

BRIEF REPORT OF RAPID REVIEW

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

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

Key findings

- ➔ No trials exist which compare cloth masks to medical masks of nil covering in the community setting
- ➔ A single, large, well-conducted cluster trial in 15 hospitals in Vietnam compared respiratory infection in healthcare workers wearing cloth masks compared with medical masks for a 5-week period
- ➔ These results were assessed for relevance to the community setting
- ➔ There is moderate certainty evidence that clinical and laboratory-confirmed respiratory infections are increased approximately 1.5 times when wearing cloth masks compared with medical masks
- ➔ 28 more people per 1000 may develop clinical respiratory infections if they wear a cloth mask compared to a medical mask. This could be 0 fewer to 71 per 1000 more infections.
- ➔ 22 more people per 1000 may develop laboratory confirmed respiratory infections if they wear a cloth mask compared to a medical mask. This could be 2 fewer to 63 per 1000 more infections.
- ➔ There is very low certainty evidence that influenza-like illness is increased approximately 1.6 times when wearing cloth masks compared with medical masks. The uncertainty is due to the low rate of influenza-like infections observed in the trial.
- ➔ Compliance with wearing masks and levels of discomfort are similar in both groups

BACKGROUND

The SARS-CoV-2 virus epidemic has been classified as a pandemic and community transmission is present in multiple regions. Person to person transmission is largely via droplet spread and contact with contaminated surfaces (<https://www.who.int/news-room/commentaries/detail/modes-of-transmission-of-virus-causing-covid-19-implications-for-ipc-precaution-recommendations>). This means close contact with infected people should be avoided, and the risk of transmission mitigated using infection prevention and control measures, including personal protective equipment (PPE) such as face masks.

The pandemic has led to a global shortage of PPE, including masks and respirators. Masks are critical in healthcare settings to protect healthcare workers from becoming infected, and are being widely promoted in community settings to prevent transmission in the general population. This is particularly relevant with 2019-nCoV, since transmission prior to symptom onset is thought to be important. Homemade or cloth masks have been used in several settings prior to the COVID-19 pandemic [1] and have been suggested as a stopgap in community settings in order to save surgical masks for use in healthcare workers. The evidence for their effectiveness, however, is unclear [2].

Guidance from global oversight bodies varies. The World Health Organization (WHO) recommends that people who are coughing or sneezing should wear masks, and healthy people should only wear masks when caring for those who may be infected with 2019-nCoV (<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public/when-and-how-to-use-masks>). The WHO has not provided guidance about the use of homemade or cloth masks and instead promote hand-washing, cough and sneeze etiquette, and physical distancing as the key to reducing transmission.

The Centers for Disease Control recommend that either patients or their carers should wear masks when being cared for at home. Currently, they do not recommend masks for the general public. (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-prevent-spread.html>) For healthcare workers, they recommend the use of homemade masks as a last resort, with a warning that their protective capacity is unknown, and homemade masks should not be classified as PPE. (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/face-masks.html>)

Evidence for the effectiveness of cloth masks comes largely from in-vitro filtration studies. These studies have shown that cloth masks may offer some protection from respiratory pathogens, despite substantially lower filtration ability compared to surgical masks [3]. Factors that may affect filtration include type of cloth used, stretching, and how the masks are washed [4]. One simulation study looked specifically at how well particles were prevented from expulsion into the air- the study found marginal protection in cloth masks, with substantially better protection in surgical masks [5].

Guidance on the rational use of cloth masks in the community is urgently needed to enable decision-makers to ensure evidence-informed policies about preventing community transmission without depleting stocks of essential PPE needed for health care settings.

Widespread wearing of any masks has been proposed to lead to less stigmatisation so that those who wear masks are not immediately identified as having COVID-19. It has also been postulated that wearing a mask will remind one not to touch one's face and create awareness more generally [6].

OBJECTIVES

To assess the effects of cloth masks for preventing transmission of SARS-CoV-2 in the community setting.

METHODS

We conducted a rapid review of the evidence including 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/>).

The search strategy was developed and conducted by an experienced information specialist (JO). Two reviewers (TK and TC) independently screened records to identify eligible studies. Two reviewers (KR and NS) conducted critical appraisal and risk of bias assessment of included studies using the Cochrane Risk of Bias 2.0 tool. NS conducted data extraction and analysis, which was checked by KR. A statistician (YB) advised on adjusted analyses. NS conducted GRADE assessment and all reviewers checked and approved the final report. No meta-analysis was done due to only a single study meeting eligibility criteria. The search strategy is shown in **Appendix 1**.

Eligibility criteria for review

- Population:** Community setting (general population and households)
- Special populations of interest are adults over 60 and those with pre-existing health conditions including HIV and TB
- Studies of healthcare workers will be included only if no community setting trials exist
- Intervention:** Facemasks which cover the mouth and nose and are made of cloth and are not medical grade quality
- Comparators:** Surgical masks, Respirators e.g. N95 masks or nil coverage
- Outcomes:** Presence of COVID-19 – measured by Ag PCR or Antibody serology
Presence of other respiratory viral infections – clinical and laboratory confirmed
Adherence to wearing mask
Adverse effects (discomfort, breathing problems)
- Study designs:** Systematic reviews
Randomised controlled trials (RCTs)
Modelling studies

RESULTS

We searched PubMed, Embase and the Cochrane Library electronic databases on 31 March 2020. Details of each search are provided in **Appendix 1**. All records were uploaded into EndNote. 821 records were screened and 9 potentially eligible full-text checked for eligibility of which a single RCT met inclusion criteria. **Appendix 2** contains the flow diagram of the search.

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

Screening of references from systematic reviews did not yield any additional studies.

No studies specific to SARS-CoV-2 were identified. No eligible studies of cloth masks used in the community setting were identified. We therefore identified the cluster trial conducted in healthcare workers to provide indirect evidence and report the findings here.

Characteristics of included study

A cluster trial of 15 hospitals was conducted in Hanoi, Vietnam over 6 weeks [7]. Seventy-four wards across the hospitals were randomised to adopt cloth masks, medical masks, or usual practice (a mixture of medical, cloth and no masks) for their health-workers to prevent respiratory infections. 1607 healthcare workers were followed-up daily for any respiratory symptoms, were asked to keep daily diary records, and provided with thermometers for daily temperature readings. Swabs were done on participants who were symptomatic on the day of reporting.

We judged the trial to be of overall high quality using the Cochrane Risk of Bias 2.0 tool specific to cluster trials, but identified the lack of blinding of participants and researchers to the intervention as a possible source of measurement and detection bias. However, the use of thermometers and laboratory confirmation for positive symptoms reduces this potential bias.

Evidence of effectiveness

See **Appendix 3** for all figures of forest plots and **Appendix 4** for GRADE table.

Using the GRADE approach, we marked down the overall certainty of evidence from this study as it was conducted in healthcare workers, not the general public. We did not deem the lack of coronavirus-specific infections to further limit directness, as the main virus identified in the study was rhinovirus which is both droplet and airborne spread.

1. Clinical Respiratory Illness

There is moderate certainty from analysis of crude data that participants wearing cloth masks were 1 and a half times more likely to exhibit CRI than those wearing medical masks (RR = 1.57; 95%CI 0.99, 2.48).

When data is adjusted for clustering the effect remains similar (RR = 1.57 (95% CI 0.87, 2.84) and for adjusting for clustering and confounding (RR = 1.56 (95% CI 0.98, 2.49)).

2. Influenza-like illness

There is very low certainty that participants wearing cloth masks were more likely to exhibit ILI than those wearing medical masks (RR = 13.25 (95% CI:1.74, 100.96). The very low certainty was due to the imprecision in the data due to the very low event rate and resultant wide confidence interval.

When data is adjusted for clustering the effect remains similar (RR = 13.25 (95% CI 0.98, 179.00) and for adjusting for clustering and confounding (RR = 13.00 (95% CI 1.69, 100.03).

3. Laboratory-confirmed viruses

There is moderate certainty that participants wearing cloth masks were more likely to have laboratory-confirmed viral illness than those wearing medical masks (RR = 1.66, 95% CI: 10.95, 2.91). When data is adjusted for clustering the effect remains similar (RR = 1.66 (95% CI 0.81, 3.40) and for adjusting for clustering and confounding (RR = 1.54 (95% CI 0.88, 2.70).

4. Compliance with wearing masks

There is moderate certainty that compliance in both groups was the same (RR = 1.00 (95% CI: 0.90, 1.11). Both groups were 56% compliant.

5. Adverse effects

There is moderate certainty that discomfort in both groups was the same (RR = 1.05 (95% CI: 0.92, 1.12). 42.6% wearing cloth masks compared to 40.4% wearing surgical masks complained of discomfort, with general discomfort and breathing problems reported most frequently.

CONCLUSION

There is no evidence from RCTs regarding the prevention of viral respiratory illnesses using cloth masks in the community setting. A single, large cluster trial in healthcare workers provides indirect evidence that cloth masks increase the risk to wearers compared to medical masks. Given the lack of supportive evidence directly for the efficacy, effectiveness or safety of cloth masks, they should only be used in trial settings where effects can be monitored and potential harms identified early.

REFERENCES

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4. Neupane BB, Mainali S, Sharma A, et al. Optical microscopic study of surface morphology and filtering efficiency of face masks. *PeerJ*. 2019.
5. van der Sande M, Teunis P, Sabel R. Professional and home-made face masks reduce exposure to respiratory infections among the general population. *PloS one*. 2008 Jul 9;3(7):e2618.
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7. MacIntyre CR, Seale H, Dung TC, et al. A cluster randomised trial of cloth masks compared with medical masks in healthcare workers. *BMJ open*. 2015 Apr 22;5(4):e006577.

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

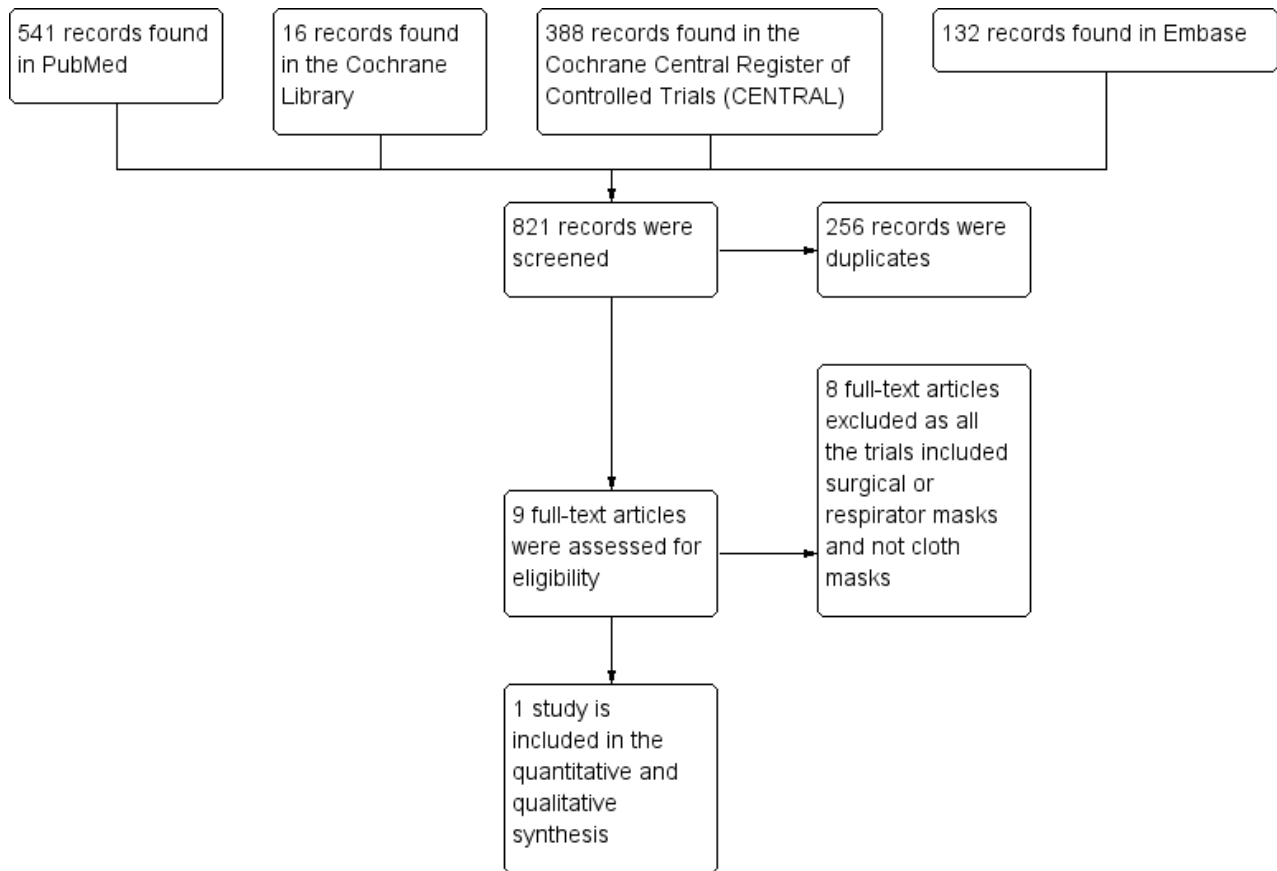
Embase

	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		

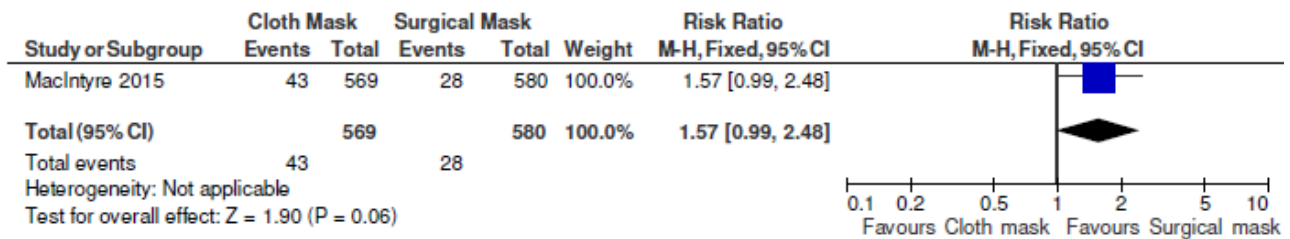
Appendix 2: Flow diagram of search



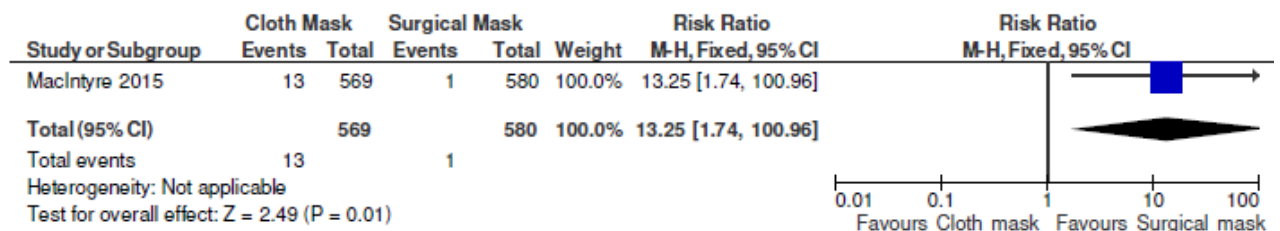
Appendix 3: Forest plots

1 Cloth masks compared to surgical masks CRUDE

1.1 Clinical Respiratory Illness



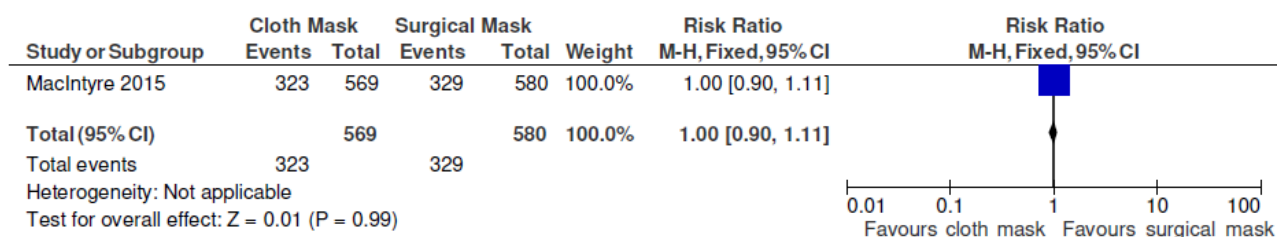
1.2 Influenza-like illness *Temp and 1 symptom



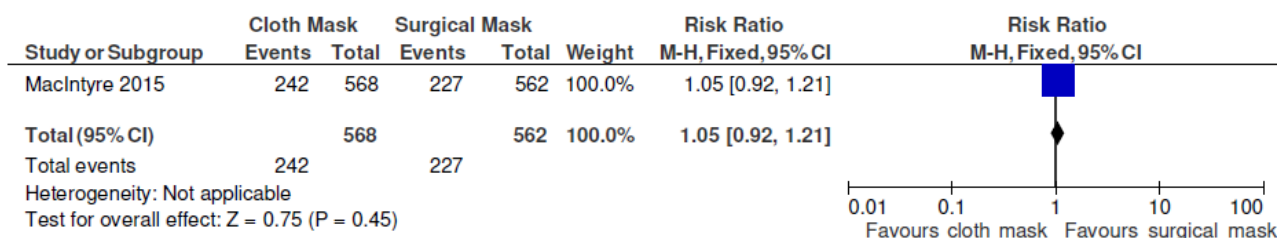
1.3 Laboratory-confirmed viral respiratory infection



1.4 Compliance with wearing mask

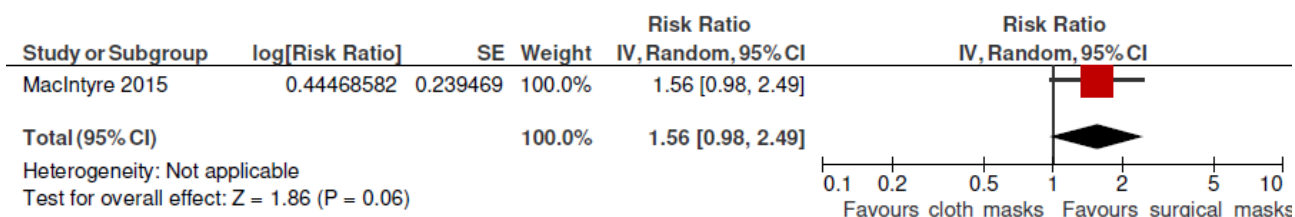


1.5 Discomfort

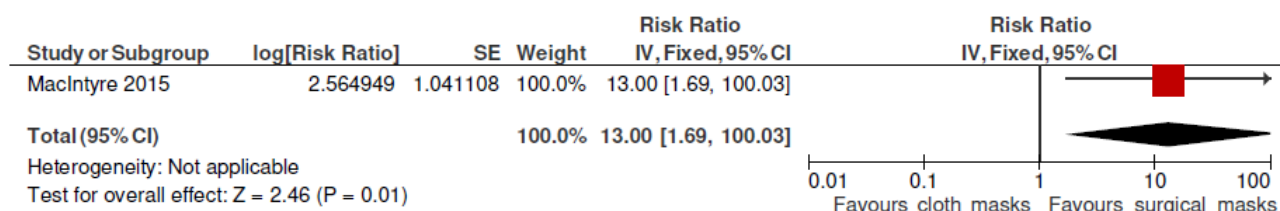


2 Cloth masks compared to surgical masks ADJUSTED for clustering and confounders

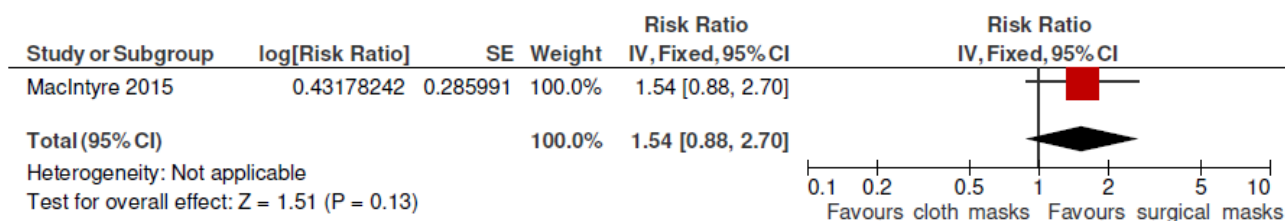
2.1 Clinical Respiratory Illness



2.2 Influenza-like illness *Temp and 1 symptom

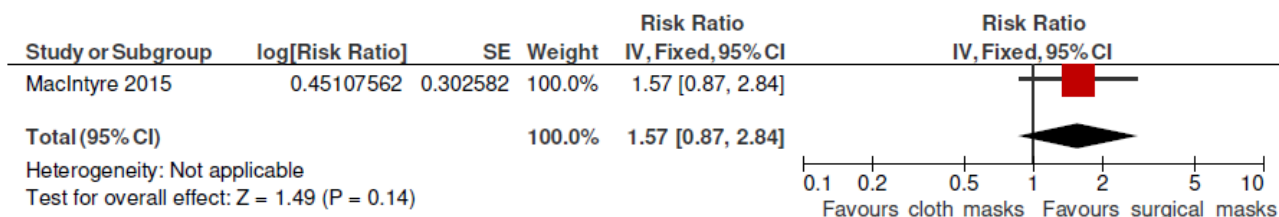


2.3 Laboratory-confirmed viral respiratory infection

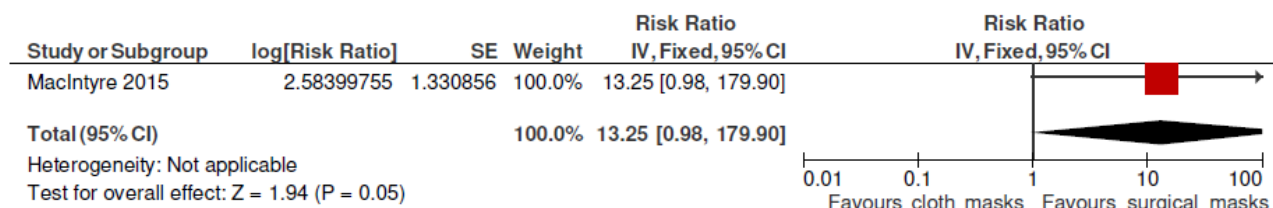


3 Cloth masks compared to surgical masks ADJUSTED for clustering only

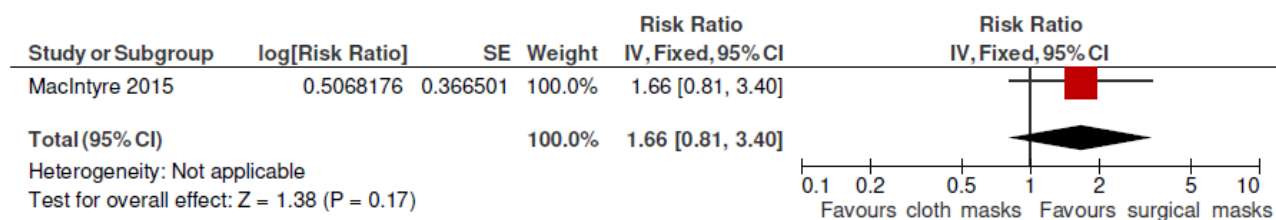
3.1 Clinical Respiratory Illness



3.2 Influenza-like illness *Temp and 1 symptom



3.3 Laboratory-confirmed viral respiratory infection



Appendix 4: GRADE table

Question: Cloth masks compared to surgical masks for preventing SARS-CoV-2

Settings: community

Bibliography: Siegfried N. Cloth masks for prevention of SARS-CoV 2 in the community.

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Cloth masks compared to surgical masks CRUDE	Control	Relative (95% CI)	Absolute		
Clinical Respiratory Illness (follow-up 5 weeks)												
1	randomised trials	no serious risk of bias ¹	no serious inconsistency ²	serious ³	no serious imprecision	none	43/569 (7.6%)	28/580 (4.8%)	RR 1.57 (0.99 to 2.48) ⁴	28 more per 1000 (from 0 fewer to 71 more)	⊕⊕⊕○ MODERATE	CRITICAL
Influenza-like illness *Temp and 1 symptom												
1	randomised trials	no serious risk of bias ¹	no serious inconsistency ²	serious ³	very serious ⁵	none	13/569 (2.3%)	1/580 (0.17%)	RR 13.25 (1.74 to 100.96) ⁶	21 more per 1000 (from 1 more to 172 more)	⊕○○○ VERY LOW	CRITICAL
Laboratory-confirmed viral respiratory infection (follow-up 5 weeks)												
1	randomised trials	no serious risk of bias ¹	no serious inconsistency ²	serious ⁷	no serious imprecision	none	31/569 (5.4%)	19/580 (3.3%)	RR 1.66 (0.95 to 2.91) ⁸	22 more per 1000 (from 2 fewer to 63 more)	⊕⊕⊕○ MODERATE	CRITICAL
Compliance with wearing mask (follow-up 5 weeks)												
1	randomised trials	no serious risk of bias ¹	no serious inconsistency ²	serious ³	no serious imprecision	none	323/569 (56.8%)	329/580 (56.7%)	RR 1 (0.9 to 1.11)	0 fewer per 1000 (from 57 fewer to 62 more)	⊕⊕⊕○ MODERATE	IMPORTANT
Discomfort (follow-up 5 weeks)												
1	randomised trials	no serious risk of bias ¹	no serious inconsistency ²	serious ³	no serious imprecision	none	242/568 (42.6%)	227/562 (40.4%)	RR 1.05 (0.92 to 1.21)	20 more per 1000 (from 32 fewer to 85 more)	⊕⊕⊕○ MODERATE	IMPORTANT

¹ Risk of Bias: We did not downgrade for risk of bias. There was adequate randomisation and the participants were recruited and provided consent before the wards were randomised so allocation concealment was acceptable for a cluster trial. Blinding of participants and providers was not possible; however we did not mark down for measurement or performance bias as participants were contacted daily and were aware that any symptoms resulted in swabs for laboratory.

² Inconsistency: The results are from a single trial only. Ideally replicability is preferred. The trial is large and well-conducted so we did not downgrade for this.

³ Indirectness: Marked down once for indirectness. The population is healthcare workers and our PICO is focused on community settings and the general public. However, we judged the evidence to be relevant to the general public as infections are likely to be more prevalent in the hospital setting and so there is a larger background control rate compared to the general public. This implies that any effect observed in the hospital setting is likely to be greater than in the community setting and therefore very hard to measure in a trial setting unless it is very large.

⁴ RR for adjusting for clustering (RR = 1.57 (95% CI 0.87, 2.84) and for adjusting for clustering and confounding (RR = 1.56 (95% CI 0.98, 2.49).

⁵ Imprecision: We marked down twice. The event rate is = 1 and the resultant confidence interval is very wide.

⁶ RR for adjusting for clustering (RR = 13.25 (95% CI 0.98, 179.00) and for adjusting for clustering and confounding (RR = 13.00 (95% CI 1.69, 100.03).

⁷ Indirectness: Marked down once for indirectness. The population is healthcare workers and our PICO is focused on community settings and the general public. However, we judged the evidence to be relevant to the general public as infections are likely to be more prevalent in the hospital setting and so there is a larger background control rate compared to the general public. This implies that any effect observed in the hospital setting is likely to be greater than in the community setting and therefore very hard to measure in a trial setting unless it is very large. We did not mark down for lack of coronavirus confirmation, as the rhinovirus was the main virus found (85%) and it spreads via droplet as well as airborne.

⁸ RR for adjusting for clustering (RR = 1.66 (95% CI 0.81, 3.40) and for adjusting for clustering and confounding (RR = 1.54 (95% CI 0.88, 2.70).