Author’s response to reviews

Title: Hand washing with soap and water together with behavioural recommendations prevents infections in common work environment: an open cluster-randomized trial

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Authors’ response to the comments of the reviewers

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The authors appreciate the comments of the expert reviewers and have addressed them to further improve the manuscript.

Reviewer’s report

Title: Hand washing with soap and water together with behavioural recommendations prevents infections in common work environment: an open cluster-randomized trial

Version: 1 Date: 13 September 2011
Reviewer: Benjamin Cowling
Reviewer's report:
I read this article on hand washing in an office environment with interest. I was confused that the intervention seemed to increase sick leave, whereas there was a reduction in infections? Authors speculate that this may be because participants in the intervention arm were more likely to stay at home when sick. But even so, the intervention increase the risk of this primary outcome and so I wonder whether the title, abstract and discussion should be given a bit more balance. For example the abstract results section should report both primary outcomes, and the abstract discussion might mention the caveat that sick leave was increase in one intervention arm.

The authors agree with the referee that increase in sick leaves in the intervention arm is indeed of interest. The abstract has been revised as suggested.

Reviewer's report
Title: Hand washing with soap and water together with behavioural recommendations prevents infections in common work environment: an open cluster-randomized trial
Version: 1 Date: 10 November 2011
Reviewer: Qian Li
Reviewer's report:
Major Compulsory Revisions:
1) Since participants in the control arm did not forced to not use soap/water or alcohol rub, the effectiveness from IR1 may only due to the behavioral recommendations.

Discussion on this topic has been added on p. 16-17.

Since soap/water is the most commonly used personal hygiene method, switching from soap/water to alcohol rub may occur in IR2. Thus, the comparable effectiveness of IR2 and control arm may indicate that switching hygiene habits could not improve reduction in acute illness.

The authors would not like to speculate that the observation would indicate that changing any existing hand cleaning technique would be useless in general. According to our instructions, the IR2 group, and the controls, still had the old water-and-soap access available and, as a matter of fact, were recommended to use it in toilets and at situations with visible dirt on hands. In IR2, alcohol rubbing was on top of the old technique, and in this set-up, did not produce any
improvement.

The authors need to discuss above issues. The limitation section of the paper touched base on these, but is not sufficient.

These issues have been discussed as shown above.

Minor Essential Revisions:
1) The conclusions in the abstract should specify water and soapy together with behavioral recommendations (not just “improved personal hygiene measures” which includes alcohol-based hand rub) can reduce the occurrence of self reported acute illnesses in common work environment.

The conclusions in the abstract have been rephrased as suggested.

2) A proportion test is used to compare the endpoints between arms and different time points. Some details are needed. Is the proportion test chi-square test?

Details of the proportion test have been included on p. 10. Similarity of episode rates was tested using Yate’s Chi-Square test. We formulated the binary variable and made the proportion of reported weeks with an onset of defined episode in each arm. The equality of each of these proportions for the soap and alcohol intervention arms with the corresponding proportion obtained for the control arm was tested separately with Yate’s Chi-Square test (Pearson's Chi-square with continuity correction).

Discretionary Revisions
1) The trial was conducted in common work environment. It would be helpful to describe the types of industries in each arm.

The participating companies included two leading retailers in Finland, two banks, a mining and metallurgical technology provider and a stainless steel producer. All three arms included work environments from all above industries. A detailed description of this has been given in the protocol paper “STOPFLU: is it possible to reduce the number of days off in office work by improved hand-hygiene? Savolainen-Kopra C, Haapakoski J, Peltola PA, Ziegler T, Korpela T, Anttila P, Amiryousefi A, Huovinen P, Huvinen M, Noronen H, Riikkala P, Roivainen M, Ruutu P, Teirilä J, Vartiainen E, Hovi T. Trials. 2010 Jun 4;11:69”. An extra reference to this paper has been added to the Materials and Methods, p.7.

2) Authors can investigate the sample size needed, given certain power, to detect the differences between arms. This may help to answer the question why endpoints of IR2 were not significantly different from control arm as in other paper.

According to an experimental sample size calculation the number of reported
weeks in intervention arms was sufficient to detect differences between arms. However, in the protocol paper “STOPFLU: is it possible to reduce the number of days off in office work by improved hand-hygiene? Savolainen-Kopra C, Haapakoski J, Peltola PA, Ziegler T, Korpela T, Anttila P, Amiryousefi A, Huovinen P, Huvinen M, Noronen H, Riikkala P, Roivainen M, Ruutu P, Teirilä J, Vartiainen E, Hovi T. Trials. 2010 Jun 4;11:69.” we have justified reasons to omit sample size calculations. After conducting the study we still feel that a simple sample size calculation may not give a reliable estimate of the required sample size when a number of factors influence circulation of infections in the office environment. Also, we do not want to rule out possibility that alcohol hand rub would cause a decreasing effect on infection episodes, if the number of follow-up persons was greater. Discussion on this has been added to p. 16.

Editorial Requests:

As your research involves humans please include a statement of ethical approval in the Methods section of the manuscript, including the name if the body which gave approval, with a reference number where appropriate. Any experimental research on humans must be in compliance with the Helsinki Declaration.

The statement of the ethical approval has been given in the beginning of the Materials and methods section: “The protocol was accepted by the Institutional Review Board.” The reference number (9/2008) has been added on p. 7.