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Downsides of face masks and possible mitigation strategies: a systematic review and meta-analysis

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ABSTRACT

Objective To identify, appraise and synthesise studies evaluating the downsides of wearing face masks in any setting. We also discuss potential strategies to mitigate these downsides.

Design Systematic review and meta-analysis.

Data sources PubMed, Embase, CENTRAL and EuropePMC were searched (inception–18 May 2020), and clinical registries were searched via CENTRAL. We also did a forward–backward citation search of the included studies.

Inclusion criteria We included randomised controlled trials and observational studies comparing face mask use to any active intervention or to control.

Data extraction and analysis Two author pairs independently screened articles for inclusion, extracted data and assessed the quality of included studies. The primary outcomes were compliance, discomforts, harms and adverse events of wearing face masks.

Results We screened 5471 articles, including 37 (40 references); 11 were meta-analysed. For mask wear adherence, 47% (95% CI 25% to 68%, p<0.0001), more people wore face masks in the face mask group compared with control; adherence was significantly higher (26%, 95% CI 8% to 46%, p<0.01) in the surgical/medical mask group than in N95/P2 group. The largest number of studies reported on the discomfort and irritation outcome (20 studies); fewest reported on the misuse of masks, and none reported on mask contamination or risk compensation behaviour. Risk of bias was generally high for blinding of participants and personnel and low for attrition and reporting biases.

Conclusions There are insufficient data to quantify all of the adverse effects that might reduce the acceptability, adherence and effectiveness of face masks. New research on face masks should assess and report the harms and downsides. Urgent research is also needed on methods and designs to mitigate the downsides of face mask wearing, particularly the assessment of possible alternatives.

Systematic review registration Open Science Framework website https://osf.io/sa6kf/ (timestamp 20-05-2020).

Strengths and limitations of this study

- This is the first systematic review to investigate the downsides of wearing face masks.
- We included non-randomised study designs in addition to randomised controlled trials, as trials frequently under-reported or failed to report harms.
- We reported two deviations from the study protocol, relating to the measurement of effect and the subgroup analysis.

INTRODUCTION

Respiratory viruses are predominantly transmitted by aerosol, droplets and fomites.[1] Face masks—such as surgical masks, N95 masks and face shields, and substitutes for surgical masks such as home-made cloth masks—are a physical barrier to aerosol and droplet transmission. During the COVID-19 pandemic, some jurisdictions have implemented policies mandating the use of masks in public places, on public transport or in other crowded environments to prevent people becoming infected or infecting others.

While most health organisations mandate the use of face masks by health workers when caring for patients during a pandemic, recommendations for mask wear in the community vary widely and include: use by all, use only in certain situations (eg, on public transport or in crowded places where social distancing is not possible), and no specific recommendations about mask use.

Several trials have evaluated the impact on respiratory infections by use of surgical and N95 masks, which may, at best, modestly reduce acute respiratory infection transmission.[2–4] Population observational studies suggest that masks have a more substantial effect.[5] However, the downsides of mask-wearing were either not considered or not reported in most studies. Most trials have focused on face masks protecting the wearer, rather than others in the community, are often low powered, and include confounding factors resulting in the current

evidence for the efficacy of face masks being less than adequate.[6]

The current controversies, mixed messaging and debate over the use of face masks to prevent the spread of COVID-19 warrants further investigation into their use. Anecdotal evidence, and some studies, suggest that there may be a variety of downsides arising from mask use, including: discomfort, sense of difficulty breathing and communication problems particularly for those who use lip reading.[6 7] Our aim is to systematically identify and summarise these downsides to assist policymakers when formulating mask-wearing policies in public settings. We also discuss potential strategies to mitigate downsides of mask-wearing.

Box 1 List of extracted information

- **General information:** study authors, location, study design, duration, aim and setting.
- **Participants:** health status, disease (if applicable), sample size, age, gender, smoker status and comorbidities.
- **Intervention and comparator(s):** number of participants, type of face covering, adjunct interventions, number of face coverings used, duration of use and disposal.
- **Outcomes:** definition, measurement instrument, number of adverse events or harms reported (the outcomes were discomforts, harms and adverse events of wearing face masks, adherence to face mask wearing, misuse of masks, discomfort and other physical irritation from masks, psychological outcomes (eg, fear), dyspnoea (difficulty breathing and shortness of breath) and other physiological impacts, communication impacts and mask contamination).

METHODS

This systematic review is reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.[8] We followed the '2 week systematic review' processes for the review.[9] The review protocol was developed prospectively and uploaded to the Open Science Framework data on 20 May 2020 (see: https://osf.io/sa6kf/). Deviations from the protocol are reported in the Methods section and highlighted as a limitation in the Discussion section.

Inclusion criteria

We included studies of people of any age or gender, in any setting. We included studies of any face covering aimed at reducing virus transmission, including surgical masks, N95 masks, cloth masks (both homemade and commercially available) (see online supplemental appendix 1 for a summary of included face masks and their intended purpose). Studies evaluating the use of masks for non-virus transmission purposes (eg, valved masks for preventing inhalation of airborne contaminants such as particles, gases or vapours) were excluded (see online supplemental appendix 2 for a complete list of excluded face masks).

We included studies comparing the use of face mask to any active intervention (eg, another mask or another intervention such as hand washing) and studies comparing the use of face mask to control (comprising standard practice, ie, face masks not explicitly provided to study group) in situations where their use was not mandatory.

We included only primary studies, that is, randomised controlled trials (RCTs) and observational studies of any design. We intentionally included this range of study types to identify appropriate data that corresponded with the listed outcomes. For example, surveys are appropriate for identifying frequency of discomfort, and breathing trials are appropriate for understanding physiological changes. We excluded studies that could not provide a quantitative estimate of the size or frequency of adverse effects such as case reports, case series, as well as qualitative studies, and reviews.

Search strategies

We searched PubMed, Embase, Cochrane CENTRAL, EuropePMC (inception–18 May 2020). The search string was designed for PubMed and translated for use in other databases using the Polyglot Search Translator (online supplemental appendix 3).[10] Clinical trial registries were searched via Cochrane CENTRAL, which includes the WHO International Clinical Trials Registry Platform (ICTRP) and clinicaltrials.gov. On 22 May 2020, we conducted a backwards and forwards citation analysis in Scopus, on all of the included studies.

No restrictions by language or publication date were imposed. We included publications that were published in full; abstract-only publications were included if they had an accompanying record (eg, trial registry record or another public report), with additional information.

Study selection and screening

Two author pairs (MB and NK, AMS and JC) independently screened the titles and abstracts against the inclusion criteria. One author (JC) retrieved full text, and two author pairs (MB and NK, AMS and JC) screened the full texts. Disagreements were resolved by discussion or a third author (PG or CDM).

Data extraction

A data extraction form was piloted on three studies. Two author pairs (MB and NK, AMS and JC) extracted the data (see box 1).

Assessment of risk of bias in included studies

Two author pairs (MB and NK, AMS and JC) independently assessed the risk of bias using the Cochrane Risk of Bias Tool.[11] Disagreements were resolved by discussion or a third author (CDM or PG). Each potential source of bias was graded as low, high or unclear, and judgements were supported by a quote from the study.

Measurement of effect and data synthesis

Where feasible (≥2 studies reporting the same outcome), we expressed outcome measures as odds ratios (ORs) with 95% CIs, analysed using Review Manager (RevMan

V.5). Anticipating considerable heterogeneity among the included studies, we used a random effects model. We reported the adherence to face mask wear using risk difference (RD) rather than OR to more clearly convey the differences in adherence between the intervention and control group (not prespecified in the protocol).

When meta-analysis was not possible or appropriate, we followed the guidance of the Cochrane Collaboration (Cochrane Handbook Section 12.2).[11] When narrative synthesis was required, we reported the results separately for each harm or adverse outcome.

The individual was used as the unit of analysis, where possible; otherwise, we extracted the information as it was presented, for example, the number of harms in each group. We attempted to contact investigators or study sponsors to provide missing data.

We used the I^2 statistic to measure heterogeneity. Because we included fewer than 10 trials, we did not create a funnel plot.

We did not prespecify subgroup or sensitivity analyses. However, as data were available, we conducted a subgroup analysis of adherence to mask-wearing by studies that evaluated face mask wear alone and those evaluating face mask together with hand washing.

Patient and public involvement

Patients and the public were not involved in the design and conduct of this review.

RESULTS

Database searches identified 4691 publications, supplemented with 2035 references from forward and backward citation searches and other sources, totalling 6726. After deduplication, 5471 references were screened by title and abstract; we full-text screened 214 references, excluding 174 (see online supplemental appendix 4 for a list of excluded studies with reasons). We included 40 articles[12–51] corresponding to 37 studies (table 1 reports the characteristics of included studies) and meta-analysed 11 studies.[15 21 22 26 31–34 41 45 47] (figure 1).

Risk of bias

Inclusion of both observational studies and RCTs could explain the high risk of bias across the included studies. Reporting of sequence generation, allocation concealment and blinding of outcome assessment was poor in 20%–30% of studies. Due to the nature of interventions, blinding of participants was rare. For RCTs, we reported blinding of outcome assessment for the main trial (not the adverse events), as some outcomes were lab confirmed and were considered of low risk. We found no evidence of incomplete outcome data or selective reporting of outcomes. Funding statement, funder's role and authors' conflict of interests were adequately reported in most studies (see figure 2, and figure 3 in online supplemental appendix 5).

Adherence to face mask wearing

Seventeen studies (14 RCTs, 3 observational)[10 13 17] reported on adherence to face mask wearing; of these 11 studies had sufficient data to pool and were meta-analysed.

Face mask versus control comparison

Comparison of face masks with control was subgrouped into studies comparing face mask alone versus control and studies of face mask plus hand washing versus control (figure 3).

Face masks alone versus control (five studies) showed the face mask group had a significantly higher face mask wear compared with control (RD: 0.46, 95% CI 0.24 to 0.67, p<0.0001). Studies evaluating face mask plus hand washing versus control (n=3) similarly showed significantly higher face mask wear in the face mask group (RD: 0.47 (95% CI 0.07 to 0.88, p<0.0001).

Overall, seven studies (3303 participants) compared face masks with control. Face mask wear was 47% higher in the face mask group, although heterogeneity was very high (RD: 0.47, 95% CI 0.25 to 0.68, p<0.0001, I^2=98%.)

We explored the possible sources of heterogeneity. Excluding studies with three or more domains at high risk of bias did not decrease heterogeneity (I^2=96% for face mask vs control; 99% for face mask plus hand washing vs control) (figure 4, online supplemental appendix 5). We excluded study population as the source of heterogeneity, because subgrouping studies by those in a community/household settings (which included both index cases and their contacts) versus those in a hospital setting (which included healthy healthcare workers) likewise did not decrease heterogeneity (I^2=99% for community/household studies, and 97% for hospital studies) (figure 5, online supplemental appendix 5). We excluded intervention and control as sources of heterogeneity, since all studies compared medical/surgical masks to control (no mask), although some mask-wear did occur in the control groups.

We consider the outcome measurement to be the most likely other source of heterogeneity. All studies relied on self-reporting of the outcome; only one verified this by counting the number of masks used.[21] What was considered 'wearing a face mask' varied: it was unclear,[15 21 45] involved wearing a face mask 'always or mostly/often',[22 47] included wearing a face mask while on hospital property, performing a healthcare worker role[26] and included face mask wear during a shift for 70% of time or more.[32] The follow-up was very short (5–9 days) for four studies[15 21 22 47]; it was longer for three studies (21–77 days).[26 32 45]

Face mask (surgical/medical) versus face mask (N92/P2 mask)

Four studies (7960 participants) compared adherence for different face masks.[31 33 34 41] Face mask wear was significantly higher in the surgical/medical face mask group than in the N95/P2 group, OR=1.26 (95% CI 1.08 to 1.46, p<0.01). Heterogeneity was very low (I^2=27%) (figure 4).

Table 1 Characteristics of included studies

First author (country, year)	Study design	Setting	Study duration	Type of participants: Healthy A	Healthy Ch	Sick* A	Sick* Ch	Number of participants	Type of face mask intervention†: Surgical	N95	Any	Other	Type of reported outcomes (adverse effects) analysed: Discomfort and irritation	Dyspnoea and other physiological	Misuse	Adherence	Psychological impacts	Communication impacts	Mask contamination
Aiello[12] (USA, 2012)	C-RCT	RH	3M	✓				1188; 37 RH	✓				✓			✓			
Allison[13] (USA, 2010)	Single-arm study	Sch	1M	✓	✓			20 A, 503 Ch	✓							✓			
Baig[14] (USA, 2010)	S	H	1M	✓				149‡		✓			✓					✓	
Barasheed[15] (Australia, 2014)	C-RCT	Tents	1W	✓	✓	✓		164; 22 tents	✓							✓			
Bryce[16] (Canada, 2008)	S	H	1WS	✓				137		✓			✓			✓			
Canini[17] (France, 2010)	C-RCT	HH	1Inf-S	✓	✓		✓	306; 105 HH	✓				✓			✓	✓		
Chen[18] (China, 2016)	Multiple cross-over lab-based trials	Lab	NR	✓				15		✓				✓					
Chugtai[20] (China, 2019)‡	Prevalence	H	2M	✓				148	✓				✓			✓		✓	✓
Cowling[22] (Hong Kong, 2008)	C-RCT	HH	7M	✓	✓	✓	✓	370; 128 HH§	✓							✓			
Cowling[21] (Hong Kong, 2009)	C-RCT	HH	8M	✓	✓	✓	✓	1015; 322 HH§	✓							✓			
Foo[24] (Singapore 2006)	S	H	2S	✓				340			✓		✓						
Forgie[25] (Canada, 2009)¶	S	ED	2M	✓	✓			80**	✓			✓					✓		
Jacobs[26] (Japan, 2009)	RCT	H	2M	✓				33	✓							✓			
Kao[27] (Taiwan, 2004) ††	Before–after	H	2M	✓				39		✓			✓						
Larson[13] (USA, 2010) with additional data from Ferng *et al* 2011[23]	C-RCT	HH	19M	✓	✓			2708; 617 HH§	✓				✓			✓	✓	✓	
Lee[29] (Singapore, 2011)‡‡	Single arm study	Lab	NR	✓				14		✓				✓					
Lim[30] (Singapore, 2006)	S	H	1Y	✓				212		✓			✓						
MacIntyre[31] (Australia 2009)	C-RCT	HH	2WS	✓			✓	290 A; 145 HH	✓			✓	✓			✓	✓		
MacIntyre[33] (China, 2011)	C-RCT	H	3M	✓				1441; 15 H	✓	✓			✓			✓		✓	
MacIntyre[34] (China, 2013)	C-RCT	H	3M	✓				1669; 19 H	✓	✓			✓			✓			

Continued

Table 1 Continued

First author (country, year)	Study design	Setting	Study duration	Type of participants: Healthy A	Healthy Ch	Sick* A	Sick* Ch	Number of participants	Type of face mask intervention†: Surgical	N95	Any	Other	Type of reported outcomes (adverse effects) analysed: Discomfort and irritation	Dyspnoea and other physiological	Misuse	Adherence	Psychological impacts	Communication impacts	Mask contamination
MacIntyre[32] (Vietnam, 2015) with additional data from Chughtai *et al* 2016[19]	C-RCT	H	5W	✓				1607; 14 H	✓			✓	✓			✓			
Martel[35] (Canada, 2013)§§	Direct observation study	ED	1M	✓				115			✓		✓		✓			✓	
Nickell[36] (Canada, 2004)	S	H	1M	✓				2001	✓	✓			✓				✓	✓	
Ong[37] (Singapore, 2020)	S	H	2M	✓				158	✓				✓						
Or[38] (Hong Kong, 2018)	Lab-based study	Lab	NR	✓				84		✓			✓					✓	
Person[39] (France, 2018)	Randomised cross-over trial	NC¶	NR	✓				44	✓					✓					
Radonovich[40] (USA, 2009)	Multiple cross-over trial	H	NC	✓				27	✓	✓		✓	✓					✓	
Radonovich[41] (USA, 2019)	C-RCT	H	3.7Y	✓				2862	✓	✓						✓			
Rebmann[42] (USA, 2013)	Multiple cross-over trial	H	2D	✓				10		✓					✓				
Roberge[12] (USA, 2012)	Cross-over	Lab	3M	✓				20	✓					✓					
Shenal[12] (USA, 2012)	Multiple cross-over field trial	H	NR	✓				27	✓			✓	✓						
Simmerman[45] (Thailand, 2011)	RCT	HH	16M	✓			✓	465	✓							✓			
Suess[47] (Germany, 2012) with additional data from Suess *et al* 2011[46]	C-RCT	HH	2Inf-S	✓			✓	111 HH	✓				✓			✓			
Thomas[48] (USA, 2011)	NC¶¶	HB-E	NR	✓					✓	✓								✓	
Vanjak[49] (France, 2006)	S	H	2M	✓				238 patients and 210 staff			✓				✓				
Wong[50] (Hong Kong, 2013)	RCT	PCC	2M	✓				1031 patients and nine doctors			✓						✓		
Yeung[37] (Singapore, 2020)	S	HH	1W	✓				2231 HH		✓					✓				

Continued

Table 1 Continued

First author (country, year)	Study design	Setting	Study duration	Type of participants				Number of participants	Type of face mask intervention†			Type of reported outcomes (adverse effects) analysed						
				Healthy		Sick*			Surgical	N95	Any	Other	Discomfort and irritation	Dyspnoea and other physiological	Misuse	Adherence	Psychological impacts	Communication impacts	Mask contamination
				A	Ch	A	Ch												

*Sick adults or children, with influenza, influenza-like illness or upper respiratory tract infections.
†Only face masks arms of the included studies.
‡Authors state 159 surveys returned but 10 were excluded from analysis as ineligible.
§Number of households that were allocated.
¶Participants in the waiting room of ED could be sick due to an infection.
**Pairs of adults and children.
††Patients with end-stage renal disease without any influenza or ILI.
‡‡Data reported here are for the N95 group.
§§Two nested studies: study 1: direct observation study (data in this row)+ Study 2: survey.
¶¶In the first part of the study, the pilot recited each word with the aircraft engine off when wearing and not wearing either the surgical face mask or one of the N95 respirators. In the second part of the study, the same procedure occurred, except that the 407-helicopter engine was running at idle.
***Reports three studies: pilot study 1: lab testing; pilot study 2: small clinical testing; study 3: main study, which is extracted here.
A, healthy adults; Ch, children; C-RCT, cluster randomised controlled trial; D, days; ED, emergency departments; H, hospitals; HB-E, helicopter bell (used for helicopter emergency medical services); HH, households; Inf-S, influenza season; Lab, laboratory; M, months; N/A, not applicable; NC, not clear; NR, not reported; PCC, primary care clinics; RCT, randomised controlled trial; RH, residence halls; S, survey; Sch, schools; Tel, telephone survey of home residents; W, weeks; WS, winter season; Y, year.

Studies not included in the meta-analysis

Randomised controlled trials (n=3)

One study in a residential hall setting reported similar duration of face mask wear per day in the face mask alone group versus face mask plus hand washing group (mean of 5.08 and 5.04 hours/day, respectively).[12] Another in a household setting reported that within the face mask group, there were no significant differences between individuals with ILI among contacts versus no ILI among contacts, for face mask use.[17] Finally, 22 of 44 households randomised to the 'education with sanitiser and face masks' arm reported having used a mask within 48 hours of episode onset.[28]

Observational studies (n=3)

In an elementary school setting, approximately twice as many teachers as students wore face masks.[13] A mean compliance score with N95 use guidelines was 21.2 (on a 25-point scale) among frequent users of N95 respirators in a hospital setting.[16] Another study among healthcare workers found that majority of survey respondents (91%) wore one to two masks per day (range 1–4).[20]

Misuse

Mask misuse appears less studied than other harms and discomforts. A study of 10 nurses observed for 10 min/hour over two shifts found that they touched their face two to three times per hour, their mask five times per hour and their eyes once per 2 hours, when observed by students.[42] In a study of health workers, 13 of the 53 who responded (25%) reported wearing masks only covering their mouth, not their nose.[49] One study conducted in two hospitals,[35] observed triage nurse behaviour with 118 patients with fever and cough, found that in only 18% of cases the nurses informed patients of the need to wear a mask, and in half of those, gave instruction on the need to cover both mouth and nose. A cross-sectional study evaluating the proficiency of the Singaporean public in wearing N95 masks found only 90/714 subjects passed the visual mask fit test; the most common criteria performed incorrectly were: strap placement, leaving a visible gap between the mask and skin and tightening the nose-clip.[51]

Discomfort and irritation

Several RCTs of specifically measured mask wear discomfort,[17 31–33 47] but most only recorded spontaneously reported events[12 28 34] or did not report any.[15 21 22 26 41 45 50] A trial of household index influenza cases allocated to wear masks or no mask found the 51 allocated to masks wore them on average 3.8 hours/day and 38 (76%) reported discomfort (table 2).[17] A study of healthcare workers in Beijing asked to wear masks for their full shift found 84% complained of at least one problem (table 2).[20] In a German household study, 65/172 participants reported problems with mask wearing, most commonly warmth, pain and shortness of breath.[47]

In a trial of healthcare workers comparing surgical and N95 masks to prevent influenza, more workers found

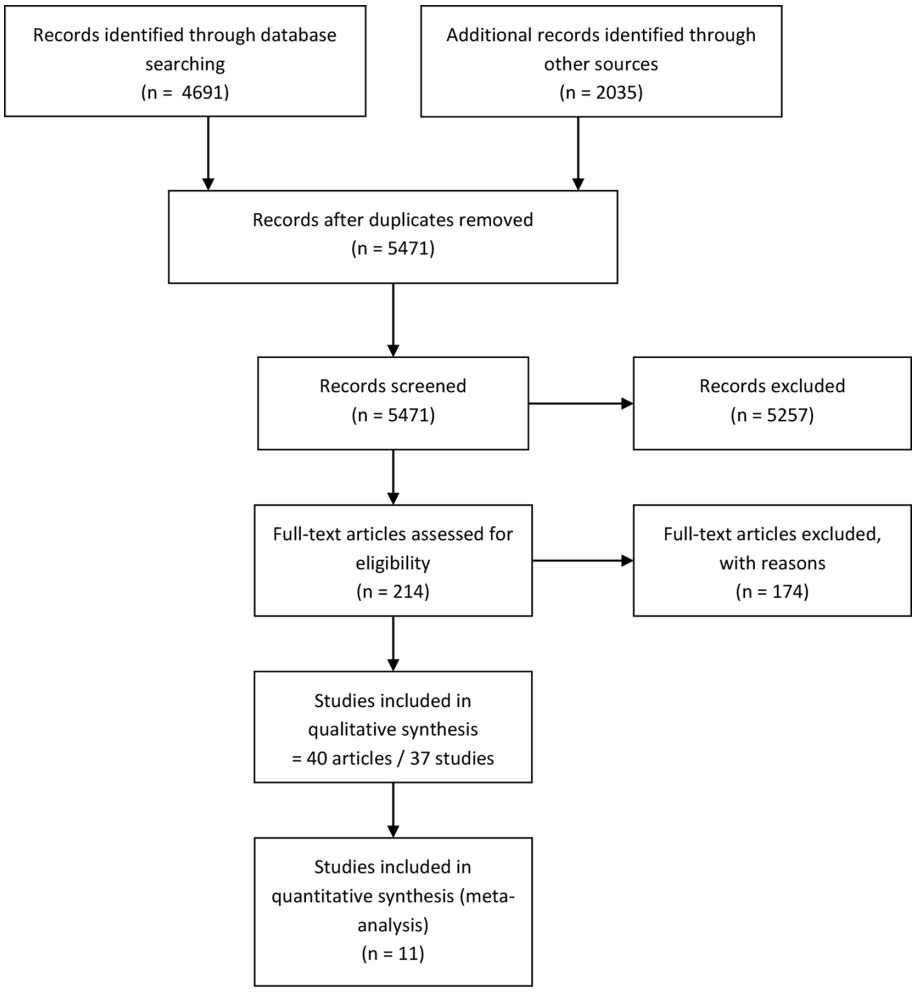

Figure 1 PRISMA flow diagram.

the N95 uncomfortable (42%) than the medical mask (10%) when worn an average of 5 hours per day,[33] with significant differences in headaches, difficulty breathing and pressure on the nose (table 2). A trial of cloth versus medical masks in healthcare workers found similar rates of discomfort.[32] A community trial comparing surgical and P2 (N95) masks found >50% reporting concerns, primarily discomfort, with similar rates (15% vs 17%) across groups.[31]

Discomfort increases with duration of mask wearing. A cross-over field trial of 27 healthcare workers found increased discomfort over time; half the subjects were unwilling to wear a medical mask for the full 8-hour shift despite regularly wearing them for short periods.[44]

Two surveys of healthcare staff in Singapore during the SARS epidemic assessed headache and skin reactions.[24 30] In one survey, 79/212 (37%) reported face mask associated headaches, 26 (33%) reported headache frequency

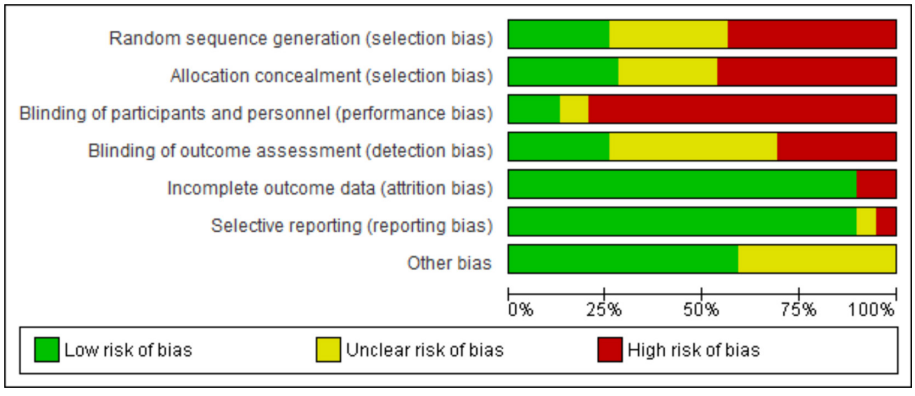

Figure 2 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

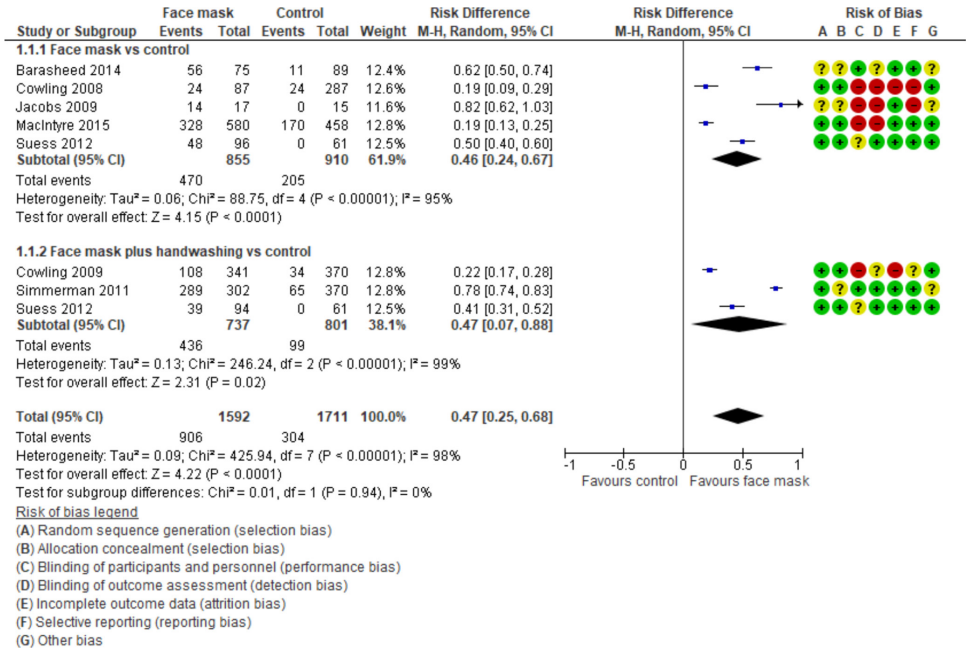

Figure 3 Comparison of adherence to face masks versus control.

exceeding six times/month and 6 had taken sick leave.[30] Another survey of healthcare workers in Singapore found that of the 307 staff who used masks regularly, 60% reported acne, 51% facial itch and 36% rash from N95 mask use.[24] A COVID-19 survey of healthcare workers in Singapore found that 128/158 (81%) developed de novo personal protective equipment (PPE)-associated headaches, increasing with duration of use (>4 hours).[37]

One study (2×2 factorial design) examined the potential of mask fit test and training to mitigate discomfort but found no clinically or statistically important differences between arms.[38]

Six observational studies reported either general discomfort[33] or spontaneously reported events among participants who wore face masks.[14 16 27 35 40]

Psychological

Six studies reported on psychological impacts from wearing face masks (four RCTs and two observational).

Fear

A three-arm RCT in a household setting found significantly higher risk perception scores in the mask group (38/60) than non-mask groups (30/60) (p<0.001); participants in the mask group were more fearful that they and their family would get sick from influenza.[23 28]

In an observational study, children in a paediatric emergency department waiting room (n=80) were shown pictures of clinicians wearing either a surgical mask or a clear face shield; 18 children (22.5%) reported surgical masks to be more frightening due to an inability to see clinicians' faces, and 14 children (17.5%) reported face shields to be more frightening. However, 47 children (59%) reported that neither were frightening.[25]

Stigma

In a two-arm cluster-RCT, 15 (29%) patients wearing masks reported they did not like being seen wearing a mask.[17] In a three-arm RCT, more children reported disliking their parents wearing a P2 mask than a surgical mask (8/92 vs 6/94); however, the difference was not significant.[31]

Loneliness

One observational study reported on the loneliness outcome. In a survey investigating the psychosocial effects associated with working in a hospital during the

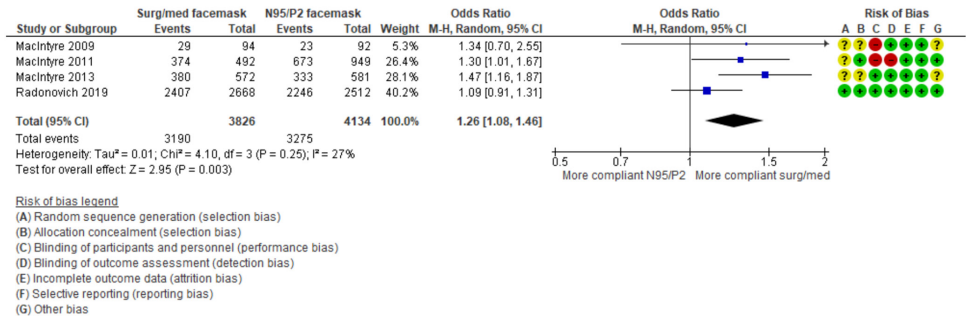

Figure 4 Comparison of adherence to surgical/medical face masks vs N95/P2 masks.

Table 2 Types of discomfort assessed in trials of face masks used to prevent viral transmission

First author, year (type of mask)	Population, number	Difficulty breathing	Facial irritation or discomfort	Headache	Other
Canini, 2010[17] (surgical masks)	Household, 105 index cases	34%	14%	–	46% warmth
Chughtai, 2019[20] (surgical masks)	Healthcare workers, 148	12%	17%	6%	–
MacIntyre, 2011[33] (surgical)	Healthcare workers, 492	12%	11%	4%	–
MacIntyre, 2011[33] (N95)	Healthcare workers, 949	19%	52%	13%	–
MacIntyre, 2015[32] (cloth vs medical)	Healthcare workers, 1130	18%	35%	–	–

SARS outbreak, 222 (13%) respondents reported a sense of isolation as one reason masks were perceived as bothersome.[36]

Empathy

One RCT reported that the wearing of a face mask by doctors had a negative effect on patient perceptions of the doctors' empathy during consultations, with a mean Consultation and Relational Empathy score in the mask group of 33.93 (SD=7.65, n=514) and 34.91 (SD=7.84, n=516) in the no mask group (p=0.04).[50]

Dyspnoea and other physiological consequences

Studies of physiological impacts were generally done on masks designed for dust, vapours and other non-transmission purposes; few studied surgical or N95 masks.

A French cross-over study (44 subjects) found surgical masks had no impact on 6 min walking time, but subjects had an increased sense of dyspnoea with a mask: 5.6 versus 4.6 cm on a 10 cm visual analogue scale (p<0.001),[39] which may come from the increased effort required. A study in 14 adults found that N95 masks increased respiratory resistance in 30 seconds of breathing by over 100%, resulting in average reduction in nasal spirometry of 37%.[29] A study of 20 subjects on a treadmill found the surgical masks increased respiratory rate by 1.6 breaths/min (p=0.02), heart rate by 9.5 beats/min (p<0.001) and transcutaneous CO_2 levels of 2.2 mm Hg (p<0.001).[43] Finally, a Chinese study of 15 subjects wearing a monitoring garment for respiratory signals found that N95 masks increased both subjective breathing resistance (from none to mild) and increased respiratory rate; the muscle activity of sternomastoid, scalene, diaphragm and abdominal; and the fatigue of scalene and intercostal.[18]

Communication

Nine studies (two RCT, seven observational) reported on communication difficulties while wearing face masks.

A trial comparing the use of surgical and N95 masks by healthcare workers to prevent influenza found more workers in the N95 mask group than the surgical mask group reported mask causing trouble with patient communication (8% vs 3%).[33] Another household-based trial of 15 participants who wore a surgical mask for approximately 60 min while performing various tasks[23 28] found that participants did not report any interference with communication while answering the phone.

In a cross-over trial of 27 healthcare workers,[40] more participants in the surgical mask group reported diminished communication acuity (visual, auditory or vocal) as the reason for discontinuing mask use before the end of an 8-hour shift (seven complaints compared with four complaints among N95 mask wearers).

Of 2001 healthcare workers in Toronto responding to a survey during the SARS outbreak, difficulty communicating (47%) and difficulty recognising people (24%) were identified as key reasons masks (surgical or N95) were perceived as being particularly bothersome.[36] In a survey of 149 healthcare workers,[14] 41 (27.5%) of respondents reported a difficulty 'always'/'most of time' in verbally communicating with patients while wearing a mask.

In another Canadian survey (115 healthcare workers),[35] 26 (23%) respondents reported that wearing masks interfered with their relationships with their patients. Among 148 healthcare workers asked to wear a mask during a 6–8 hour shift, 11 (7.4%) reported trouble communicating with patients.[20]

In a study of three participants evaluating the impact of wearing a surgical or N95 mask on radio reception, all participants were able to accurately record all pilot-recited words regardless of the type of mask worn by the pilot. However, when the aircraft engine was turned on, the accuracy decreased for the N95 mask, compared with surgical or no mask.[48]

In another lab-based study, the performance or absence of fit testing prior to mask use did not affect communication, as two participants (out of 21) in each group reported ease of talking to be unsatisfactory.[38]

Mask contamination and other issues

One concern about mask use is the potential for contamination of the mask surface and subsequent self-inoculation to the wearer's eyes or when demasking. No studies examined that directly, but one study of the healthcare workers

found on average 10% of masks had viral contamination after usage and that was higher for masks worn >6 hours (OR 7.9, 95% CI 1.01 to 61.99) or >25 patients seen (OR 5.02, 95% CI 1.35 to 18.60).[20] Given the rates of misuse (see Misuse section above), this contamination raises concerns about self-inoculation.

Several authors have raised concerns about 'risk compensation'—non-adherence to other precautions because of the sense of protection—but we found no studies that quantify its extent.

DISCUSSION

We identified 37 studies reporting downsides, harms and adverse events associated with the wearing of face masks: 15 RCTs and 22 observational studies. The largest number of studies reported on the discomfort and irritation outcome (20 studies), fewest on misuse of mask (four studies), with no studies directly investigating or quantifying mask contamination or risk compensation behaviour. The only meta-analysable outcome was adherence to face mask wear (17 studies, 11 meta-analysed). Forty-seven per cent more people wore face masks in the face mask group compared with control, although the percentage of people wearing face masks in the control group was non-zero in five studies; face mask wear adherence was also significantly higher (26%) in the surgical/medical mask group than the N95/P2 group. Risk of bias was generally high for blinding of participants and personnel, and selection bias, and low for attrition and reporting biases.

This is the first systematic review to investigate the downsides of wearing face masks and forms an important step as a bridge between research and action. The review aligns with the aims of the behavioural, environmental, social and systems interventions collaboration (BESSI) and addresses important evidence gaps in the appropriate use of face masks. The review's strength lies in its inclusion of non-randomised study designs in addition to RCTs, as trials frequently under-report or fail to report harms.[52] Additionally, the inclusion and exclusion criteria were tested and refined on a test library of 98 references, prior to screening the full search results. The key limitation includes the hospital setting of most of the included studies: as hospital workers are accustomed to wearing masks, the conclusions may not be fully generalisable to the community. Although this varies among the studies that reported mask use in hospital setting, as there are different confounding factors that may contribute to increased reporting of irritation (eg, length of shift, air-conditioning on the wards and whether the staff were wearing the full PPE, which adds to the full discomfort). We report two differences between the protocol and the review: first, the comparison of face mask to control in the adherence outcome was reported using RD (rather than preplanned OR) to more clearly convey the differences between the two groups (OR for compliance with face mask wear was reported for the face mask vs face mask comparison, however). Second, not having anticipated data availability, we did not prespecify a subgroup analysis of the intervention (face mask wearing) by studies that evaluated face mask wear alone and studies evaluating face mask with hand washing. Potential behavioural or cultural bias may have been introduced into the findings due to some cultural groups already being more accustomed to wearing face masks when coughing or sick. However, among our included studies, only four were conducted in the community in Asian countries, and of these studies, three reported adherence to face mask use as an issue and one study reported that 264 out of the 624 of the participants who have failed N95 fit test have used masks previously. Furthermore, the use of face masks/coverings in the various study settings compared with their use in a real-life pandemic may differ from a behavioural perspective, and this may affect findings related to adherence. However, other reported harms, such as physiological changes, may be less affected by the differences in circumstance.

Several recent systematic reviews have focused on the effectiveness of masks in preventing or reducing viral transmission; some of these reviews reported on harms in the included studies.[8 18 42 53] However, none specifically focused on the wider set of studies examining the physiological, psychological and other adverse effects addressed in this review. The Cochrane review on physical barriers noted the impact of masks on discomfort and communication in some of the randomised trials, and its findings are consistent with this review but did not extend to studies with outcomes other than viral transmission or non-randomised study design.[3]

The downsides identified in this review should aid in designing strategies to mitigate problems and guide the situations where the benefits of masks might outweigh the downsides. Patient preferences for surgical masks (as indicated by the higher adherence than to the N95 masks), would suggests that the mitigation of discomforts may also increase adherence to face mask wear, and hence their effectiveness, whether for preventing transmission of the virus by the wearer (eg, surgical masks) or for preventing inhalation of viral particles in the environment (eg, N95 masks). Mitigation might be achieved by considering of the when, where and how of mask wearing (including the fitting process required for some masks like FFP and N95) as the choice of alternative would be dependent on the specific context; that is, it may not be appropriate to use surgical masks or other face masks interchangeably with respirator masks in situations where the goal is to prevent inhalation of aerosolised viral particles as they are not designed for that purpose unlike respirator masks or by mask redesign or substitution with alternatives (eg, face shields).

Potential mitigation strategies

Limiting circumstances: use of face masks should be restricted to higher risk circumstances, including

crowded, indoor spaces, where physical distancing is not possible, for example, public transport. This recommendation corresponds with suggestions by Chu *et al*, who reported that optimum face mask use in public settings could result in a large reduction in infection.[5] Conversely, exercising outdoors is both low risk and has higher downside of wearing masks, because of the increased perceived dyspnoea.

Limiting duration of face mask wear: duration increases both discomfort and non-adherence. Duration might be decreased by demasking during breaks or scheduling mask breaks. Changing masks more often will help with adherence and the contamination risks but will increase costs and environmental problems with waste disposal, as well as lead to potential contamination/transmission risks if not performed appropriately.

Modification for specific groups: some groups are likely to have greater difficulty with mask wearing adherence and correct usage, including children, some patients with mental illnesses, those with cognitive impairment or respiratory disorders such as asthma or chronic airways disease and patients with recent facial trauma or oromaxillofacial surgery.[54–56]

Substitution: face shields may provide an alternative to face masks, which may mitigate several of the downsides (eg, reducing the communication difficulties and breathing resistance), while also providing eye protection. However, there is little evidence on the discomforts of wearing face shields and on the degree of protection provided, as airborne particles could escape through the upward and downwards jet.[57 58] Other innovative mask designs currently being developed require discomfort and adherence evaluations in addition to the droplet penetration.

Currently, existing research does not allow firm conclusions as there are insufficient data to quantify all of the adverse effects that might reduce the acceptability, adherence and effectiveness of face masks. Any new research on face masks should assess and report the harms and downsides, including behavioural issues (ie, risk compensation behaviour) and the psychological impact of mandated face mask wear. There is an urgent need for priority funding for high-quality research on methods and designs to mitigate downsides of face mask wearing, particularly the assessment of possible alternatives.

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