

## **14 Randomized control trials (RCTs) conducted worldwide testing the effectiveness of masks on reducing the transmission of respiratory viruses**

- **11/14 of the RCTs reveal that masks are either useless, or do not add to good hand hygiene or are actually counterproductive**
- **3/14 of the RCTs that have tested the effectiveness of masks in preventing transmission of respiratory viruses SUGGEST but do not provide ANY statistically significant evidence in intention to treat analysis that masks might be useful**

### **The first 2 studies directly tested source control and essentially provided no support for the claim that wearing a mask benefits others:**

1. **2016 Being study by MacIntyre, et al.** Tested source control- that wearing a mask benefits others- small study group and not statistically significant benefit of mask wearing and clinical respiratory illness not not against ILI and lab confirmed viral respiratory infections
  - a. A comparison between the mask versus no-mask groups showed a protective effect against clinical respiratory illness, but not against ILI and laboratory-confirmed viral respiratory infections.
  - b. <https://bmjopen.bmj.com/content/6/12/e012330>
2. **2010 France study by Canini, et al,** randomly placed “sick” people or “index patients” and their household contacts together into either a mask or a non-mask control group. The index patients observed good adherence to wearing the 3 ply mask. In 1 week
  - a. 15.8% of household contracts in the no mask group
  - b. 16.2% in the mask group developed Influenza like illness (ILI)
  - c. **Not statistically significant difference - AND “in various sensitivity analyses, we did not identify any trend in the results suggesting effectiveness of facemasks.”**
  - d. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0013998>

### **The next 3 RCTs studied the any benefit of mask wearing over hand hygiene**

3. **2010 New York study by Larson, et al.** comparing mask wearing versus mask plus hand hygiene group expressing symptoms of upper respiratory infection
  - a. 42% of those in hand hygiene group experienced symptoms
  - b. 61% than those in the mask plus hand hygiene group experienced symptoms
  - c. **found that the hand hygiene group were less likely to develop any symptoms of an upper respiratory infection than those in mask plus hand hygiene group. This is a statistically significant difference and suggests wearing mask actually undermines the benefits of hand hygiene**
  - d. <https://pubmed.ncbi.nlm.nih.gov/20297744/>

4. **2011 Bangkok study by Simmerman, et al.** studied mask plus hand hygiene and hand hygiene only group
  - a. ILI in the mask plus hand hygiene group 18%
  - b. ILI in the control group of 9%
  - c. ILI in the hand hygiene group only of 17%-
  - d. **THIS is statistically significant Secondary attack rate of ILI was twice as high in the mask plus hand hygiene group compared to control group**
  - e. <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1750-2659.2011.00205.x>
5. **2009 Hong Kong study by Cowling, et al.,**
  - a. Interventions started at 36 hours of the onset of symptoms
  - b. Mask plus hand hygiene group beat the control group to a statistically significant degree in one measure
  - c. Hand hygiene group beat control group to a statistically significant degree in 2 measures
  - d. Hand hygiene with or without facemasks seemed to reduce influenza transmission, but the differences compared with the control group were not significant.

**E. <https://www.acpjournals.org/doi/10.7326/0003-4819-151-7-200910060-00142>**

**6. 2009 Japanese study by Jacobs, et al.** found that “those in the mask group were significantly more likely to experience headaches and that face mask use in health care workers has not been demonstrated to provide benefit.” <https://pubmed.ncbi.nlm.nih.gov/19216002/>

7. **2012 German study by Suess, et al.** interventions began within 48 hours
  - a. Mask group
  - b. Mask plus hand hygiene group- found significantly lower levels of lab confirmed influenza (not ILI)
  - c. The combination not either group separately resulted in the significantly lowered lab confirmed influenza
  - d. <https://bmcinfectdis.biomedcentral.com/articles/10.1186/1471-2334-12-26>
8. **2020 Denmark study by Bundgaard, et al.** ONLY test mask wearing’s specific effectiveness against COVID 19
  - a. Large 4,862 participants RCT into one mask wearing group (high quality 3 layer surgical masks) and a control group.
  - b. Study took place spring 2020
  - c. 93% of the mask group wore it “predominantly as recommended”
  - d. 1.8% of the mask group tested positive for covid in 1 month
  - e. 2.1% of the control group tested positive for covid in 1 month
  - f. NOT statistically significant
  - g. <https://pubmed.ncbi.nlm.nih.gov/33205991/>

***CDC values the observational Missouri study of 2 hairdressers as “showing that wearing a mask prevented the spread of infection” while it does not really at all and had no control group. 2 masked stylists provided services for 139 people who were mostly masked for days after developing covid symptoms- the 67 who chose to be tested all tested negative and the 72 others non reported symptoms-  
LIMITATION- none of the people PRIOR to the two stylists becoming symptomatic were contacted to be evaluated and no other measures were taken into account- like hand hygiene and proximity- of stylist not being face to face but rather face to the back of the customer***

**9. 2015 Vietnam study by MacIntyre, et al.** studied over 1,100 participants to evaluate the development of ILI symptoms and the penetration of particles through surgical masks compared to cloth masks. There was not a no-mask control group. The study was over 4 weeks for health care workers wearing a two layer cloth mask at all times except in the toilet or during lunch breaks

- a. 13x more likely to develop ILI by wearing cloth mask than those in surgical mask group- statistically significant
- b. Surgical masks were “poor” letting 44% of particles in
- c. Cloth masks were “extremely poor” letting 97% of particles through
- d. N95 hospital respirators let 0.1% of particles through
- e. Wearing cloth masks “may potentially increase the infection risks for health care workers” stated in the study. “A contaminated cloth mask may transfer pathogen from the mask to the bare hands of the wearer which could lead to hand hygiene being compromised.”
- f. Double masks- increased the risk of infection because of moisture, liquid diffusion and pathogen retention
- g. CDC follow up in Sept 202 stated when hospitals washed the cloth masks the health care workers were only about half as likely to get infected as when they washed the cloth masks themselves. Still the CDC 2020 publication says “we do not recommend cloth masks for health workers”
- h. [https://www.researchgate.net/publication/275360639\\_A\\_cluster\\_randomised\\_trial\\_of\\_cloth\\_masks\\_compared\\_with\\_medical\\_masks\\_in\\_healthcare\\_workers](https://www.researchgate.net/publication/275360639_A_cluster_randomised_trial_of_cloth_masks_compared_with_medical_masks_in_healthcare_workers)

**10. 2014 Saudi Arabia study by Barasheed, et al** of Australian pilgrims in Saudi Arabia staying in tents together studied a mask group compared to a control group and found the ILI expression of symptoms being:

- a. 31% in the masked group
- b. 53% in the control group
- c. HOWEVER it relied on the self reporting of “subjective fever”
- d. ACTUAL lab tests revealed the OPPOSITE
  - i. Twice as many in the masked group developed respiratory viruses as in the control group
  - ii. NOT statistically significant difference but definitely points to whether or not masks are providing genuine benefit
  - iii. <https://pubmed.ncbi.nlm.nih.gov/25336079/>

11. **2008 Hong Kong study by Cowling et al.** looked at secondary attack rates of influenza like illnesses and found

- a. Secondary attack of ILI twice as likely in mask group as in the hand hygiene group
- b. NOT statistically significant
- c. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2364646/>

12. (a per protocol analysis) **Per Protocol deviates from randomization as it allows participants to self select into or out of an intervention group.** 2009 Sydney study by **MacIntyre, et al.**, found a significant effect when combining the surgical mask group with a group wearing N95 hospital respirators

- a. Authors wrote “a causal link cannot be demonstrated because adherence was not randomized”
- b. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2662657/>

13. ( subgroup analysis) **Subgroup analysis-cherry picking as researchers hunt for anything of statistical significance** 2010 study in Michigan by **Aiello, et al.,**

2010 study- revealed lower rates of ILI in its mask plus hand hygiene than its control group while mask only group did not

Mask only group reduced the ILI symptoms by 2% not statistically significant

<https://pubmed.ncbi.nlm.nih.gov/20088690/>

14. (subgroup) 2012 study in Michigan by **Aiello, et al.,** concluded “masks alone did not provide a benefit” They did not study the combined benefits of mask plus hand hygiene compared to hand hygiene alone.

<https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0029744>

**INTENTION to treat analysis which means that ALL participants are kept in the treatment group to which they were originally assigned and NONE are excluded from the analysis regardless of whether they actually received the intended treatment. THIS preserves the benefits of randomization, which can not be assumed when using other methods of analysis” Eric MCoy an MD at Univ of California Irvine.**

**REVIEWS of the RCT research**

Cochrane Reviews by Jefferson, et al. examines 13 out of the 14 RCTS

**CONCLUSION:** all but the odds ratios for both the mask plus hand hygiene group and the hand hygiene only group were twofold in the opposite direction from the hypothesized protective effect.”

**Perski, et al, did a Bayesian analysis of 11 of the 14 RCTs concluded that “when it comes to the benefits or harms of wearing face masks the scientific evidence should be considered equivocal. Available evidence from RCTs is equivocal as to whether or not wearing face masks in community settings results in a reduction in clinically or laboratory confirmed viral respiratory infections.”**

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