

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Downsides of face masks and possible mitigation strategies: a systematic review and meta-analysis
AUTHORS	Bakhit, Mina; Krzyzaniak, Natalia; Scott, Anna Mae; Clark, Justin; Glasziou, Paul; Del Mar, Chris

VERSION 1 – REVIEW

REVIEWER	mike etkind None. PPI volunteer.
REVIEW RETURNED	03-Oct-2020

GENERAL COMMENTS	My comments on an earlier version have been adequately taken into account in this revise.
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REVIEWER	Dr. Rolf Neubert Public & patient reviewer, the Netherlands
REVIEW RETURNED	13-Oct-2020

GENERAL COMMENTS	<p>Dear editor, dear authors,</p> <p>Bakhit et al. have (re-)submitted a revised version of their BMJ-manuscript 'Downsides of face masks and possible mitigation strategies: a systematic review and meta-analysis' to BMJ Open. It's my honor to serve as a public & patient reviewer for both versions.</p> <p>I appreciate that the authors addressed my concerns in their revised version.</p> <p>However, instead of reformulating my concerns into a disclaimer, especially for my comment regarding potential regional bias in mask wear adherence due to cultural familiarization to mask wear, I would have liked the authors to have a look into the studies included in their review, check for regions of study participants, comment with a (rough) overview of culturally (i.e. regionally) determined relevant behavioural differences and give a (revised?) appraisal of the included studies.</p> <p>To my understanding, the same concept of adding a disclaimer derived from a reviewer's comment or question, has also been applied to scientific questions, which is not my business but in my eyes weakens the manuscript.</p> <p>While I'm still not convinced about the 'scientific beauty' of the manuscript, I do agree that a starting point needs to be defined and set for the studied research question, showing which – and</p>
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	<p>how little – work has been published so far. And hopefully assisting in generating funds for future research.</p> <p>I deeply do agree that research into the downsides of face mask wear and appropriate mitigation strategies is necessary, also taking into account all aspects from a user's viewpoint. Given the ongoing pandemic, this applies equally and urgently for all groups: the general public, patients and health care workers.</p> <p>I can conclude the above by recommending acceptance of the manuscript with minor revisions, in case the scientific reviewers would agree with the revised version.</p> <p>Looking forward to see new studies appear, initiated by this manuscript, that take the mask wearers' (dis)comfort and adherence into account and come up with viable mitigation strategies.</p> <p>13-10-2020, Rolf Neubert</p> <p>P.S.: A note to the editor: as you surely are aware of, as a public & patient reviewer, thus not being a peer scientist, I cannot judge on some of the Review Checklist categories and Statistics needs. So please keep in mind that 'Yes' is a judgement up to my own knowledge, while 'N/A' signifies a question I'm not able to answer, but still might well be applicable to the manuscript.</p>
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REVIEWER	John Thomas Norfolk and Norwich University Hospital, Norwich, UK
REVIEW RETURNED	15-Oct-2020

GENERAL COMMENTS	<p>Thank you for inviting me to re-review this systematic review by Bakhit et al following their revision.</p> <p>Firstly as mentioned in my initial review, I believe the methodology utilised by the authors have been appropriate and carried out well, given the limitations of the currently available data (in terms of quality and heterogeneity of included studies, which have been duly acknowledged in the discussion).</p> <p>Overall, I believe the revised discussion is much more nuanced than it was previously and the authors have addressed most of the concerns I raised initially.</p> <p>The only remaining concerns I have are the following:</p> <p>i) The comments the authors make regarding the use of face shields as alternatives to facemasks still may be overstated:</p> <p>In the conclusion of the abstract authors state: "Urgent research is also needed on methods and designs to mitigate the downsides of facemask wearing, particularly the assessment of alternatives such as face shields."</p> <p>Similarly in the concluding statement of the paper on Page 23 authors state: "There is an urgent need for high quality research on methods and designs to mitigate downsides of facemask wearing, particularly assessment of alternatives such as face shields."</p> <p>Although the authors have downplayed this suggestion in the revised manuscript, it still comes across to the reader that face</p>
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	<p>shields can be potentially used as an alternative to facemasks. Again, there is no evidence to indicate that out of all the alternatives to facemasks that face shields might provide a suitable, more comfortable alternative whilst effectively preventing transmission of viruses such as SARS-CoV-2 - this may mislead the author into thinking it is. As a result I would suggest avoid specifically stating "such as face shields" in the concluding sentences of the abstract and the main text, and rather simply state "assessment of alternatives."</p> <p>ii) The authors have attempted to clarify the statement on Page 22 Lines 35-42 in the revision: "As suggested by the higher adherence to surgical masks than to the N95 masks, mitigation of discomforts may also increase adherence to facemask wear, and hence their effectiveness – whether for preventing transmission of the virus by the wearer (e.g. surgical masks) or for preventing inhalation of viral particles in the environment (e.g. 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) or by redesign or substitution with alternatives (e.g. face shields)".</p> <p>Whilst this is an improvement, I would suggest the authors explicitly state in the discussion (perhaps as an expansion of "when, where, and how") that the choice of alternative would be dependent on the specific context i.e. 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 (unless there is definitive evidence from real-world studies to suggest that this does not have any significant effect on transmission rates)</p>
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REVIEWER	Thomas Czipionka Institute for Advanced Studies
REVIEW RETURNED	02-Nov-2020

GENERAL COMMENTS	<p>I have read through the responses to reviewers and will mainly highlight issues that arise from these responses or were not previously addressed.</p> <p>The paper itself addresses an important aspect in the current crisis. It is understandable that given the heterogenous nature of the studies that ARE available, the review cannot fully live up to a systematic review in all areas.</p> <p>On page five it says 'the use of masks for non-virus transmission purposes (e.g. valved masks)' This sentence is unclear. What are non-virus transmission purposes?</p> <p>In any case, this is crucial point. There is the problem that people use valved respirators, which protect themselves but may not protect others due to the valve that allows own virions to escape the mask unhindered. I read in the response to first round reviewer comments that these respirators were excluded, but appendix 1, to which authors refer, does not a priori state that.</p> <p>Also puzzling is the response to comment 27: FFP2 masks are valved and were therefore excluded from analysis. The terms N95 and FFP1 are often used interchangeably and refer to the same</p>
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	<p>type of mask. The studies that were included only referred to N95 masks.</p> <p>FFP2 is a standard used in the EU to assess filtering properties. This has nothing to do with valves. There are FFP2 respirators with and without valves. Also incorrect in this response is that N95 (US standard) and FFP1 (EU standard) are nearly equivalent. FFP1 has to filter 80%+ and N95 95%+ of a certain particle type. N95 are closer to the 94% filter capacity of FFP2.</p> <p>Discussion section: On page 20 it says Face shields may provide an alternative to facemasks, which may mitigate several of the downsides. This was already addressed by reviewer comments 3 and 31, but notwithstanding, authors stick with the essence of the statement. Face shields have been identified as not being a good source control and have already been banned in some countries.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

4. My comments on an earlier version have been adequately taken into account in this revise.

Author response:

We would like to thank you for your efforts.

Reviewer: 2

5. I appreciate that the authors addressed my concerns in their revised version. However, instead of reformulating my concerns into a disclaimer, especially for my comment regarding potential regional bias in mask wear adherence due to cultural familiarization to mask wear, I would have liked the authors to have a look into the studies included in their review, check for regions of study participants, comment with a (rough) overview of culturally (i.e. regionally) determined relevant behavioural differences and give a (revised?) appraisal of the included studies. To my understanding, the same concept of adding a disclaimer derived from a reviewer's comment or question, has also been applied to scientific questions, which is not my business but, in my eyes, weakens the manuscript.

Author response:

Thanks for your comment. We went through the included studies. Even though 4 of them were conducted in a region where they are known to wear face masks more culturally (Asian countries), 3 of these studies reported adherence issues and 1 reported that among of those who failed face mask fitting test (n= 624) 264 have reported previous face mask use. We have added an additional statement in our discussion section.

Change:

Page 17, L4-7

6. While I'm still not convinced about the 'scientific beauty' of the manuscript, I do agree that a starting point needs to be defined and set for the studied research question, showing which –

and how little –work has been published so far. And hopefully assisting in generating funds for future research.

Author response:

This systematic review is reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. We believe that our work is an important step to highlight the research gaps and guide future trials.

Change:

We have added the need for priority funding to the further research statement. Page 18, L33-35

7. I deeply do agree that research into the downsides of face mask wear and appropriate mitigation strategies is necessary, also taking into account all aspects from a user's viewpoint. Given the ongoing pandemic, this applies equally and urgently for all groups: the general public, patients and health care workers.

Author response:

We agree as well that further research is urgently needed.

Change:

See #6

8. I can conclude the above by recommending acceptance of the manuscript with minor revisions, in case the scientific reviewers would agree with the revised version. Looking forward to see new studies appear, initiated by this manuscript, that take the mask wearers' (dis)comfort and adherence into account and come up with viable mitigation strategies.

Author response:

Thanks for your comment and efforts.

Change:

No change

Reviewer: 3

9. Firstly as mentioned in my initial review, I believe the methodology utilised by the authors have been appropriate and carried out well, given the limitations of the currently available data (in terms of quality and heterogeneity of included studies, which have been duly acknowledged in the discussion). Overall, I believe the revised discussion is much more nuanced than it was previously and the authors have addressed most of the concerns I raised initially.

Author response:

Thanks for your positive feedback

Change:

No change

10. The comments the authors make regarding the use of face shields as alternatives to facemasks still may be overstated: In the conclusion of the abstract authors state: "Urgent research is also needed on methods and designs to mitigate the downsides of facemask wearing, particularly the assessment of alternatives such as face shields."

Similarly in the concluding statement of the paper on Page 23 authors state: "There is an urgent need for high quality research on methods and designs to mitigate downsides of facemask wearing, particularly assessment of alternatives such as face shields."

Although the authors have downplayed this suggestion in the revised manuscript, it still comes across to the reader that face shields can be potentially used as an alternative to facemasks. Again, there is no evidence to indicate that out of all the alternatives to facemasks that face shields might provide a suitable, more comfortable alternative whilst effectively preventing transmission of viruses such as SARSCoV-2 - this may mislead the author into thinking it is. As a result I would suggest avoid specifically stating "such as face shields" in the concluding sentences of the abstract and the main text, and rather simply state "assessment of alternatives."

Author response:

Thanks for your comment. We have avoided stating "such as face shields" in both of our Abstract and our final study conclusion.

Change:

Abstract Page 2, and the concluding statement in Page 18

11. The authors have attempted to clarify the statement on Page 22 Lines 35-42 in the revision: "As suggested by the higher adherence to surgical masks than to the N95 masks, mitigation of discomforts may also increase adherence to facemask wear, and hence their effectiveness – whether for preventing transmission of the virus by the wearer (e.g. surgical masks) or for preventing inhalation of viral particles in the environment (e.g. 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) or by redesign or substitution with alternatives (e.g. face shields)".

Whilst this is an improvement, I would suggest the authors explicitly state in the discussion (perhaps as an expansion of "when, where, and how") that the choice of alternative would be dependent on the specific context i.e. 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 (unless there is definitive evidence from real-world studies to suggest that this does not have any significant effect on transmission rates)

Author response:

Thanks for your comment and your suggestion. We have added the recommended statement in our discussion

Change:

We have added the following statement "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 i.e. 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 (e.g. face shields)." Page 17, L27-30

Reviewer: 4

12. I have read through the responses to reviewers and will mainly highlight issues that arise from these responses or were not previously addressed. The paper itself addresses an important aspect in the current crisis. It is understandable that given the heterogenous nature of the studies that ARE available, the review cannot fully live up to a systematic review in all areas.

Author response:

Thanks for your comment. This systematic review is reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.

Change:

No change

13. On page five it says 'the use of masks for non-virus transmission purposes (e.g. valved masks)' This sentence is unclear. What are non-virus transmission purposes?

Author response:

We have added additional clarification. Non-virus transmission purposes of masks include inhalation of airborne contaminants such as particles, gases or vapour

Change:

We have clarified the non-masks purposes on Page 5, L9-10

14. In any case, this is crucial point. There is the problem that people use valved respirators, which protect themselves but may not protect others due to the valve that allows own virions to escape the mask unhindered. I read in the response to first round reviewer comments that these respirators were excluded, but appendix 1, to which authors refer, does not a priori state that.

Author response:

Thanks for pointing out this typo. We were referring to Appendix 2 that include a complete list of excluded studies of facemasks.

Change:

Page 5, L10

15. Also puzzling is the response to comment 27: FFP2 masks are valved and were therefore excluded from analysis. The terms N95 and FFP1 are often used interchangeably and refer to the same type of mask. The studies that were included only referred to N95 masks. FFP2 is a standard used in the EU to assess filtering properties. This has nothing to do with valves. There are FFP2 respirators with and without valves. Also incorrect in this response is that N95 (US standard) and FFP1 (EU standard) are nearly equivalent. FFP1 has to filter 80%+ and N95 95%+ of a certain particle type. N95 are closer to the 94% filter capacity of FFP2.

Author response:

Thanks for your comment and we apologise for the misunderstanding. In our sample of included studies, they were only referred to as N95. We did not exclude studies of FFP1/2 unless it was mentioned that the masks were valved.

Change:

No change

16. Discussion section: On page 20 it says Face shields may provide an alternative to facemasks, which may mitigate several of the downsides. This was already addressed by reviewer comments 3 and 31, but notwithstanding, authors stick with the essence of the statement. Face shields have been identified as not being a good source control and have already been banned in some countries.

Author response:

We agree. Please see our responses to reviewer 3, comment number 10 & 11

Change:

No change

VERSION 2 – REVIEW

REVIEWER	Dr. Rolf Neubert Public / private reviewer, no related institution The Netherlands
REVIEW RETURNED	20-Jan-2021

GENERAL COMMENTS	<p>Dear authors, dear editor,</p> <p>the issues I had found and mentioned in an earlier version's review have been addressed in an appropriate way. From my public/patient's point of view there are no more concerns that would ask for further revisions or prevent publication.</p> <p>Let me express once more my hope that this publication will lead to (the funding of) studies that explicitly include the face mask wearer's point of view on mitigations and possible improvements, be it patients, care givers, general public or medical professionals.</p> <p>Sincerely, Rolf Neubert</p>
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REVIEWER	Dr John Thomas Norfolk and Norwich University Hospital, UK
REVIEW RETURNED	24-Jan-2021

GENERAL COMMENTS	Having reviewed the previous iterations of this manuscript, I believe the edits the authors have now made have sufficiently addressed my prior concerns. Hence, I would recommend that this manuscript is now suitable for acceptance in the journal.
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REVIEWER	Thomas Czipionka Institute for Advanced Studies
REVIEW RETURNED	28-Jan-2021

GENERAL COMMENTS	<p>All issues have been addressed, with the exception of the issue of face shields, with which I feel uncomfortable. Many commonly sold face shields spread rather than protect from aerosols. This may be resolved in editing.</p> <p>The authors may also want to refer to the latest reviews on face masks, e.g. https://www.pnas.org/content/118/4/e2014564118.short and https://www.acpjournals.org/doi/10.7326/M20-6625</p>
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VERSION 2 – AUTHOR RESPONSE

Reviewer: 2

1. Dear authors, dear editor,

The issues I had found and mentioned in an earlier version's review have been addressed in an appropriate way. From my public/patient's point of view there are no more concerns that would ask for further revisions or prevent publication.

Let me express once more my hope that this publication will lead to (the funding of) studies that explicitly include the face mask wearer's point of view on mitigations and possible improvements, be it patients, care givers, general public or medical professionals.

Author response:

We would like to thank you for your efforts.

Change:

No change

Reviewer: 3

2. Comments to the Author:

Having reviewed the previous iterations of this manuscript, I believe the edits the authors have now made have sufficiently addressed my prior concerns. Hence, I would recommend that this manuscript is now suitable for acceptance in the journal.

Author response:

Thanks for your positive feedback and efforts.

Change:

No change

Reviewer: 4

3. Comments to the Author:

All issues have been addressed, with the exception of the issue of face shields, with which I feel uncomfortable. Many commonly sold face shields spread rather than protect from aerosols. This may be resolved in editing. The authors may also want to refer to the latest reviews on face masks, e.g., <https://www.pnas.org/content/118/4/e2014564118.short> and <https://www.acpjournals.org/doi/10.7326/M20-6625>

Author response:

Thanks for your comment. We agree with you that the degree of protection provided by face shields is questionable. That is why in our manuscript we are recommending further research to investigate the benefits and harms of using face shields in the community.

Thanks for sharing with us the latest review. We have cited them in our review and further clarified the uncertainty of using face shields.

Change:

"Substitution. Face shields may provide an alternative to facemasks, which may mitigate several of the downsides (e.g. 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."