syndrome"[Mesh] OR sars[TW] OR "Severe Acute Respiratory Syndrome"[TW] OR "Severe Acute Respiratory infection"[TW] OR "sudden acute respiratory syndrome"[TW] OR "Severe Acute Respiratory Syndrome"[TW]	35 683
#20	#12 AND #19	727
#21	#20 AND 2002:2021[DP]	727
#22	#15 OR #18 OR #21	1 713

Embase.com (search run 10/11/2020)

No.	Query	Results
#1	(('aerosol filtration' OR cloth OR disposable OR elastomeric OR face OR ffp OR ffp1 OR ffp2 OR ffp3 OR filter OR filtering OR medical OR n95 OR n99 OR respiratory OR reusable OR surgical) NEAR/5 (mask* OR respirator OR respirators)):ab,ti,kw	8 843
#2	facemask*:ab,ti,kw OR 'face shield*':ab,ti,kw	2 541
#3	((face OR facial OR eye OR ocular OR nose OR nasal) NEAR/5 (cover* OR barrier OR protect* OR shield*)):ab,ti,kw	9 642
#4	#1 OR #2 OR #3	19 657
#5	((covid OR coronavirus OR ncov) NEAR/3 (19 OR 2019 OR novel OR wuhan)):ab,ti,kw	62 175
#6	covid19:ab,ti,kw OR 'sars-cov-2':ab,ti,kw OR sars2:ab,ti,kw OR 'sars 2':ab,ti,kw OR 'severe acute respiratory syndrome coronavirus 2':ab,ti,kw OR 'sars-cov-19':ab,ti,kw OR 'wuhan seafood market pneumonia virus':ab,ti,kw	62 834
#7	#5 OR #6	65 998
#8	#4 AND #7	1 125
#9	#8 AND [2020-2021]/py	1 123
#10	influenza*:ab,ti,kw OR flu:ab,ti,kw OR flus:ab,ti,kw	156 417
#11	#4 AND #10	589
#12	#11 AND [2019-2021]/py	87
#13	sars:ab,ti,kw	31 620
#14	(('severe acute respiratory' OR 'sudden acute respiratory') NEXT/2 (syndrome* OR infect*)):ab,ti,kw	14 734
#15	#13 OR #14	35 370
#16	#4 AND #15	597
#17	#16 AND [2002-2021]/py	597
#18	#9 OR #12 OR #17	1 274

Scopus (search run 10/11/2020)

No.	Query	Results
#1	TITLE-ABS(("aerosol filtration" OR cloth OR disposable OR elastomeric OR face OR ffp OR ffp1 OR ffp2 OR ffp3 OR filter OR filtering OR medical OR n95 OR n99 OR respiratory OR reusable OR surgical) W/5 (mask* OR respirator OR respirators))	12 147
#2	TITLE-ABS(facemask* OR "face shield*")	2 044
#3	TITLE-ABS((face OR facial OR eye OR ocular OR nose OR nasal) W/5 (cover* OR barrier OR protect* OR shield*))	24 977
#4	#1 OR #2 OR #3	37 865
#5	TITLE-ABS((covid OR coronavirus OR ncov) W/3 (19 OR 2019 OR novel OR wuhan))	65 865
#6	TITLE-ABS(covid19 OR "sars-cov-2" OR sars2 OR "sars 2" OR "severe acute respiratory syndrome coronavirus 2" OR "sars-cov-19" OR "wuhan seafood market pneumonia virus")	18 008
#7	#5 OR #6	70 408
#8	#4 AND #7	1 156
#9	#8 AND PUBYEAR > 2019	1 154
#10	TITLE-ABS(influenza* OR flu OR flus)	154 936
#11	#4 AND #10	572
#12	#11 AND PUBYEAR > 2018	83
#13	TITLE-ABS (sars)	113 514
#14	TITLE-ABS (("severe acute respiratory" OR "sudden acute respiratory") PRE/2 (syndrome* OR infect*))	13 418
#15	#13 OR #14	116 586
#16	#4 AND #15	541
#17	#16 AND PUBYEAR > 2001	535
#18	#9 OR #12 OR #17	1 345

Cochrane Central Register of Controlled Trials (search run 10/11/2020)
Wiley platform

No.	Query	Results
#1	MeSH descriptor: [Masks] explode all trees	1 549
#2	MeSH descriptor: [Respiratory Protective Devices] explode all trees	71
#3	(("aerosol filtration" OR cloth OR disposable OR elastomeric OR face OR ffp OR ffp1 OR ffp2 OR ffp3 OR filter OR filtering OR medical OR n95 OR n99 OR respiratory OR reusable OR surgical) NEAR (mask* OR respirator OR respirators)):ti,ab,kw (Word variations have been searched)	2 763
#4	(facemask* OR "face shield" OR "face shields"):ti,ab,kw (Word variations have been searched)	713
#5	((face OR facial OR eye OR ocular OR nose OR nasal) NEAR (cover* OR barrier OR protect* OR shield*)):ti,ab,kw (Word variations have been searched)	1 309
#6	{OR #1-#5}	5 550
#7	MeSH descriptor: [Coronavirus Infections] this term only	437
#8	((covid OR coronavirus OR ncov) NEAR/3 (19 OR 2019 OR novel OR wuhan)):ti,ab,kw (Word variations have been searched)	2 771
#9	(covid19 OR "sars-cov-2" OR sars2 OR "sars 2" OR "severe acute respiratory syndrome coronavirus 2" OR "sars-cov-19" OR "wuhan seafood market pneumonia virus"):ti,ab,kw (Word variations have been searched)	1 146
#10	{OR #7-#9}	2 871
#11	#6 AND #10 with Publication Year from 2020 to 2020, in Trials	42
#12	MeSH descriptor: [Influenza, Human] explode all trees	2 683
#13	MeSH descriptor: [Influenzavirus A] explode all trees	870
#14	MeSH descriptor: [Influenzavirus B] explode all trees	286
#15	MeSH descriptor: [Influenzavirus C] explode all trees	0
#16	(Influenza* OR flu OR flus):ti,ab,kw (Word variations have been searched)	11 257
#17	{OR #12-#16}	11 257
#18	#6 AND #17 with Publication Year from 2019 to 2020, in Trials	5
#19	MeSH descriptor: [SARS Virus] explode all trees	9
#20	MeSH descriptor: [Severe Acute Respiratory Syndrome] explode all trees	262
#21	("SARS"):ti,ab,kw (Word variations have been searched)	2 046
#22	(("severe acute respiratory" OR "sudden acute respiratory") NEXT (syndrome* OR infect*)):ti,ab,kw (Word variations have been searched)	572
#23	{OR #19-#22}	2 214
#24	#6 AND #23 with Publication Year from 2002 to 2020, in Trials	38
#25	#11 OR #18 OR #24	58

Additional searches in other sources	References retrieved
Grey literature sources (including preprints): • 1foldr Hub Coronavirus Research Repository (https://coronavirus.1science.com) • COVID-19 SARS-CoV-2 preprints from medRxiv and bioRxiv (https://connect.biorxiv.org/relate/content/181) • Centers for Disease Control and Prevetion (https://www.cdc.gov) • Centre for mathematical modelling of infectious diseases (https://cmmid.github.io/topics/covid19) • COVID-END (https://www.mcmasterforum.org/networks/covid-end) • Evidence-Aid (https://evidenceaid.org) • Health Information and Quality Authority (Ireland, https://www.hiqa.ie) • JBI COVID-19 Special collection (https://jbi.global/covid-19) • L·OVE (https://iloveevidence.com) • Norwegian Institute of Public Health (https://www.fhi.no/en) • Oxford COVID-19 Evidence Service (https://www.cebm.net/oxford-covid-19-evidence-service) • UNCOVER (https://www.ed.ac.uk/usher/uncover)	230
Backwards and forward citation chasing for the following references: • Chu DK, Akl EA, Duda S, Solo K, Yaacoub S, Schünemann HJ, et al. Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis. The Lancet. 2020;395(10242):1973-87. • Wang Y, Tian H, Zhang L, Zhang M, Guo D, Wu W, et al. Reduction of secondary transmission of SARS-CoV-2 in households by face mask use, disinfection and social distancing: a cohort study in Beijing, China. BMJ global health. 2020;5(5):e002794.	81
In-house COVID-19 references library	1 189

Selection process

In a first step, titles and abstracts were distributed between four review teams of at least two independent reviewers each, and screened using the above selection criteria and the web application Rayyan [3]. Discrepancies between reviewers were resolved by consensus, and references were imported into Endnote X7. A similar approach as the one used for title and abstract screening was applied for the full-text screening, distributing the tasks between teams of at least two reviewers each. The task was performed by each reviewer independently using a copy of the Endnote library, and discrepancies were again resolved by consensus. The library copies of included studies were finally merged into one Endnote master library.

Quality and risk of bias assessment

Included studies were assessed for selection, performance, attrition, and reporting bias using the 2011 Cochrane risk of bias tool for randomised trials (Table 3) in the case of randomised and cluster randomised controlled trials [4,5].

Table 3. Assessment criteria for randomised trials

Selection bias (yes/no/unclear)		Performance bias	Detection bias	Attrition bias	Reporting bias	Other
No random sequence generation	No allocation concealment	No blinding of participants and personnel	No blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias

🔴 high risk of bias

🟡 unclear

🟢 low risk of bias

For observational studies, a simplified form based on the Cochrane ROBINS-I tool for non-randomised intervention studies was applied (Table 4), taking into account confounding, in particular [6].

Table 4. Assessment criteria for observational studies

Selection bias	Confounding	Information bias	Detection bias	Attrition bias	Reporting bias	Other
Eligibility criteria when selecting participants into study		E.g. ascertainment of intervention or exposure missing, recall bias	Measurement of outcome	Missing data; Loss to follow up	Selective reporting	Other bias

high risk of bias

unclear

low risk of bias

For the sake of time, the quality and risk of bias assessment was performed at the same time as the data extraction, and by one single reviewer.

No specific quality and risk of bias tool was used for the assessment of experimental and modelling studies.

Data extraction

Data were extracted in Microsoft Excel using a pre-determined and tested extraction form. Apart from basic study characteristics such as study design, study period and number of participants, the extraction covered aspects such as setting, type of intervention, the type of mask used and measured outcomes.

For the sake of time, the references were distributed between reviewers and each study was extracted and summarised by one single reviewer, together with the quality and risk of bias assessment.

Data analysis

Regarding the effect and effect size of mask use to prevent transmission, the identified and included studies were considered too heterogeneous regarding study population, setting and outcome measures in order to be statistically pooled, and therefore no meta-analysis was performed.

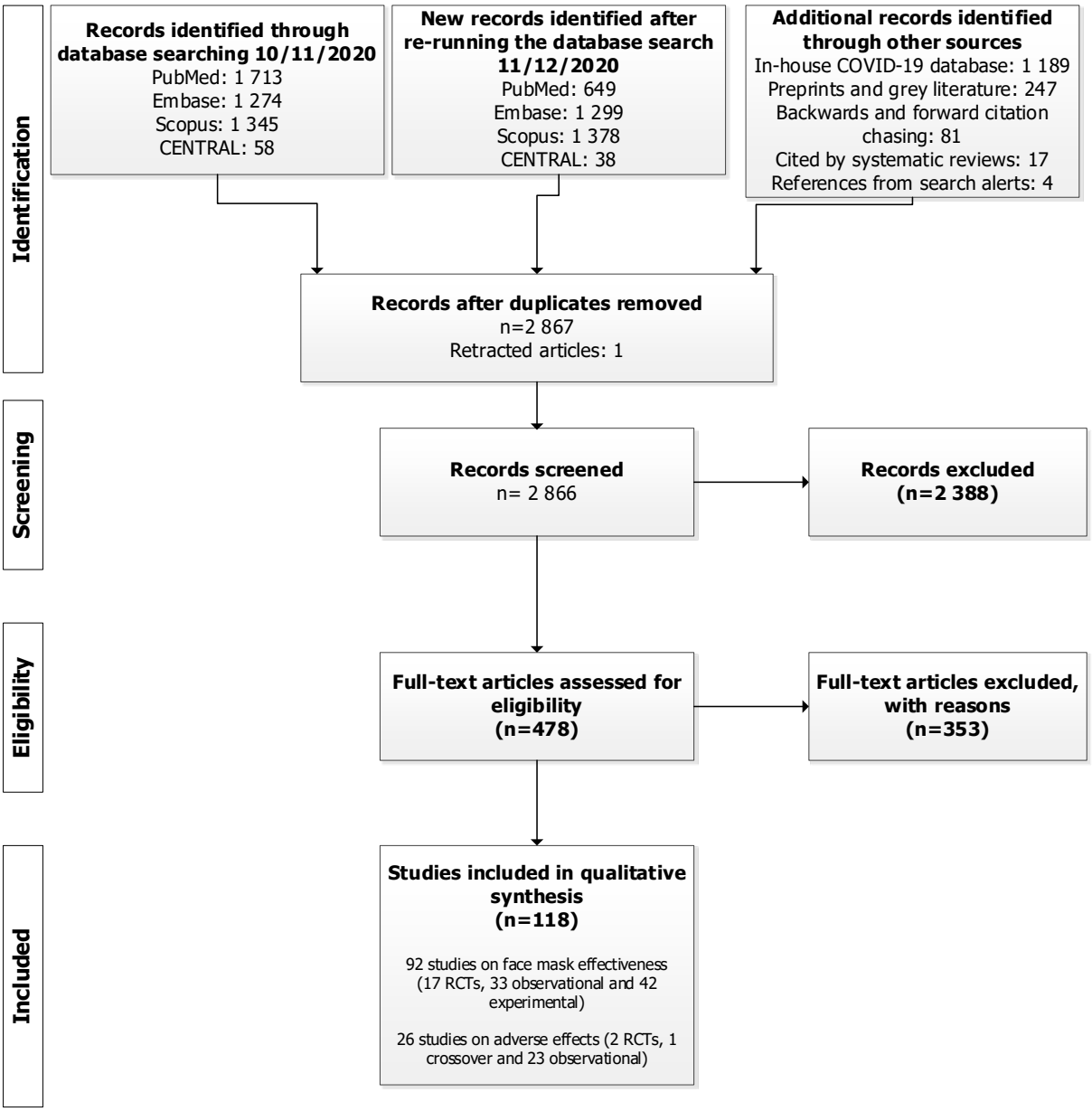
The included studies were sorted by type of virus and setting, and the confidence or certainty in the effect direction and effect estimate or association between the wearing of face masks and transmission, was provided using the GRADE approach that specifies four levels of certainty for a body of evidence: very low, low, moderate and high. GRADE considers five key domains when assessing a body of evidence for a specific question or outcome: risk of bias, inconsistency, indirectness, imprecision and publication bias [7].

Review results

Search results

The database searches identified a total of 7 754 records, and 1 538 records were identified through other sources. After de-duplication, 2 867 records were kept. Of those, 2 866 were assessed through title and abstract screening and 478 were selected for full-text screening. Ultimately, 118 records were included in the review, 92 on mask effectiveness and 26 on the potential adverse effects of mask use (Figure 1).

Figure 1. PRISMA flowchart



Characteristics of included studies

The following tables summarise the characteristics and risk of bias assessment of the 50 identified randomised and observational studies on face mask effectiveness. Experimental studies on face mask effectiveness (n=42) and studies on potential adverse events of face mask user (n=26) are not included in this summary.

Table 5. Face mask use in the community, SARS-CoV-2: randomised controlled trials

Reference	Country	Study period	Description of intervention	Type of mask	Measured outcome(s)	No. of participants and cases in intervention group	No. of participants and cases in control group	Relative risk OR odds ratio (Confidence interval)	Selection bias		Perfomance bias	Detection bias	Attrition bias	Reporting bias	Other
									Random sequence	Allocation concealment	Blinding participants	Blinding measurement	Incomplete outcome data	Selective reporting	
Bundgaard 2020-Nov [8]	Denmark	04/2020-05/2020	Participants in intervention group instructed to wear when outside home for one month. Participants were provided with medical face masks.	Surgical	SARS-CoV-2 infection defined as positive PCR in oropharyngeal/nasal sample, development of antibodies during the study period or hospital diagnosis of SARS-CoV-2 infection or COVID-19	3 030 (42)	2 994 (53)	OR: 0.82 (0.53-1.23) p 0.33							

OR= Odds ratio; PCR= polymerase chain reaction.

Table 6. **Face mask use in the community, SARS-CoV-2: observational studies**

Reference	Country	Study period	Description of intervention / exposure / protective factor	Type of mask	Measured outcome(s)	Intervention/ case group: Sample size and no. of participants with outcome	Control group: Sample size and no. of participants with outcome	Effect estimate (e.g. Relative risk, odds ratio) (Confidence interval)	Selection bias	Confounding	Information /ascertainment bias	Detection bias	Attrition bias	Reporting bias	Other
Doung-ngern, 2020-Nov [9] Case-control	Thailand	03/2020-04/2020	Compliance with wearing face mask (also hand hygiene, social distance)	Medical and non- medical masks	COVID-19 infection (Monitoring of symptoms +/- PCR)	211 (29 wear mask)	839 (198 wear mask)	OR: 0.16 (0.07-0.36) p < 0.001	🔴	🔴	🔴	🟢	🟢	🟢	🟢
Hong, 2020-Jun [10] Cross-sectional cohort	China	01/2020-03/2020	Wearing a face mask	Not specified	COVID-19 infection diagnosed by PCR	123 (10)	74 (14)	8.1% vs. 19.0%; p < 0.001	🔴	🔴	🔴	🟢	🟢	🟢	🟢
Lopez, 2020- Sep [11] Cross-sectional cohort	United States	07/2020	Face mask vs no face mask	Not specified	Seropositivity History of mask wearing (yes/no)	22	731	aOR = 0.58 (0.15-3.87) p 0.49	🔴	🔴	🔴	🟢	🟢	🟢	🟢
Payne, 2020-Jun [12] Cross-sectional cohort	United States	03/2020-04/2020	Wearing a face mask	Not specified	COVID-19 infection (Monitoring of symptoms +/- lab)	238 (158)	99 (19)	0.30 (0.17 - 0.52)	🔴	🔴	🔴	🟢	🔴	🟢	🟢

Reference	Country	Study period	Description of intervention / exposure / protective factor	Type of mask	Measured outcome(s)	Intervention/ case group: Sample size and no. of participants with outcome	Control group: Sample size and no. of participants with outcome	Effect estimate (e.g. Relative risk, odds ratio) (Confidence interval)	Selection bias	Confounding	Information /ascertainment bias	Detection bias	Attrition bias	Reporting bias	Other
Wang, 2020-Sep [2] Cross-sectional cohort	China	01/20-02/20	Index case wearing mask after symptom onset, no of family members wearing face masks (compared to none)	Not specified	COVID-19 infection (unclear definition)	4 (families with transmission)	27 (families with transmission)	OR: 0.21 (0.06-0.79) p 0.02							Unadjusted OR, social network analysis of unclear significance

aOR= adjusted odds ratio; CI= confidence interval; coef= coefficient; OR= Odds ratio.

Table 7. **Face mask use in the community, SARS-CoV-2: ecological studies**

Reference	Country	Study period	Description of intervention / exposure / protective factor	Type of mask	Measured outcome(s)	Intervention/ case group: Sample size and no. of participants with outcome	Control group: Sample size and no. of participants with outcome	Effect estimate (e.g. Relative risk, odds ratio) (Confidence interval)	Selection bias	Confounding	Information /ascertainment bias	Detection bias	Attrition bias	Reporting bias	Other
Cheng, 2020-Apr [13] Ecological	Multi-country	01/2020-04/2020	Community-wide masking in Hong Kong Special Administrative Region vs countries without community-wide mask use	Surgical mask	Number of cases per million population	Not available	Not available	cases per million population Hong Kong Special Administrative Region g: 129 Singapore 259.8 Spain 2 983 Switzerland 2 580 P<0.001	🔴	🔴	🔴	🔴	🟢	🟢	Serious confounding
Li, 2020-Aug [14] Ecological	United States	03-2020-05/2020	Mandatory use of face masks in public	Not specified	Evolution of the epidemic	9 U.S. states	6 U.S. states	Decrease in slope of epidemic curve in states with mandated face mask use	🔴	🔴	🟢	🔴	🟢	🟢	Serious confounding
Bo, 2020-Oct, [15] Ecological	Multi-country	01/2020-04/2020	Mandatory face mask use	Not specified	Reproduction number	64 sites (cities or countries)	382 sites	-15.14% (-21.79 - -7.93)	🔴	🔴	🟢	🔴	🟢	🟢	🟢
Kenyon, 2020-Apr, [16] Ecological	Multi-country	01/2020-03/2020	National policies to promote the wearing of face masks in public	Not specified	Cumulative number of cases per million inhabitants	8 countries	41 countries	Linear regression coef. -326, (95% CI -601--51), P=0.021	🔴	🔴	🔴	🟢	🟢	🟢	🟢

Reference	Country	Study period	Description of intervention / exposure / protective factor	Type of mask	Measured outcome(s)	Intervention/ case group: Sample size and no. of participants with outcome	Control group: Sample size and no. of participants with outcome	Effect estimate (e.g. Relative risk, odds ratio) (Confidence interval)	Selection bias	Confounding	Information /ascertainment bias	Detection bias	Attrition bias	Reporting bias	Other
Mitze, 2020 [17] Ecological	Germany	01/2020-05/2020	Mandatory face mask use	Not specified	Registered COVID-19 cases	Synthetic control group including districts before mandatory face mask use	Not available	Difference in cumulative number of cases after 20 days: 23% 1.32% per day							
Miyazawa, 2020- Jun, [18] Ecological	Multi-country	03/2020-05/2020	Face mask wearing rate	Not specified	Death rates due to COVID-19	Correlation between face mask wearing rate and death rate due to COVID-19 in 22 countries with available data	Not available	Spearman correlation coefficient: 0.79 (p<0.001) beta 0.061 (p<0.001)							
Maloney, 2020-Oct [19] Ecological	United States	Not specified	Mandatory face mask use	Not specified	Number of new COVID-19 cases before and after introduction of mask mandate	38 states	Not available	Mean number of new COVID-19 cases before vs. after the mandatory use of mask: 654 (N=1138, SD=1357) vs. 639 (N=1177, SD=975) p NS							
Von Batten, 2020-Jun [20] Ecological	United States	Until 05/2020	Mandatory face mask use	No specified	Number of COVID-19 infection cases	7 states	44 states	Pearson correlation coefficient r -0.41, p 0.00							

Reference	Country	Study period	Description of intervention / exposure / protective factor	Type of mask	Measured outcome(s)	Intervention/ case group: Sample size and no. of participants with outcome	Control group: Sample size and no. of participants with outcome	Effect estimate (e.g. Relative risk, odds ratio) (Confidence interval)	Selection bias	Confounding	Information /ascertainment bias	Detection bias	Attrition bias	Reporting bias	Other
Kanu, 2020-Nov, [21] ecological	United States	03/2020-06/2020	Mandatory face mask use	Not specified	Number of COVID-19 infection cases	Before-after study in one state	Not available	incidence declined by 82%							
van Dyke, 2020-Nov, [22] Ecological	United States	06/2020-08/2020	Mandatory face mask use	Not specified	COVID-19 incidence	24 counties	81 counties	0.08 cases per 100,000 per day vs 0.11 cases per 100,000 per day;							
Karaivanov, 2020-Oct [23] Ecological	Canada	03/2020-08/2020	Mandatory face masks use	Not specified	Number of COVID-19 infection cases	34 public health districts	Not available	>25% weekly reduction in new COVID-19 cases							

aOR= adjusted odds ratio; CI= confidence interval; coef= coefficient; OR= Odds ratio.

Table 8. **Face mask use in healthcare, SARS-CoV-2: observational studies**

Reference	Country	Study period	Description of intervention / exposure / protective factor	Type of mask	Measured outcome(s)	Intervention/ case group: Sample size and no. of participants with outcome	Control group: Sample size and no. of participants with outcome	Effect estimate (e.g. Relative risk, odds ratio) (Confidence interval)	Selection bias	Confounding	Information /ascertainment bias	Detection bias	Attrition bias	Reporting bias	Other
Çelebi, 2020 Aug [24] Case - control	Turkey	03/2020-05/2020	Staying in the same personnel break room as an HCW without wearing medical mask for more than 15 minutes	Medical mask	RT-PCR confirmed COVID-19	47	134	aOR = 7.422, (CI 1.898-29.020), P=.04	🟢	🔴	🔴	🟢	🟢	🟢	🟢
Chatterjee, 2020-May [25] Case-control	India	04/2020-05/2020	Wearing a face mask	Not specified	RT-PCR confirmed COVID-19	378	373	aOR=0.35 (CI 0.22-0.57) p<0.001	🔴	🔴	🔴	🟢	🔴	🟢	
Self, 2020-Sep [26] Cross-sectional	United States	04/2020-06/2020	Use of face covering (surgical mask, N95 or PAPR) during all encounters	Surgical mask, N95 respirator or powered air purifying respirator (PAPR)	Seroprevalence	Not available	Not available	Fisher's exact test. Risk difference: 6% of seropositivity in group wearing always a face covering vs 9% in group not always wearing a face covering (p=0.012)	🔴	🔴	🔴	🔴	🟢	🟢	

Reference	Country	Study period	Description of intervention / exposure / protective factor	Type of mask	Measured outcome(s)	Intervention/ case group: Sample size and no. of participants with outcome	Control group: Sample size and no. of participants with outcome	Effect estimate (e.g. Relative risk, odds ratio) (Confidence interval)	Selection bias	Confounding	Information /ascertainment bias	Detection bias	Attrition bias	Reporting bias	Other
Saban, 2020- Oct [27] Cohort	Israel	N/A	Wearing a face mask	Surgical, N95 respirator	COVID-19 infection (Monitoring of symptoms +/- PCR)	46 patients wore a mask o	96 patients did not wear a mask	1/142 patients exposed to the COVID-19+ physician reported being sick. 16/142 patients (11.3%) had a COVID-19 RT-PCR test, including the patient reporting symptoms. All of them were negative.							
Sims, 2020- Nov [28] Cohort	United States	04/2020- 05/2020	Wearing N95/PAPR, surgical/other masks or no mask	Any type of mask (surgical, N95, PAPR)	Seroprevalence	Not available	Not available	Seropositivity was significantly lower in individuals wearing any type of mask (10.9%; CI: 10.1%–11.6%) than for those not wearing a mask (17.5%;CI: 16.0- 19.2%)							

Reference	Country	Study period	Description of intervention / exposure / protective factor	Type of mask	Measured outcome(s)	Intervention/ case group: Sample size and no. of participants with outcome	Control group: Sample size and no. of participants with outcome	Effect estimate (e.g. Relative risk, odds ratio) (Confidence interval)	Selection bias	Confounding	Information /ascertainment bias	Detection bias	Attrition bias	Reporting bias	Other
Oksanen, 2020-Aug [29] Cross-sectional cohort	Finland	03/2020-07/2020	Surgical face mask or FFP2/3	Surgical mask and respirator	COVID-19 infection (unclear definition) and occupational infection	41 HCW with COVID-19 16 wearing surgical mask 14 occupational 0 cases in group wearing respirator	25 not wearing mask 8 occupational	No statistical assessment of the effect estimate	🔴	🔴	🔴	🟡	🟢	🟢	
Akinbami, 2020-Sep [30] Cross-sectional cohort	United States	05/2020-06/2020	Consistently using a surgical mask or a N95 respirator	Surgical mask and N95 respirator	Seroprevalence	16 397 (6.9%)	Not available	Surgical mask: aOR 0.86, 95% CI 0.75–0.98 N95: aOR 0.83, 95% CI 0.72–0.95	🔴	🔴	🔴	🔴	🟢	🟢	

aOR= adjusted odds ratio; CI= confidence interval; FFP= filtering face piece, HCW= healthcare workers, PARP=powered air purifying respirators, PCR= polymerase chain reaction.

Table 9. **Face mask use in the community, other viruses: randomised controlled trials**

Reference	Country	Study period	Description of intervention	Type of face mask	Measured outcome(s)	No. of participants and cases in intervention group	No. of participants and cases in control group	Relative risk OR odds ratio (Confidence interval)	Selection bias		Perfomance bias	Detection bias	Attrition bias	Reporting bias	Other
									Random sequence	Allocation concealment	Blinding participants	Blinding measurement	Incomplete outcome data	Selective reporting	
MacIntyre, 2009 [31] Cluster randomised	Australia	2006-2007	Medical face mask or N95 respirator worn by parents when in the same room with child with fever and respiratory symptoms	Surgical / N95 respirator	Influenza like illness and laboratory confirmed viral infection	274 surgical mask (19) 264 N95 (14)	296 (16)	All Masks RR 1.11 (0.62-2.03) P 0.75 Surgical RR 1.29 (0.69-2.31) P 0.46 N95Mask RR 0.95 (0.49-1.84) p 1							
Suess, 2012 [32] Cluster randomised	Germany	2009-2011 winter season	Index patients with a diagnosis of influenza and household members were randomised in three groups: 1. masks use at all times by household members when in the same room with an index case, 2. mask use and hand hygiene and 3. control (no intervention)	Surgical	Secondary attack rate (SAR) 1. RT-PCR confirmed influenza (LCI) 2. Influenza like illness (ILI)	Group 1: 26 households (LCI SAR 9%) Group 2: 28 households (LCI SAR 15%)	30 households (LCI SAR 23%)	aOR (ref. Group 3) Group 1: 0.39 95% CI 0.13-1.17 p 0.09 Group 2 :0.62 95% CI 0.23-1.65 p 0.34 Secondary analysis full implementation within 36 hours from symptom onset aOR: Group 1: 0.13; 95% CI = 0.01-1.28; p = 0.08 Group 2: 0.16; 95% CI = 0.03-0.92; p = 0.04							

Reference	Country	Study period	Description of intervention	Type of face mask	Measured outcome(s)	No. of participants and cases in intervention group	No. of participants and cases in control group	Relative risk OR odds ratio (Confidence interval)	Selection bias		Perfomance bias	Detection bias	Attrition bias	Reporting bias	Other
									Random sequence	Allocation concealment	Blinding participants	Blinding measurement	Incomplete outcome data	Selective reporting	
Canini, 2010 [33] Cluster randomised	France	2008-2009 influenza season	Index patient with fever, respiratory symptoms and positive test for influenza together with household was randomised (1:1 ratio) into intervention (mask use) or control group (no mask use). Intervention consisted of wearing a surgical mask from medical visit and for a period of 5 days each time another household member was in the same room or in a confined place (e.g. in a car).	Surgical	Secondary attack rate of influenza-like illness	52 households (148 contacts) (24 – 16.2%)	53 households (158 contacts) (25 – 15.8%))	Difference in attack rate 0.40% (95%CI: 210% to 11%, p= 1.00) Multivariate adjusted OR: 0.95 (95%CI: 0.44 to 2.05, p= 0.90)							Study was stopped early, did not have as many participants and power as planned

Reference	Country	Study period	Description of intervention	Type of face mask	Measured outcome(s)	No. of participants and cases in intervention group	No. of participants and cases in control group	Relative risk OR odds ratio (Confidence interval)	Selection bias		Perfomance bias	Detection bias	Attrition bias	Reporting bias	Other
									Random sequence	Allocation concealment	Blinding participants	Blinding measurement	Incomplete outcome data	Selective reporting	
Cowling, 2009 [34] Cluster randomised	China	01/2008-09/2008	Index patients with a diagnosis of influenza and household members were randomised in three groups: MH: masks use at all times by household members when in the same room with an index case and hand hygiene, HH: hand hygiene and C: control (no intervention)	Surgical	Secondary attack rate (SAR) 1. RT-PCR confirmed influenza (LCI) 2. Influenza-like illness	HH: 257 (14) MH: 258 (18) Face mask use <36 hrs from symptom onset: LCI: HH: 5 MH: 4	279 (28) Face mask use <36 hrs from symptom onset: 12	LCI: aOR HH: 0.57 (95%CI 0.26-1.22) MH: 0.77 (95%CI 0.38-1.55) <36 hrs from symptom onset: LCI: HH: 0.46 (95%CI 0.15-1.43) MH: 0.33 (95% CI 0.13-0.87)	●	●	●	●	●	●	●
Cowling, 2008 [35] Cluster randomised	China	02/2007 – 09/2007	Index case with influenza diagnosed by rapid test together with household members were randomised to 1. control, 2. surgical mask and hand hygiene, 3. hand hygiene	Surgical	Secondary attack rate (SAR) 1. Laboratory confirmed influenza either NTS positive for influenza by viral culture or PCR 2. Influenza like illness (ILI)	Surgical mask and hand hygiene group: 258 (18) Hand hygiene group: 257 (14)	279 (28)	Laboratory confirmed influenza OR Surgical mask and hand hygiene: 0.77 (CI 0.38-1.55) Hand hygiene: 0.57 (CI 0.26-1.22) Face mask use earlier than 36hrs after symptom onset OR Surgical mask and hand hygiene: 0.33 (CI 0.13-0.87) Hand hygiene 0.46 (CI 0.15-1.43)	●	●	●	●	●	●	●

Reference	Country	Study period	Description of intervention	Type of face mask	Measured outcome(s)	No. of participants and cases in intervention group	No. of participants and cases in control group	Relative risk OR odds ratio (Confidence interval)	Selection bias		Perfomance bias	Detection bias	Attrition bias	Reporting bias	Other
									Random sequence	Allocation concealment	Blinding participants	Blinding measurement	Incomplete outcome data	Selective reporting	
Simmerman, 2011 [36] Cluster randomised	Thailand	04/2008-08/2009	Index patients with a diagnosis of influenza and household members were randomised in three groups: MH: masks use at all times by household members when in the same room with an index case and hand-washing, HW: hand-washing and C: control (no intervention)	Surgical	Influenza-like illness (ILI) RT-PCR confirmed influenza (LCI)	HW 292 (ILI 50, LCI 66) MH 291 (ILI 51, LCI 66) Intervention within 48hrs from symptom onset HW 191 (ILI 40, LCI 58) MH 195 (ILI 46, LCI 51)	302 (ILI 26, LCI 58) Intervention within 48hrs from symptom onset 200 (ILI: 18 LCI: 45)	aOR LCI: HW 1·20 (CI 0·76, 1·88) p 0·442 MH 1·16 (CI 0·74, 1·82) p 0·525 ILI: HW 2·09 (CI 1·25, 3·50) p 0·005 MH 2·15 (CI 1·27, 3·62) p 0·004 Intervention within 48hrs from symptom onset LCI: HW 1·06 (CI 0·62, 1·82) p 0·819 MH 1·15 (CI 0·68, 1·93) p 0·609 ILI: HW 2·38 (CI 1·32, 4·29) p 0·004 MH 2·16 (CI 1·14, 4·07) p 0·018							Performance bias due to contamination: 17.6% using masks in the control group

Reference	Country	Study period	Description of intervention	Type of face mask	Measured outcome(s)	No. of participants and cases in intervention group	No. of participants and cases in control group	Relative risk OR odds ratio (Confidence interval)	Selection bias		Perfomance bias	Detection bias	Attrition bias	Reporting bias	Other
									Random sequence	Allocation concealment	Blinding participants	Blinding measurement	Incomplete outcome data	Selective reporting	
MacIntyre, 2016 [37]	China	11/2013-01/2014	Index cases (patients with ILI) were randomly allocated into intervention and control arm. In the intervention arm index cases wore a medical mask at home. whenever they were in the same room as a household member. They were allowed to remove their masks during meal times and while asleep.	Surgical	(1) clinical respiratory illness (CRI), (2) ILI, and (3) laboratory-confirmed viral respiratory infection (LVRI) among household members	123 index cases and 302 household contacts in intervention arm There were 4 cases of CRI, 1 case of ILI and 1 case of L in 1 case LVRI among household members	122 index cases and 295 household contacts in control arm There were 6 cases of CRI, 3 cases of, ILI and 1 case of LVRI among household members	Intention to treat. Results show potential benefit of medical masks for source control. CRI: RR: 0.65 (CI: 0.18-2.29) ILI: RR 0.32 (CI 0.03-3.11) LVRI: RR 0.97 (CI:0.06-15.5)							Small sample size

Reference	Country	Study period	Description of intervention	Type of face mask	Measured outcome(s)	No. of participants and cases in intervention group	No. of participants and cases in control group	Relative risk OR odds ratio (Confidence interval)	Selection bias		Perfomance bias	Detection bias	Attrition bias	Reporting bias	Other
									Random sequence	Allocation concealment	Blinding participants	Blinding measurement	Incomplete outcome data	Selective reporting	
Larson, 2010 [38] Cluster randomised	United States	11/2006 – 06/2008	Households were block randomised into one of three groups: (1) the Education group; (2) the Hand Sanitizer group, and (3) the Hand Sanitizer and Face Mask group,.	Surgical	(ILI) Influenza like illness, (URIs) Upper respiratory infections and (I) Influenza	169 household in hand sanitizer group 201 households in Hand sanitizer and face mask group	174 households in control (education) group	Mask use associated with lower secondary transmission rates. URI/ILI/Influenza (3408 episodes) Hand Sanitizer and Face mask use: OR 0.82 (CI0.70 – 0.97) – Compared to Education/control group							
Aiello, 2010 [39] Cluster randomised	United States	01/2007 – 03/2007	Face mask and hand hygiene group (FM+HH) participants instructed to use face masks as much as possible in the residence and apply hand hygiene. There was a face mask only (FM) group and a control group.	Not specified	Influenza-like illness (ILI)	367 individuals in face mask and hand hygiene group; and 378 individuals in the face mask only group	552 in the control group	Survival analysis. FM+HH group: Adjusted RR of 0.87 (CI: 0.73-1.02, p=0.08) compared to control FM only group: Adjusted RR of 0.90 (CI: 0.77-1.05, p=0.19) compared to control							Possible contamination bias (e.g. use of masks and hand hygiene by control group participants)

Reference	Country	Study period	Description of intervention	Type of face mask	Measured outcome(s)	No. of participants and cases in intervention group	No. of participants and cases in control group	Relative risk OR odds ratio (Confidence interval)	Selection bias		Perfomance bias	Detection bias	Attrition bias	Reporting bias	Other
									Random sequence	Allocation concealment	Blinding participants	Blinding measurement	Incomplete outcome data	Selective reporting	
Alfelali, 2020 [40] Cluster randomised	Saudi Arabia	Hajj seasons 2013, 2014, 2015	Pilgrims' tents in Makkah were allocated to "facemask" (intervention) or "no facemask" group (control)	Surgical mask/ no	Laboratory confirmed viral respiratory infection (LCVRI) and clinical respiratory infection (CRI)	3864 adult participants from 149 tents to the intervention group	3823 adult participants from 169 tents in the control group.	Intention to treat analysis. Face masks did not have a protective effect Primary outcome (LCVRI): OR 1.4 (CI: 0.9-2.1) Secondary outcome: (CRI): 1.1 (CI: 0.9-1.4)	🟢	🟢	🔴	🔴	🟢	🔴	High contamination bias 24.7% of intervention group used masks daily 14.3% of control group used masks daily

aOR= adjusted odds ratio; CI= confidence interval; CRI= clinical respiratory illness; ILI= influenza-like illness; LCI= laboratory confirmed influenza; LCVI= laboratory confirmed viral infection; RR= relative risk; SAR= secondary attack rate, PCR= polymerase chain reaction.

Table 10. Face mask use in the community, other viruses: observational studies

Reference	Country	Study period	Description of intervention / exposure / protective factor	Type of mask	Measured outcome(s)	Intervention/ case group: Sample size and no. of participants with outcome	Control group: Sample size and no. of participants with outcome	Effect estimate (e.g. Relative risk, odds ratio) (Confidence interval)	Selection bias	Confounding	Information /ascertainment bias	Detection bias	Attrition bias	Reporting bias	Other
Wu, 2004 [41] matched case control	China	04/2003 – 06/2003	Wearing a mask when going out	Not specified	SARS infection	94 cases of which 27% always wore a mask	281 controls of which 43% always wore a mask	Conditional logistic regression. Mask use was protective for a SARS infection. OR for always wearing the mask was 0.3 (CI: 0.2 – 0.6) using "never" as reference	🔴	🔴	🔴	🟢	🔴	🔴	🟢
Lau, 2004 [42] Matched case-control	Hong Kong Special Administrative Region	All SARS patients whose cases were reported on or before 16/05/2003	Using a face mask in public places	Not specified	SARS infection	330 cases of which 27.9% wore a mask in public places frequently	660 controls of which 58.7% wore a mask in public places frequently	Stepwise conditional logistic regression analysis. Using a facemask frequently was a protective factor. OR (matched multivariate model) OR=0.36 (CI 0.25 – 0.52) (reference: "occasionally/ seldom/no)	🔴	🔴	🔴	🔴	🔴	🔴	🟢

Reference	Country	Study period	Description of intervention / exposure / protective factor	Type of mask	Measured outcome(s)	Intervention/ case group: Sample size and no. of participants with outcome	Control group: Sample size and no. of participants with outcome	Effect estimate (e.g. Relative risk, odds ratio) (Confidence interval)	Selection bias	Confounding	Information /ascertainment bias	Detection bias	Attrition bias	Reporting bias	Other
Tuan, 2006 [43] Cross-sectional cohort	Vietnam	02/2003-04/2003	Using face masks when in contact with cases in the household	Not specified	SARS infection	9 (0)	147 (7)	OR 0 (0.00-20.93) p 1							

CI= confidence interval; OR= Odds ratio.

Table 11. Face mask use in healthcare, other viruses: randomised controlled trials

Reference	Country	Study period	Description of intervention	Type of mask	Measured outcome(s)	No. of participants and cases in intervention group	No. of participants and cases in control group	Relative risk OR odds ratio (Confidence interval)	Selection bias		Perfomance bias	Detection bias	Attrition bias	Reporting bias	Other
									Random sequence	Allocation concealment	Blinding participants	Blinding measurement	Incomplete outcome data	Selective reporting	
Radonovich, 2019 [43] Cluster randomised	United States	09/2011-06/2016	Healthcare practitioners were instructed to wear respirator/mask in outpatient healthcare setting for 12 weeks (viral respiratory infection season) each year, four consecutive years, maximum total 48 weeks (or less if partial participation). No true control group (no mask use) included in this study.	N95 versus medical mask	Primary: lab-confirmed influenza (LCI) Secondary: ARI, laboratory-detected respiratory infections, laboratory-confirmed respiratory illness, and influenza like ill-ness among participants	1 993 participants in 189 clusters in N95 respirator group, 2 515 healthcare personnel seasons 207 confirmed influenza events and 1 556 acute respiratory illness events in N95 group	2 058 participants in 191 clusters in medical mask group, 2668 healthcare personnel seasons 193 confirmed influenza infection events and 1 711 confirmed acute respiratory illness events in mask group	Intention to treat cohort for confirmed influenza. No difference in incidence rate ratio (IRR) between N95 respirators and medical masks. IRR 1.18 (CI:0.95 – 1.45)							Possible exposure in community, intervention only in healthcare setting.

Reference	Country	Study period	Description of intervention	Type of mask	Measured outcome(s)	No. of participants and cases in intervention group	No. of participants and cases in control group	Relative risk OR odds ratio (Confidence interval)	Selection bias		Perfomance bias	Detection bias	Attrition bias	Reporting bias	Other
									Random sequence	Allocation concealment	Blinding participants	Blinding measurement	Incomplete outcome data	Selective reporting	
MacIntyre, 2015 [45] Cluster randomised	Vietnam	03/2004-04/2004	Cluster randomisation of 74 wards in 14 hospitals in Hanoi Group 1: Medical masks at all times during the shift Group 2: Cloth masks at all times during the shift Group 3: Standard practice (may or may not include mask use)	Surgical and cloth masks	Clinical respiratory infection (CRI), influenza-like illness (ILI), laboratory confirmed respiratory virus infection	580 Healthcare workers (HCW) randomised into medical mask group 569 HCW in Cloth mask group	458 HCW in control group (standard practice)	Intention to treat analysis. Clinical respiratory illness. CRI: RR group 2 vs group 1: 1.57 (0.99-2.48) ILI: RR group 2 vs group 1: 3.25 (1.74-100.97) LCV: RR group 2 vs group 1.66 (0.95-2.91)							Contamination bias (compliance with use of face masks was 57% in groups 1 and 2 vs 24 % in control group
Loeb, 2009 [46] Cluster randomised	Canada	09/2008-12/2008	Nurses in emergency departments, medical & pediatric units in 8 Ontario tertiary care hospitals were allocated in groups of medical masks and N95.	Medical mask, N95 respirators	Infection (I) diagnosed by hemagglutinin inhibition assays, polymerase chain reaction (PCR), and viral culture for influenza	221 nurses allocated to the N95 respirator, Influenza occurred in 48 nurses (22.9%)	225 nurses allocated to the surgical mask, influenza occurred in 50 nurses (23.6%)	absolute risk difference, −0.73%; 95% CI, −8.8% to 7.3%; P=0.86, indicating non inferiority of the surgical mask							Compliance with the intervention could not be assessed for all participants. protocol did not account for the effect of indirect contact because hand hygiene and use of gloves and gowns were not monitored. impossible to determine whether participants acquired influenza due to hospital or community exposure.

Reference	Country	Study period	Description of intervention	Type of mask	Measured outcome(s)	No. of participants and cases in intervention group	No. of participants and cases in control group	Relative risk OR odds ratio (Confidence interval)	Selection bias		Perfomance bias	Detection bias	Attrition bias	Reporting bias	Other
									Random sequence	Allocation concealment	Blinding participants	Blinding measurement	Incomplete outcome data	Selective reporting	
MacIntyre, 2011 [46] Cluster randomised	China	12/2008-01/2009	Hospitals were randomised to one of three intervention arms: (i) Medical masks, (ii) N95 fit-tested mask and (iii) N95 nonfit-tested mask	N95 respirator and medical mask	1) Clinical respiratory illness (CRI), 1) ILI, 3) laboratory-confirmed viral respiratory infection	461 individuals in N95 fit-tested mask and 488 individuals in non-fitted N95 respirator group	492 individuals in medical mask group	Intention to treat. ALL N95: CRI 0.38 (CI: 0.17-0.86) ILI: 0.58 (0.1 - 3.47) Lab Confirmed Virus: 0.19 (0.05-0.67)							Heterogeneity of behaviours
MacIntyre, 2013 [47] Cluster randomised	China	12/2009-02/2010	Participants randomised by ward to three intervention arms: (i) N95 continuously during the shift, (ii) medical mask continuously, (iii) N95 when performing high risk procedures	N95 continuously vs medical mask continuously vs N95 when high risk procedures	1) clinical respiratory illness (CRI), 2) ILI, 3) laboratory-confirmed viral respiratory infection, (iv) laboratory confirmed bacterial colonisation	581 individuals in N95 continuously group and 516 individuals in N95 when performing high risk procedures	572 individuals in the medical mask continuously group	Multivariable COV proportional hazard models. CRI: HR (i) vs (ii) 0.39 (0.21–0.71) (iii) vs (ii) 0.70 (0.39–1.24)							Contamination bias (compliance with use of face masks was 57% in the N95 group vs 66% in the medical mask group.

Reference	Country	Study period	Description of intervention	Type of mask	Measured outcome(s)	No. of participants and cases in intervention group	No. of participants and cases in control group	Relative risk OR odds ratio (Confidence interval)	Selection bias		Perfomance bias	Detection bias	Attrition bias	Reporting bias	Other
									Random sequence	Allocation concealment	Blinding participants	Blinding measurement	Incomplete outcome data	Selective reporting	
Jacobs, 2009 [48] Cluster randomised	Japan	01/2008-04/2008	Mask and no mask groups were formed using block randomization. Those in the mask group wore a face mask while on hospital property serving in their role as a healthcare worker. In the no mask group refrained from wearing a face mask while on hospital property unless required to do so as part of their job duties.	Surgical mask	Upper respiratory infection (URI)	17 individuals	15 individuals	Fisher exact test. Face mask use in healthcare workers did not show favourable effects in terms of cold symptoms or getting colds. (p =0.81)							The low number of participants in the study limits the interpretations of the results

ARI= acute respiratory infection; CI= confidence interval; CRI= clinical respiratory illness; HCW= healthcare workers; ILI= influenza-like illness; IRR= incidence rate ratio; LCI= laboratory confirmed influenza; RR= relative risk; URI= upper respiratory infection

Table 12. Face mask use in healthcare, other viruses: observational studies

Reference	Country	Study period	Description of intervention / exposure / protective factor	Type of mask	Measured outcome(s)	Intervention/ case group: Sample size and no. of participants with outcome	Control group: Sample size and no. of participants with outcome	Effect estimate (e.g. Relative risk, odds ratio) (Confidence interval)	Selection bias	Confounding	Information /ascertainment bias	Detection bias	Attrition bias	Reporting bias	Other
Nishiyama, 2008 [49] Case-control	Vietnam	10/2003-05/2004	Mask use i) always, ii) sometimes, iii) never	Not specified	SARS infection	i) mas use always: 50 individuals ii) mask use sometimes: 22 individuals	iii) mask use never: 13 individuals	Logistic regression. The group of individuals never using a mask had significantly higher odds for infection. OR 12.6 (CI:2.00-80.0)	🟡	🔴	🔴	🟢	🟢	🟢	🟢
Teleman, 2004 [50] Case-control	Singapore	03/2003	N95 respirator use when seeing patients	N95	SARS infection	36 cases of which 8.3% wore a N95 respirator	50 controls of which 46% wore a N95 respirator	Logistic regression. Large reduction in odds of being a case when wearing of N95 respirator when seeing patients. OR 0.1 (CI :0.03 – 0.4, P: 0.001)	🟢	🟢	🔴	🟢	🟢	🟢	🟢

Reference	Country	Study period	Description of intervention / exposure / protective factor	Type of mask	Measured outcome(s)	Intervention/ case group: Sample size and no. of participants with outcome	Control group: Sample size and no. of participants with outcome	Effect estimate (e.g. Relative risk, odds ratio) (Confidence interval)	Selection bias	Confounding	Information /ascertainment bias	Detection bias	Attrition bias	Reporting bias	Other
Nishiura, 2005 [51] Case-control	Vietnam	02/2003-03/2003	Using medical face masks	Surgical masks	SARS infection	43 individuals always using the mask	72 individuals not always using the mask	Logistic regression. Face mask were significantly associated with non-infection. OR 0.29 (CI 0.11-0.73, p=0.009)							
Seto, 2003 [52] Case control	Hong Kong Special Administrative Region	03/2003	Wearing a face mask (&other PPE)	paper/surgical/N95	SARS infection	Of 13 cases, 2 individuals with paper mask were cases	241 controls, of which 26 individuals wore a paper mask, 51 a surgical mask and 92 a N95 respirator.	Stepwise logistic regression. Surgical mask (p=0.007) and N95 respirator (p=0.0004) use was significantly associated with non-infection, which was not the case for paper mask (p=0.511)							

Reference	Country	Study period	Description of intervention / exposure / protective factor	Type of mask	Measured outcome(s)	Intervention/ case group: Sample size and no. of participants with outcome	Control group: Sample size and no. of participants with outcome	Effect estimate (e.g. Relative risk, odds ratio) (Confidence interval)	Selection bias	Confounding	Information /ascertainment bias	Detection bias	Attrition bias	Reporting bias	Other
Loeb, 2004 [53] Retrospective cohort	Canada	03/2003	1) Consistently wearing a N95 or surgical mask 2) Consistently wearing a surgical mask versus not consistently wearing any mask	Surgical face masks and N95 respirator	SARS infection	1) 23 nurses wore mask (wither surgical or N95 respirator) consistently, of which three (13%) acquired SARS 2) 16 nurses who always wore a N95 respirator, of which two became infected	Nine nurses did not wear a mask consistently, of which five acquired SARS	Fisher's exact test 1) Any mask use: RR 0.23 (CI 0.07 - 0.78, p = 0.02) 2) N95 respirator use: RR 0.22 (CI: 0.05 to 0.93, p = 0.06)							
Sung 2016 [55] Cohort	United States	2003-2014	Wearing of facemask for all individuals with direct contact with hematopoietic stem cell transplant patients	Surgical mask	Respiratory viral infection (RVI)	911 patients in mask cohort	920 patients in premask cohort	Study observed a decrease in overall incidence of RVI from 95/920 (10.3%) in the premask cohort to 40/ 911 (4.4%) in the mask cohort (p=0.001)							

Reference	Country	Study period	Description of intervention / exposure / protective factor	Type of mask	Measured outcome(s)	Intervention/ case group: Sample size and no. of participants with outcome	Control group: Sample size and no. of participants with outcome	Effect estimate (e.g. Relative risk, odds ratio) (Confidence interval)	Selection bias	Confounding	Information /ascertainment bias	Detection bias	Attrition bias	Reporting bias	Other
Al Radaddi, 2016 [56] Cross-sectional cohort	Saudi Arabia	03/2014-05/2014	Wearing a medical face mask or N95 respirator	Medical face mask/N95 respirator	Seropositivity for MERS-CoV	Always wearing medical mask or N95 151 (11) Always wearing a medical mask 69 (9) Always wearing of N95 116 (6)	Sometimes or never wearing medical mask N95 66 (7) Sometimes or never wearing a medical mask 142 (9) Sometimes or never wearing a N95 101 (12)	RR 0.69 (0.28–1.69) p 0.43 RR 2.06 (0.86–4.95) p 0.10 RR 0.44 (0.17–1.12) p 0.07							

CI= confidence interval; OR= odds ratio; RR= relative risk; RVI= respiratory viral infection, PPE= personal protective equipment.

References

1. Chu DK, Akl EA, Duda S, Solo K, Yaacoub S, Schünemann HJ, et al. Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis. Lancet (London, England). 2020.
2. Wang Y, Tian H, Zhang L, Zhang M, Guo D, Wu W, et al. Reduction of secondary transmission of SARS-CoV-2 in households by face mask use, disinfection and social distancing: a cohort study in Beijing, China. BMJ Glob Health. 2020;5(5).
3. Ouzzani M, Hammady H, Fedorowicz Z, Elmagarmid A. Rayyan—a web and mobile app for systematic reviews. Syst Rev. 2016;5(1):210.
4. Higgins JPT, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ. 2011;343:d5928.
5. Higgins JPT, Savović J, Page MJ, Elbers RG, JAC S. Chapter 8: Assessing risk of bias in a randomized trial. 2020. In: Cochrane Handbook for Systematic Reviews of Interventions version 61 (updated September 2020). Cochrane. Available from: https://training.cochrane.org/handbook/current/chapter-08
6. Reeves BC, Deeks JJ, Higgins JPT, Shea B, Tugwell P, GA W. Chapter 24: Including non-randomized studies on intervention effects. 2020. In: Cochrane Handbook for Systematic Reviews of Interventions version 61 (updated September 2020). Cochrane. Available from: https://training.cochrane.org/handbook/current/chapter-24
7. GRADE Handbook. 2013 [cited 1 February 2021]. Available from: https://gdt.gradepro.org/app/handbook/handbook.html#h.svwngs6pm0f2.
8. Bundgaard H, Bundgaard JS, Raaschou-Pedersen DET, von Buchwald C, Todsen T, Norsk JB, et al. Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers : A Randomized Controlled Trial. Ann Intern Med. 2020.
9. Doung-Ngern P, Suphanchaimat R, Panjangampatthana A, Janekrongtham C, Ruampoom D, Daochaeng N, et al. Case-Control Study of Use of Personal Protective Measures and Risk for SARS-CoV 2 Infection, Thailand. Emerg Infect Dis. 2020;26(11):2607-16.
10. Hong LX, Lin A, He ZB, Zhao HH, Zhang JG, Zhang C, et al. Mask wearing in pre-symptomatic patients prevents SARS-CoV-2 transmission: An epidemiological analysis. Travel Med Infect Dis. 2020;36:101803.
11. Lopez L, Weber G, Nguyen T, Kleimola K, Bereda M, Liu Y, et al. Seroprevalence of anti-SARS-CoV-2 IgG Antibodies in the Staff of a Public School System in the Midwestern United States. medRxiv [preprint]. 2020.[cited. DOI: http://dx.doi.org/10.1101/2020.10.23.20218651. Available from: https://www.medrxiv.org/content/10.1101/2020.10.23.20218651v1
12. Payne DC, Smith-Jeffcoat SE, Nowak G, Chukwuma U, Geibe JR, Hawkins RJ, et al. SARS-CoV-2 Infections and Serologic Responses from a Sample of U.S. Navy Service Members - USS Theodore Roosevelt, April 2020. MMWR Morb Mortal Wkly Rep. 2020;69(23):714-21.
13. Cheng VC, Wong SC, Chuang VW, So SY, Chen JH, Sridhar S, et al. The role of community-wide wearing of face mask for control of coronavirus disease 2019 (COVID-19) epidemic due to SARS-CoV-2. J Infect. 2020;81(1):107-14.
14. Li Y, Zhang R, Zhao J, Molina MJ. Understanding transmission and intervention for the COVID-19 pandemic in the United States. Sci Total Environ. 2020;748:141560.
15. Bo Y, Guo C, Lin C, Zeng Y, Li HB, Zhang Y, et al. Effectiveness of non-pharmaceutical interventions on COVID-19 transmission in 190 countries from 23 January to 13 April 2020. Int J Infect Dis. 2020.
16. Kenyon C. Widespread use of face masks in public may slow the spread of SARS CoV-2: an ecological study. medRxiv [preprint]. 2020.[cited. DOI: https://doi.org/10.1101/2020.03.31.20048652. Available from: http://medrxiv.org/content/early/2020/04/06/2020.03.31.20048652.abstract
17. Mitze T, Kosfeld R, Rode J, Wälde K. Face Masks Considerably Reduce Covid-19 Cases in Germany. Proc Natl Acad Sci U S A. 2020;117(51):32293-301.
18. Miyazawa D, Kaneko G. Face mask wearing rate predicts country's COVID-19 death rates. medRxiv [preprint]. 2020.[cited. DOI: 10.1101/2020.06.22.20137745. Available from: http://medrxiv.org/content/early/2020/06/23/2020.06.22.20137745.abstract
19. Maloney MJ, Rhodes NJ, Yarnold PR. Mask mandates can limit COVID spread: Quantitative assessment of month-over-month effectiveness of governmental policies in reducing the number of new COVID-19 cases in 37 US States and the District of Columbia. medRxiv [preprint]. 2020.[cited. DOI: 10.1101/2020.10.06.20208033. Available from: http://medrxiv.org/content/early/2020/10/08/2020.10.06.20208033.abstract

20. Von Batten K. The Effects of Statewide Stay-at-Home Orders, Mandatory Protective Face Mask Provisions, and COVID-19 Testing on the Number of Confirmed COVID-19 Infections. SSRN [preprint]. 2020.[cited. DOI: 10.2139/ssrn.3616422. Available from: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3616422
21. Kanu FA, Smith EE, Offutt-Powell T, Hong R, Dinh TH, Pevzner E. Declines in SARS-CoV-2 Transmission, Hospitalizations, and Mortality After Implementation of Mitigation Measures- Delaware, March-June 2020. MMWR Morb Mortal Wkly Rep. 2020;69(45):1691-4.
22. Van Dyke ME, Rogers TM, Pevzner E, Satterwhite CL, Shah HB, Beckman WJ, et al. Trends in County-Level COVID-19 Incidence in Counties With and Without a Mask Mandate - Kansas, June 1-August 23, 2020. MMWR Morb Mortal Wkly Rep. 2020;69(47):1777-81.
23. Karaivanov A, er, Lu SE, Shigeoka H, Chen C, Pamplona S. Face Masks, Public Policies and Slowing the Spread of COVID-19: Evidence from Canada. SSRN [preprint]. 2020.[cited. DOI: 10.3386/w27891. Available from: https://coronavirus.1science.com/api/resolver/?id=c588d0356e9dbb1aca979417a5351e0ec3aa29d9&idx=4
24. Çelebi G, Pişkin N, Bekleviç A, Altunay Y, Keleş AS, Tüz MA, et al. Specific risk factors for SARS-CoV-2 transmission among health care workers in a university hospital. Am J Infect Control. 2020.
25. Chatterjee P, Anand T, Singh K, Rasaily R, Singh R, Das S, et al. Healthcare workers & SARS-CoV-2 infection in India: A case-control investigation in the time of COVID-19. Indian J Med Res. 2020;151(5):459-67.
26. Self WH, Tenforde MW, Stubblefield WB, Feldstein LR, Steingrub JS, Shapiro NI, et al. Seroprevalence of SARS-CoV-2 Among Frontline Health Care Personnel in a Multistate Hospital Network - 13 Academic Medical Centers, April-June 2020. MMWR Morb Mortal Wkly Rep. 2020;69(35):1221-6.
27. Saban O, Levy J, Chowers I. Risk of SARS-CoV-2 transmission to medical staff and patients from an exposure to a COVID-19-positive ophthalmologist. Graefes Arch Clin Exp Ophthalmol. 2020;258(10):2271-4.
28. Sims MD, Maine GN, Childers KL, Podolsky RH, Voss DR, Berkiw-Scenna N, et al. COVID-19 seropositivity and asymptomatic rates in healthcare workers are associated with job function and masking. Clin Infect Dis. 2020.
29. Oksanen L-MAH, Sanmark E, Oksanen S, Anttila V-J, Paterno JJ, Lappalainen M, et al. Healthcare workers high COVID-19 infection rate: the source of infections and potential for respirators and surgical masks to reduce occupational infections. medRxiv [preprint]. 2020.[cited. DOI: 10.1101/2020.08.17.20176842. Available from: https://www.medrxiv.org/content/10.1101/2020.08.17.20176842v1
30. Akinbami LJ, Vuong N, Petersen LR, Sami S, Patel A, Lukacs SL, et al. SARS-CoV-2 Seroprevalence among Healthcare, First Response, and Public Safety Personnel, Detroit Metropolitan Area, Michigan, USA, May-June 2020. Emerg Infect Dis. 2020;26(12).
31. MacIntyre CR, Cauchemez S, Dwyer DE, Seale H, Cheung P, Browne G, et al. Face mask use and control of respiratory virus transmission in households. Emerg Infect Dis. 2009;15(2):233-41.
32. Suess T, Remschmidt C, Schink SB, Schweiger B, Nitsche A, Schroeder K, et al. The role of facemasks and hand hygiene in the prevention of influenza transmission in households: results from a cluster randomised trial; Berlin, Germany, 2009-2011. BMC Infec Dis. 2012;12(1):26.
33. Canini L, Andréoletti L, Ferrari P, D'Angelo R, Blanchon T, Lemaitre M, et al. Surgical Mask to Prevent Influenza Transmission in Households: A Cluster Randomized Trial. PLoS One. 2010;5(11):e13998.
34. Cowling BJ, Fung ROP, Cheng CKY, Fang VJ, Chan KH, Seto WH, et al. Preliminary Findings of a Randomized Trial of Non-Pharmaceutical Interventions to Prevent Influenza Transmission in Households. PLoS One. 2008;3(5):e2101.
35. Cowling BJ. Facemasks and Hand Hygiene to Prevent Influenza Transmission in Households. Ann Intern Med. 2009;151(7):437-46.
36. Simmerman JM, Suntarattiwong P, Levy J, Jarman RG, Kaewchana S, Gibbons RV, et al. Findings from a household randomized controlled trial of hand washing and face masks to reduce influenza transmission in Bangkok, Thailand. Influenza Other Respir Viruses. 2011;5(4):256-67.
37. MacIntyre CR, Zhang Y, Chughtai AA, Seale H, Zhang D, Chu Y, et al. Cluster randomised controlled trial to examine medical mask use as source control for people with respiratory illness. BMJ Open. 2016;6(12):e012330.
38. Larson EL, Ferng YH, Wong-McLoughlin J, Wang S, Haber M, Morse SS. Impact of non-pharmaceutical interventions on URIs and influenza in crowded, urban households. Public health reports (Washington, DC : 1974). 2010;125(2):178-91.

39. Aiello AE, Murray GF, Perez V, Coulborn RM, Davis BM, Uddin M, et al. Mask use, hand hygiene, and seasonal influenza-like illness among young adults: a randomized intervention trial. J Infect Dis. 2010;201(4):491-8.
40. Alfelali M, Haworth EA, Barasheed O, Badahdah AM, Bokhary H, Tashani M, et al. Facemask against viral respiratory infections among Hajj pilgrims: A challenging clusterrandomized trial. PLoS One. 2020;15(10).
41. Wu J, Xu F, Zhou W, Feikin DR, Lin C-Y, He X, et al. Risk factors for SARS among persons without known contact with SARS patients, Beijing, China. Emerg Infect Dis. 2004;10(2):210-6.
42. Lau JTF, Tsui H, Lau M, Yang X. SARS transmission, risk factors, and prevention in Hong Kong. Emerg Infect Dis. 2004;10(4):587-92.
43. Tuan PA, Horby P, Dinh PN, Mai LTQ, Zambon M, Shah J, et al. SARS transmission in Vietnam outside of the health-care setting. Epidemiology and Infection. 2006;135(3):392-401.
44. Radonovich LJ, Jr., Simberkoff MS, Bessesen MT, Brown AC, Cummings DAT, Gaydos CA, et al. N95 Respirators vs Medical Masks for Preventing Influenza Among Health Care Personnel: A Randomized Clinical Trial. JAMA. 2019;322(9):824-33.
45. MacIntyre CR, Seale H, Dung TC, Hien NT, Nga PT, Chughtai AA, et al. A cluster randomised trial of cloth masks compared with medical masks in healthcare workers. BMJ Open. 2015;5(4):e006577.
46. Loeb M, Dafoe N, Mahony J, John M, Sarabia A, Glavin V, et al. Surgical Mask vs N95 Respirator for Preventing Influenza Among Health Care Workers: A Randomized Trial. JAMA. 2009;302(17):1865-71.
47. MacIntyre CR, Wang Q, Cauchemez S, Seale H, Dwyer DE, Yang P, et al. A cluster randomized clinical trial comparing fit-tested and non-fit-tested N95 respirators to medical masks to prevent respiratory virus infection in health care workers. Influenza Other Respir Viruses. 2011;5(3):170-9.
48. MacIntyre CR, Wang Q, Seale H, Yang P, Shi W, Gao Z, et al. A randomized clinical trial of three options for N95 respirators and medical masks in health workers. American journal of respiratory and critical care medicine. 2013;187(9):960-6.
49. Jacobs JL, Ohde S, Takahashi O, Tokuda Y, Omata F, Fukui T. Use of surgical face masks to reduce the incidence of the common cold among health care workers in Japan: a randomized controlled trial. Am J Infect Control. 2009;37(5):417-9.
50. Nishiyama A, Wakasugi N, Kirikae T, Quy T, Ha le D, Ban VV, et al. Risk factors for SARS infection within hospitals in Hanoi, Vietnam. Jpn J Infect Dis. 2008;61(5):388-90.
51. Teleman MD, Boudville IC, Heng BH, Zhu D, Leo YS. Factors associated with transmission of severe acute respiratory syndrome among health-care workers in Singapore. Epidemiol Infect. 2004;132(5):797-803.
52. Nishiura H, Kuratsuji T, Quy T, Phi NC, Van Ban V, Ha LE, et al. Rapid awareness and transmission of severe acute respiratory syndrome in Hanoi French Hospital, Vietnam. The American journal of tropical medicine and hygiene. 2005;73(1):17-25.
53. Seto WH, Tsang D, Yung RW, Ching TY, Ng TK, Ho M, et al. Effectiveness of precautions against droplets and contact in prevention of nosocomial transmission of severe acute respiratory syndrome (SARS). Lancet (London, England). 2003;361(9368):1519-20.
54. Loeb M, McGeer A, Henry B, Ofner M, Rose D, Hlywka T, et al. SARS among critical care nurses, Toronto. Emerg Infect Dis. 2004;10(2):251-5.
55. Sung AD, Sung JAM, Thomas S, Hyslop T, Gasparetto C, Long G, et al. Universal Mask Usage for Reduction of Respiratory Viral Infections After Stem Cell Transplant: A Prospective Trial. Clin Infect Dis. 2016;63(8):999-1006.
56. Alraddadi BM, Al-Salmi HS, Jacobs-Slifka K, Slayton RB, Estivariz CF, Geller AI, et al. Risk Factors for Middle East Respiratory Syndrome Coronavirus Infection among Healthcare Personnel. Emerging infectious diseases. 2016;22(11):1915-20.