

BRIEF REPORT OF RAPID SYSTEMATIC REVIEW

Should medical masks be used by the general public for preventing transmission of SARS-CoV-2?

Date: 11 April 2020

Reviewers: College of Public Health Medicine Evidence-based COVID-19 Task Team, Cochrane South Africa and South African Medical Research Council Health Systems Research Unit

Declaration of interests: None of the authors have any interests to declare in respect of medical masks for preventing transmission of SARS-CoV-2 in the community.

Key findings

No trials specific to preventing transmission of SARS-CoV-2 were identified.

COMMUNITY SETTINGS

- ➔ Two cluster trials evaluated the effectiveness of medical masks versus no masks for protecting wearers from acquiring influenza-like infection among university students
- ➔ Together these trials provide evidence that medical masks may make little or no difference to the chance of infection compared to no masks (RR=0.98 (95%CI 0.81-1.19)) (*low certainty evidence*). This effect may range from a reduction of 19% chance of infection to a 19% increased chance of infection.

HOUSEHOLD SETTINGS

- ➔ Five cluster trials evaluated the effectiveness of medical masks versus no masks for protecting household members from acquiring infection from a household member who was ill with confirmed influenza-like illness.
- ➔ Together these trials provide evidence that medical masks may slightly reduce the chance of infection by 19% compared to no masks (RR = 0.81 (95% CI 0.55- 1.20)) (*low certainty evidence*). This effect may range from a reduction of 45% chance of infection to a 20% increased chance of infection.

SUMMARY

- ➔ Medical masks may provide little to no protection in the community setting, but the certainty of this evidence is low.
- ➔ Medical masks may provide a small amount of protection to members of households from household members who are ill, but the certainty of this evidence is low and some harms may also be present.
- ➔ The generalizability of these findings to the SARS-CoV-2 pandemic remains unclear.

BACKGROUND

The coronavirus disease 2019 (COVID-19) is a novel pandemic that has affected more than a million people worldwide. As there is currently no vaccine or treatment for COVID-19, non-pharmaceutical interventions are key for containing the community transmission of the virus which is mainly through respiratory droplets and touching contaminated surfaces (<https://www.who.int/news-room/commentaries/detail/modes-of-transmission-of-virus-causing-covid-19-implications-for-ipc-precaution-recommendations>). Non-pharmaceutical interventions include physical distancing measures, hand-washing and personal protective equipment (PPE).

Guidance on the use of medical masks for the general public varies between health bodies. To mitigate the transmission of COVID-19 the World Health Organization (WHO) recommends the use of PPE which include gloves, gowns and face medical/surgical or respirator face masks for healthcare workers (https://apps.who.int/iris/bitstream/handle/10665/331695/WHO-2019-nCov-IPC_PPE_use-2020.3-eng.pdf). The WHO recommends that medical masks be prioritized for certain persons such as healthcare workers, symptomatic COVID-19 infected persons, suspected and confirmed COVID-19 patients. The WHO acknowledges that there is currently no conclusive evidence supporting or opposing the use of medical masks by healthy persons in general community settings. Therefore, they recommend that decision makers considering this strategy should apply a risk-based approach that considers several factors such as the purpose of the mask use, the risk of exposure to COVID-19, and the vulnerability of persons ([https://www.who.int/publications-detail/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-\(2019-ncov\)-outbreak](https://www.who.int/publications-detail/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak)).

The Centers for Disease Control (CDC) recommends that PPE, including medical masks or respirators, be prioritized for healthcare personnel and confirmed or suspected COVID-19 patients under medical examination (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html>). They do not recommend the use of medical masks by the general public.

In a 2013-2016 Hong Kong clinic-based randomized trial of patients with influenza-like illness, analysis of a sub-group of 111 patients with confirmed respiratory virus infection found that of the 17 participants who were infected with coronavirus, the virus was detected in respiratory droplets and aerosols in 3 of 10 (30%) and 4 of 10 (40%) of exhaled breath samples collected from those without medical face masks, respectively. No virus was detected in respiratory droplets or aerosols collected from those participants wearing face masks. Although this study was small and pre-dates SARS-CoV-2, it provides some evidence of a possible protective effect of masks while acknowledging that most of those without masks did not shed detectable coronavirus in respiratory droplets or aerosols [1].

Research and guidance on the use of medical masks in the community is required to enable evidence-based policy decision-making especially so limited PPE can be optimally used.

OBJECTIVES

To assess the effects of medical masks for preventing transmission of SARS-CoV-2 in the community and household settings to inform College of Public Health Medicine guidance.

METHODS

We conducted a rapid review of the evidence. We formulated the research question using the PICO format:

- Population:** Members of the community or households without respiratory illness
- Intervention:** Medical masks (also known as surgical masks) of any type including N95 respirator masks
- Comparators:** No masks
- Outcomes:** Clinical respiratory illness; Laboratory-confirmed respiratory illness; Compliance with the intervention; Adverse effects
- Study designs:** Systematic Reviews
Randomised Controlled Trials (RCTs)

Search Strategy

We conducted systematic searching of three electronic databases (PubMed, Embase and *The Cochrane Library*) as well as the following trials registries www.clinicaltrials.gov and WHO ICTRP (<https://www.who.int/ictip/en/>), on 30th March 2020. See **Appendix 1**.

The search strategy was developed and conducted by an experienced information specialist (JO). All records were uploaded into EndNote. Two reviewers (TK and TC) independently screened records to identify eligible studies.

Data extraction and quality appraisal

Reviewers (KR, AR, DK, JTWN, RE, KB and NS, CM and VR, SD, B-MS and AH) conducted independent, duplicate critical appraisal and risk of bias assessment of included RCTs using the Cochrane Risk of Bias 2.0 tool.

Two reviewers (JTWN & NS) conducted a Risk of Bias in Systematic Reviews (ROBIS) assessment of the systematic review to identify the suitability and quality of the conduct of the review with respect to:

1. Assessing relevance of the review
2. Study eligibility criteria
3. Identification and selection of included studies
4. Data collection and study appraisal (individual study Risk of Bias assessment)
5. Synthesis and Findings
6. Overall Risk of Bias judgement

NS conducted data extraction and analysis, which was checked by KR. NS conducted GRADE assessment and checked with KB and TK. All reviewers checked and approved the final report.

RESULTS

Eight hundred and twenty-one records were screened and 9 full-text studies were checked for eligibility of which 7 RCTs met inclusion criteria. **Appendix 3** contains the flow diagram of the search.

Following the search, we also identified a recent internet-published systematic review by Jefferson et al. which included an updated version of a 2011 Cochrane review.

No additional studies were identified from www.clinicaltrials.gov or the dedicated COVID-19 WHO ICTRP platform (<https://www.who.int/ictcp/en/>).

No studies specific to SARS-CoV-2 were identified.

Characteristics of included studies

1. Systematic review

The Jefferson et al. review was judged to be highly relevant to our PICO. We judged the overall risk of bias to be low with some concerns. These included concerns about the sensitivity of the search strategy which was limited to the English language resulting in potential language bias, a lack of reporting of individual trial risk of bias (only the overall was presented), and the rationale for drawing conclusions which depart from the evidence found was not fully described. See **Appendix 3** for ROBIS.

2. Randomised Controlled Trials

Community settings

Two cluster trials evaluated the effectiveness of medical masks versus no masks for protecting wearers from acquiring influenza-like infection among university students living in residences [2, 3]. All healthy students in a residence were provided with medical masks and advised on how to wear these; students living in other residences were not provided with masks. The rate of influenza-like illness was evaluated across the residence student population during the period of study.

Household settings

Four cluster trials evaluated the effectiveness of medical masks versus no masks for protecting household members from acquiring infection from a household member who was ill with influenza-like illness [4-7]. In two trials [4, 5] only the ill household member was provided with masks; in another trial both the ill household member and their household members were given masks [6] and in another trial the ill household member and those household members who became ill during the follow-up period was advised to wear masks [7].

A fifth trial was conducted among pilgrims attending the Haj and the unit of randomization was tents [8]. We included this trial as a household trial as the effectiveness of wearing a mask compared to no mask in pilgrims who were displaying influenza-like symptoms was evaluated in those sleeping near the pilgrims rather than the effect on all the pilgrims in each tent. Both the pilgrim who was infected and those sleeping near them were given masks.

Evidence of effectiveness

We extracted numerical data for ILI from the Jefferson et al. review, but sub-grouped by community and household trials rather than combining these with hospital-based trials. We entered the data into REVMAN using the generic inverse variance option in order to pool adjusted estimates of effects using the random effects model. For Barasheed [8], no adjustment for clustering was reported. We therefore

adjusted the variance according to the methods recommended by Cochrane, assuming an ICC = 0.2 (informed by the Sues trial) and an average cluster size of 6 (assumed from the diagrams provided in the Barasheed trial report). We therefore selected to conduct a sensitivity analysis with Barasheed included and excluded from the meta-analysis due to the assumptions made as described.

We extracted data on compliance and adverse effects directly from the trial reports and report these narratively.

See **Appendix 4** for the forest plots and **Appendix 5** for GRADE table.

We extracted data on compliance and adverse effects directly from the RCTs.

1. Influenza-like Illness

Community settings

There is low certainty evidence from two trials that there is no difference in transmission between participants wearing medical masks in community settings than those not wearing medical masks (RR=0.98 (95%CI 0.81-1.19))[2, 3]. The low certainty is due to the possible risk of bias due to a lack of blinding of study participants with the study findings possibly affected by performance bias and the assessment of the outcome relied on self-reported flu-like symptoms by the participants which may lead to detection bias. The two trials were also conducted by the same investigators using the same protocol over two seasons and as such may have limited generalisability to community settings other than universities. Therefore we also downgraded for indirectness.

Household settings

There is low certainty evidence from five trials that participants wearing medical masks in household settings were less likely to have influenza-like illnesses than those not wearing medical masks (RR = 0.81 (95%CI 0.55-1.20)) [4, 5, 7-9]. The low certainty is partly due to imprecision in the data because the confidence interval of the point estimate includes the null effect and appreciable benefit and some harm. The low certainty is also due to the high risk of bias assessment because blinding of study participants was not possible therefore study findings may have been affected by performance bias. Furthermore, the assessment of the outcomes relied on self-reported flu-like symptoms.

The sensitivity analysis which excluded the trial by Barasheed, found a similar estimate of effect (RR = 0.88 (95%CI 0.57-1.36)).

2. Compliance

Community settings

One of the trials reported that those wearing masks did so for an average of 5.04 hours per day (standard deviation = 2.2 hours) [3]. Nil compliance data was reported in the other trial.

Household settings

Compliance among trials varied.

In the three trials where only the ill household member wore a mask, the index patients reported wearing masks on average 3.7 hours (SD: 2.7 hours) a day in one trial [5] and in another trial for 4.4 hours (95% CI: 3.9 to 4.9 hours)[4]. Of note in the latter trial, patients in the 'no-mask' control arm wore masks for an average of 1.4 hours (95% CI: 0.9 to 1.8). In the trial of pilgrims, compliance with facemask use by pilgrims in the 'mask' group was 56 of 75 (76%), while it was 11 of 89 (12%) in the 'no mask' control group [8].

In the trials where both the ill household member and the rest of the household were provided with masks, compliance was observed to be low in one of the trials with more than one in four household contacts in the face mask group not wearing a surgical mask at all during the follow-up period [6]. In addition, more than one in four index cases in the control and hand hygiene intervention arms reported wearing masks at home of their own accord, possibly contaminating the intervention as reported by the authors. In the other trial where household contacts were advised to wear a mask only when they became ill, the authors report that in general, daily adherence was good, reaching a plateau of over 50% [7].

3. Adverse effects

Community settings

Neither of the trials reported adverse effects.

Household settings

Three trials reported adverse effects.

In the trial by Canini et al., 38 (75%) patients from the intervention arm reported discomfort with mask use with the three main causes of discomfort being warmth (45%), respiratory difficulties (33%) and humidity (33%). Children wearing children facemasks reported feeling pain more frequently (3/12) than other participants wearing adult facemasks (1/39) [5].

In the trial by Suess et al., the main problem stated by participants (adults as well as children) was “heat/humidity” (18/34, 53% of children; 10/29, 35% of adults), followed by “pain” and “shortness of breath” when wearing a facemask [7].

In the trial by Barasheed et al., the most often reported reason for not wearing facemasks was discomfort (15%)[8].

CONCLUSION

Our review combines an evaluation of a recent systematic review based on Cochrane methods and results of our own search. No trials of medical masks to prevent human-to-human transmission of SARS-CoV-2 were identified.

Together, current evidence from two trials indicates that wearing of medical masks may not be effective to prevent widespread community transmission of respiratory viral illnesses, but this evidence is of low certainty. Evidence from five trials indicates that wearing of medical masks may prevent transmission from ill household members to other members of their households, but this evidence is also of low certainty. In the trials of household transmission, compliance with wearing of masks was varied with several trial investigators reporting that participants in the control ‘no mask’ groups also wore masks, potentially reducing the estimate of effectiveness.

The generalizability of these results to the current SARS-CoV-2 pandemic remain unclear but provides reasonable indirect evidence to inform policy and guidance.

REFERENCES

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3. Aiello AE, Perez V, Coulborn RM, et al. Facemasks, hand hygiene, and influenza among young adults: a randomized intervention trial. *PloS one*. 2012;7(1):e29744.
4. MacIntyre CR, Zhang Y, Chughtai AA, et al. Cluster randomised controlled trial to examine medical mask use as source control for people with respiratory illness. *BMJ open*. 2016 Dec 30;6(12):e012330.
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6. Cowling BJ, Chan KH, Fang VJ, et al. Facemasks and hand hygiene to prevent influenza transmission in households: a cluster randomized trial. *Annals of internal medicine*. 2009;151(7):437-46.
7. Suess T, Remschmidt C, Schink SB, 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 infectious diseases*. 2012;12:26.
8. Barasheed O, Almasri N, Badahdah AM, et al. Pilot Randomised Controlled Trial to Test Effectiveness of Facemasks in Preventing Influenza-like Illness Transmission among Australian Hajj Pilgrims in 2011. *Infectious disorders drug targets*. 2014;14(2):110-6.
9. Cowling BJ, Fung RO, Cheng CK, et al. Preliminary findings of a randomized trial of non-pharmaceutical interventions to prevent influenza transmission in households. *PloS one*. 2008;3(5):e2101.

Appendix 1: Search strategy of 30 March 2020

PubMed

Search	Query	Results
#5	Search ((#2 AND #3 AND #4) NOT (animals[mh] NOT humans[mh]))	541
#4	Search (systematic[sb] OR randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized [tiab] OR placebo [tiab] OR drug therapy [sh] OR randomly [tiab] OR trial [tiab] OR groups [tiab])	4810567
#3	Search (Respiratory tract infections[mh] OR respiratory tract infection[tiab] OR respiratory tract infections[tiab] OR respiratory infection[tiab] OR respiratory infections[tiab] OR influenza[tiab] OR SARS[tiab] OR emerging infections[tiab] OR coronavirus[mh] OR coronavirus[tiab] OR coronaviruses[tiab] OR covid*[tiab] OR 2019-ncov[tiab] OR tuberculosis[tiab] OR respiratory virus[tiab] OR respiratory viruses[tiab])	583074
#2	Search (Masks[mh] OR mask[tiab] OR masks[tiab] OR facemask[tiab] OR facemasks[tiab] OR respirator[tiab] OR respirators[tiab] OR respiratory protective devices[mh] OR respiratory protective device[tiab] OR respiratory protective devices[tiab])	43587

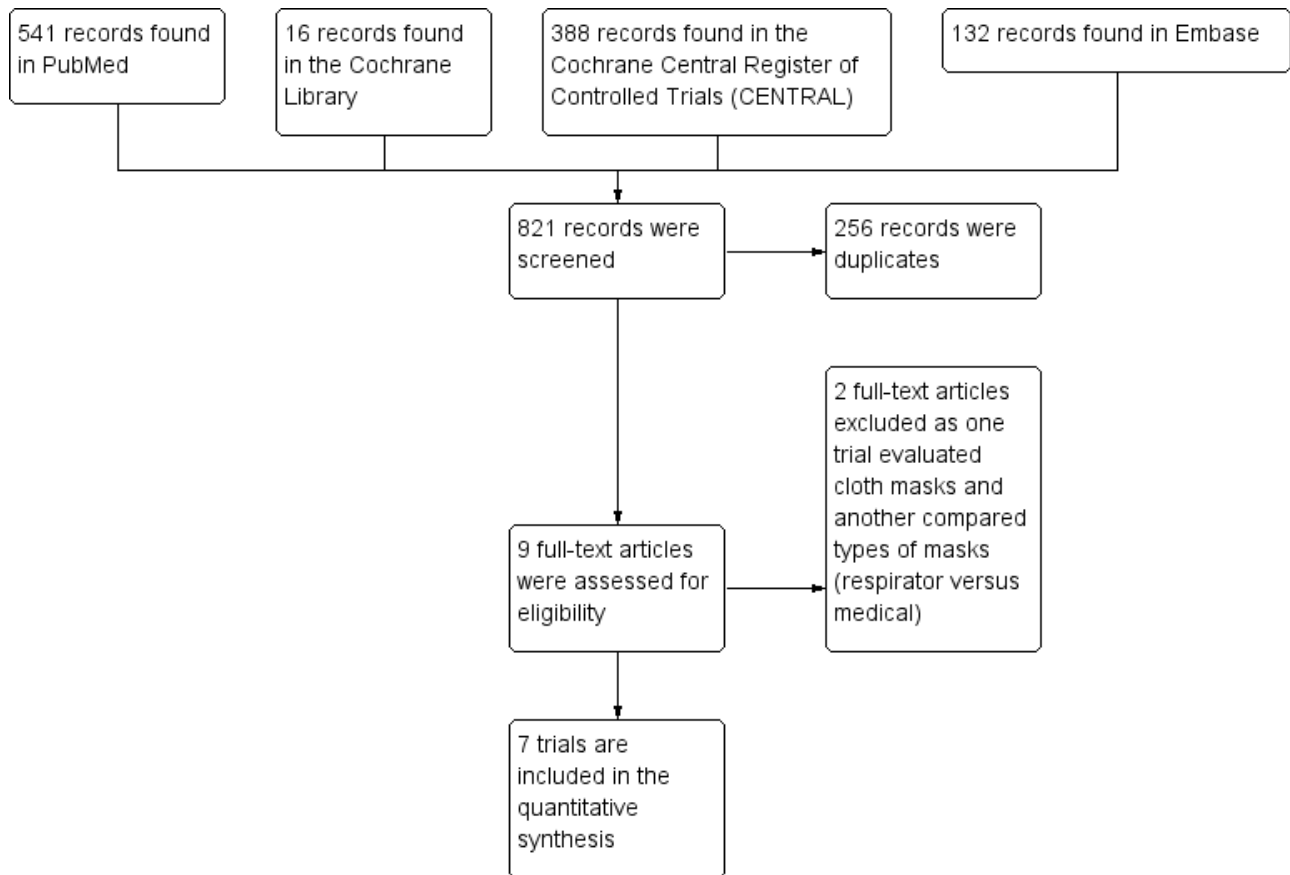
Embase

	Searches	Results
1	masks.mp.	10594
2	respiratory protective devices.mp.	160
3	(mask or masks or facemask or facemasks or respirator or respirators or "respiratory protective device" or "respiratory protective devices").ab,kw,ti.	55548
4	1 or 2 or 3	55566
5	respiratory tract infections.mp.	21298
6	coronavirus.mp.	18618
7	("respiratory tract infection" or "respiratory tract infections" or "respiratory infection" or "respiratory infections" or influenza or SARS or "emerging infections" or coronavirus or coronaviruses or covid* or "2019-ncov" or tuberculosis or "respiratory virus" or "respiratory viruses").ab,kw,ti.	431411
8	5 or 6 or 7	436045
9	4 and 8	1668
10	limit 9 to human	1362
11	limit 10 to ((conference abstracts or embase) and (clinical trial or randomized controlled trial or controlled clinical trial or multicenter study or phase 1 clinical trial or phase 2 clinical trial or phase 3 clinical trial or phase 4 clinical trial))	98
12	limit 10 to ((conference abstracts or embase) and (evidence based medicine or consensus development or meta analysis or outcomes research or "systematic review"))	43
13	11 or 12	132

Cochrane Library

ID	Search	Hits
#1	MeSH descriptor: [Respiratory Tract Infections] explode all trees	14151
#2	MeSH descriptor: [Coronavirus] explode all trees	11
#3	MeSH descriptor: [Coronavirus Infections] explode all trees	12
#4	("respiratory tract infection" OR "respiratory tract infections" OR "respiratory infection" OR "respiratory infections" OR influenza OR SARS OR "emerging infections" OR coronavirus OR coronaviruses OR covid* OR "2019-ncov" OR tuberculosis OR "respiratory virus" OR "respiratory viruses"):ti,ab,kw	22521
#5	#1 OR #2 OR #3 OR #4	30433
#6	MeSH descriptor: [Masks] explode all trees	1505
#7	MeSH descriptor: [Respiratory Protective Devices] explode all trees	66
#8	(mask OR masks OR facemask OR facemasks OR respirator OR respirators OR "respiratory protective device" OR "respiratory protective devices"):ti,ab,kw	8075
#9	#6 OR #7 OR #8	8075
#10	#5 AND #9 in Cochrane Reviews, Trials	404
16 Cochrane Reviews retrieved 388 Trials retrieved		

Appendix 2: Flow diagram of search



Appendix 3: ROBIS for Jefferson et al. review

ID	Publication year	Number and type of studies	Publication limits	Language limits	ROBIS Domains				Overall
					1	2	3	4	
Influenza-like Illness									
Jefferson	2020	7 RCTs on medical masks vs nil	Yes ¹	Yes ²	Low	High	Low	Low	Some concerns ³

1 Only one databases searched – PUBMED

2 Only English-language database, no Chinese-specific literature searched

3 No rationale provided for conclusions which do not match findings

ROBIS DOMAINS:

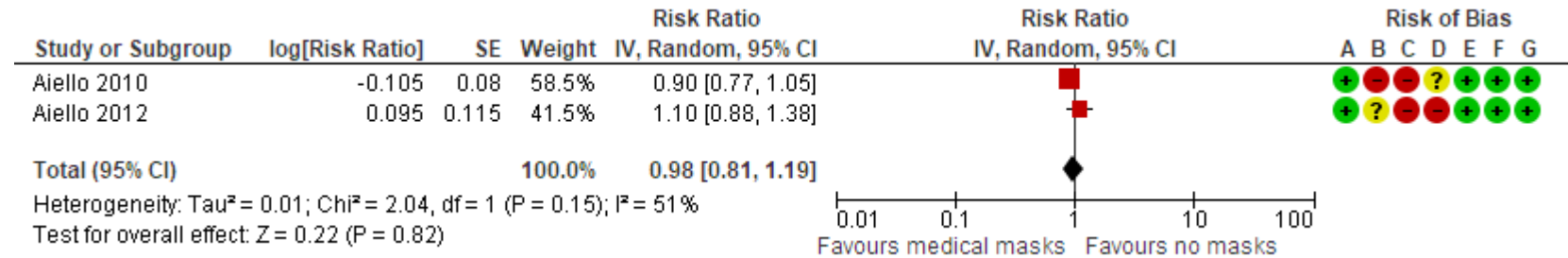
1. Study eligibility criteria
2. Identification and selection of included studies
3. Data collection and study appraisal (individual study Risk of Bias assessment)
4. Synthesis and Findings
5. Overall Risk of Bias judgement

Appendix 4: Risk of Bias Assessment for RCTs

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Aiello 2010	+	-	-	?	+	+	+
Aiello 2012	+	?	-	-	+	+	+
Barasheed 2014	-	+	-	?	+	?	+
Canini 2010	?	+	-	-	-	?	?
Cowling 2008	+	?	?	+	-	+	+
MacIntyre 2016	+	?	-	-	+	+	+
Suess 2012	+	+	-	+	?	+	+

Appendix 5: Forest plots

Community Setting: Influenza-like illness

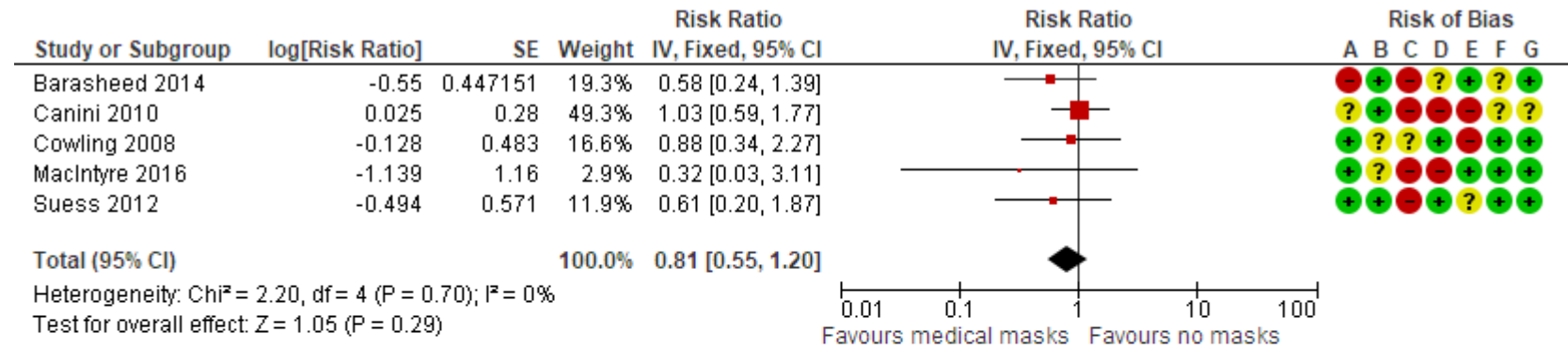


Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

Household Setting: Influenza-like illness

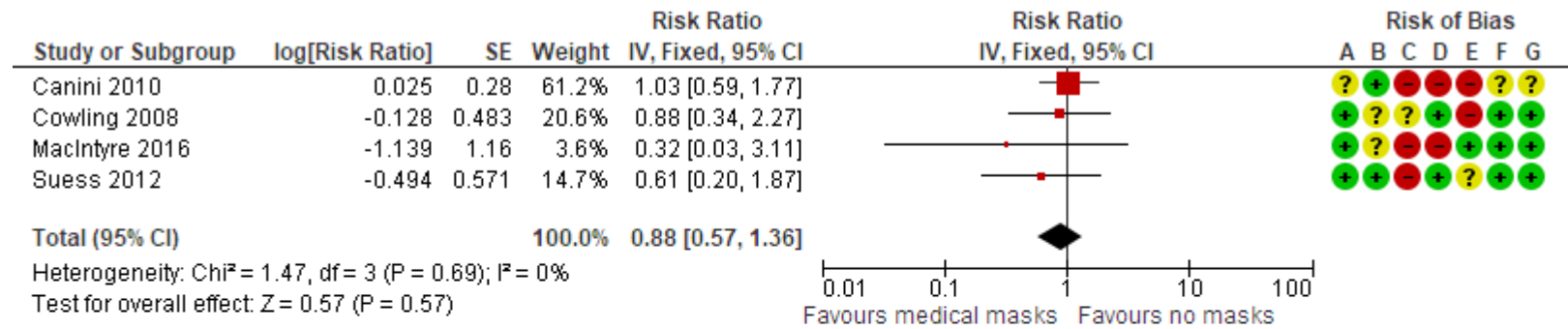
With Barasheed included



Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

Without Barasheed



Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

Appendix 6: GRADE table

Community Settings

Certainty assessment							№ of patients		Effect	Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Medical masks	No masks Community	Relative (95% CI)		

Influenza-like illness

2	randomised trials	serious ^a	not serious	serious ^b	not serious	none	735	834	RR 0.98 (0.81 to 1.19)	⊕⊕○○ LOW	CRITICAL
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CI: Confidence interval; RR: Risk ratio; OR: Odds ratio

Explanations

a. Risk of Bias: Blinding of participants was not possible so performance bias is possible across all trials, although this may have been partly offset by clustering. However, the risk of detection bias is high as outcomes relied on self-report of flu-like symptoms

b. Indirectness: Both the trials were conducted by the same trial team with the same protocol conducted over a period of two different influenza seasons. As such as we marked down for indirectness as the conditions may not be applicable to the broader community beyond the university setting

Household Settings

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Medical masks	No masks Household	Relative (95% CI)	Absolute (95% CI)		

Influenza-like Illness

5	randomised trials	serious ^a	not serious	not serious	serious ^b	none	690	719	RR 0.81 (0.55 to 1.20)	1 fewer per 1,000 (from 1 fewer to 1 fewer)	⊕⊕○○ LOW	CRITICAL
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CI: Confidence interval; RR: Risk ratio

Explanations

a. Risk of Bias: Blinding of participants was not possible so performance bias is possible across all trials, although this may have been partly offset by clustering. However, the risk of detection bias is high as outcomes relied on self-report of flu-like symptoms

b. Imprecision: Downgraded once as the confidence interval includes 1 and appreciable benefit and some harm