Author's response to reviews

Title: Implementation of an educational intervention to improve hand washing in primary schools: process evaluation within a randomised controlled trial

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Version: 3 Date: 24 July 2013

Author's response to reviews: see over
24 July 2013

Dear Mr Dizon,

RE: MS: 1267121664912683

Thank you for your consideration of our manuscript “Implementation of an educational intervention to improve hand washing in primary schools: process evaluation within a randomised controlled trial”. We are grateful to the two reviewers who have provided very thoughtful comments on this revised manuscript. We address each of their points below.

We look forward to hearing from you.

Yours sincerely

[Signature]

DR CATHERINE CHITTLEBOROUGH
Response to reviewers’ comments

Reviewer 1 (Claudia H Lau)
The authors have addressed all of my previous concerns.

Minor Essential Revisions

1. Results, end of first paragraph: My only new minor comment is the reference to Table 3 at the end of the first Results paragraph. Do you mean Table 2 instead?

   We thank the reviewer for picking up this error, which we have corrected.

Reviewer 4 (Matthew Freeman)
The paper reports on a process evaluation of a school-based hygiene program in the United Kingdom. The paper has been refined and indeed greatly improved by the authors. This version of the paper has improved readability and structure and includes a number of important discussion points that can be relevant to the broader public health community about implementing school-based handwashing programs. The purpose of the study is well supported by the methods utilized.

Major compulsory revisions:

- In the methods section, you state that you used logit link. However in the results you report a risk ratio. A log-binomial model (link log) will produce a risk ratio, while link logit produces an odds ratio. Please reconcile.

   We thank the reviewer for picking up this error. We did indeed use the link log to produce risk ratios. We have changed “logit” to “log” in the Methods.

Minor essential revisions:

- I appreciate the additional discussion of methods in this version of the manuscript, but I suggest that the authors revise and reorganize this section to provide additional clarity. Report the number of schools and each method in one place in a sentence such as, “A process evaluation was conducted that included school logs (n=178 schools), FGDs with pupils (n=8 schools), etc. Paragraphs within the analysis sub-section could be broken up into separate sections to describe the different methods, including paragraphs on outcome variables, quantitative analysis approaches, and qualitative analysis. I have made some specific suggestions below.

   The process evaluation introduction on p7-8 now includes information on the data sources as suggested. The analysis section has been rearranged and divided into separate paragraphs for the quantitative and qualitative analyses.

- I would still like to see additional literature cited in the discussion section that can situate these findings within the broader public health community interested in school-based health promotion programs. Are there other process evaluations that have shown similar results in terms of fidelity, etc. If this is only a process evaluation of a specific program in the UK, it may be of little added value to the rest of the sector.
We have added extra detail about fidelity etc. found in other process evaluations of health promotion and education interventions in schools in the Discussion.

- Table 1 requires a more specific title and overall N of schools. Column 2, reporting the mean number of minutes for FGDs is unnecessary. Perhaps additional columns reporting the intervention and control schools separately would be useful. Add the dates and footnotes to specify the analysis so that the table can stand alone from the paper.

Table 1 has been reformatted to include extra detail about the timing of data collection for each source, and the aspect of intervention implementation that the data source is used to assess. Extra detail has also been added to the Methods to clarify which schools participated in the different components of the process evaluation (see also point above about reorganization of Methods).

- Table 2: The title, as it currently reads is unclear and doesn’t explicitly state the comparison being made. Use the word “compared to,” to discuss the ratio you are reporting, rather than “or.” Use the title “univariate” not “univariable.” Use the title “Multivariable logistic regression” (this is not multivariate) and report “aRR” instead of “RR.” You don’t need to report so many significant digits for the p values, two (i.e., p=0.53) is sufficient. The methods section needs to specify why you chose 194 pupil as the cut point for this analysis. Is that the mean? Is that a relevant number for external validity or should you choose a more appropriate set of ordinal values? Same with % eligible for free meals. I suggest you spend more time discussing these findings in the results and discussion as the variable uptake of the intervention is the key purpose of your study.

The title of Table 2 has been updated.
We use the convention recommended by Peters (Multifarious terminology: multivariable or multivariate? univariable or univariate? Paediatric and Perinatal Epidemiology 2008; 22: 506), and have therefore not changed our use of “univariable”. Peters states that “where there is just one explanatory variable the model should be termed ‘univariable’ (rather than ‘univariate’ or ‘bivariate’), and where there is more than one, then ‘multivariable’ should be the label used (rather than ‘multivariate’).”
Adjusted RR (aRR) has been updated.
The convention for reporting p values in many high-ranking health and epidemiology journals is three significant figures, so this has not been changed.
Details of cut points (at median) for large school size and high proportion eligible for free school meals are described in the Methods.
The results from Table 2 are described in the Results, and extra information about these results has also been added to the Discussion.

- Table 3: The title needs clarification. Are you considering the process evaluation to only be the 8 schools that received the FGDs? From the abstract, it appears that you categorize all data collection activities described as the process evaluation?

We have clarified that some data sources in this paper include all 178 schools (e.g. log sheets), but only four intervention schools participated in the direct observation of intervention delivery. The title of Table 3 is now “Components of the intervention observed in the four intervention schools participating in the direct observation”.

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Discretionary revisions:

- In the abstract, the purpose is stated as to assess “fidelity, dose and reach.” In the results, the authors discuss reach, dose, fidelity, acceptability, and sustainability, in that order. I suggest you make the abstract match the results.

  This has been corrected.

- Comma missing p2: “acceptable to schools[,] but its reach”

  This has been corrected.

- Remove/add comma p3: “…where, when[,] and why variations…”

  This has been corrected.

- Please check comma usage throughout the paper, as you alternate between application (i.e. see page 6) or not (see examples above) of the Oxford comma

  Consistency of comma usage throughout the paper has been reviewed.

- p6: “The resource [packs were] developed?”

  This has been corrected.

- p7: “Four intervention and four control schools in the sub-study were purposively selected…” How were they purposively selected? Was there a reason to select specific types of schools?

  The eight schools were selected based on the strata of school size (>194 pupils vs. ≤194 pupils) and proportion eligible for free school meals (FSM>6.4% vs. ≤6.4%). These cutoffs represent the median. This information is included in the methods. So the four intervention schools were: 1 large size, high FSM; 1 large size, low FSM; 1 small size, high FSM; 1 small size, low FSM. This was done to ensure heterogeneity among the schools taking part in the focus groups, interviews and observations.

- I suggest a separate section for ethics.

  The section about ethics has been moved and is now in a separate paragraph.

- p7: Suggest that you move the selection of schools to a separate section and more completely explain what was done in the full suite of schools, the 24 schools in the “sub-study” and then the 8 schools in the “process evaluation.” I thought that the entire study was a process evaluation (informed by the title and discussion on p22 of the discussion), so I am confused by the heading on p8 (and title in table 3) that leads with a discussion of 8 schools that received FGDs. More clarity in one place in the manuscript of what schools were assessed for what components would be helpful.
The Methods section has been rearranged to incorporate these helpful suggestions. The first subsection describes the educational resource pack. This is followed by a description of the selection of 178 schools, with 24 in the sub-study. The “Process evaluation” subheading introduces all the data sources (log sheets, HPA staff interviews, followed by the focus groups, teacher interviews and observations conducted in 8 of the substudy schools.

- Please discuss the challenges of FGDs with children aged 6-7 (KS1). This seems awfully young for FGDs. Is there literature that supports the use of FGDs in children of that age? Were any participatory activities used?

There is increasing acknowledgement of the validity of children’s own views within research, rather than obtaining children’s perspectives indirectly through the adults who are responsible for them, such as parents, care givers, or teachers (Morgan et al. 2002; Docherty & Sandelowski 1999; Kirk 2007). It has been previously recommended that children should be 6 years or older to possess the social and language skills required to be effective participants in focus groups (Heary & Hennessy 2002). The focus groups were piloted with pupils in Year 1 (age 5), but this younger age group was not included in the process evaluation because of difficulties obtaining responses to questions without significant prompting, and uncertainty about whether the pupils comprehended what they were agreeing to during the assent process. A participatory drawing activity was included to help children express their thoughts about the facilities they use to wash their hands. This information is included in the Methods. The richness of the data from the focus groups with pupils, particularly the data used in our previous publication (Chittleborough et al. 2012), demonstrates the value of allowing children to present their perspective using their own voices.

- I’m confused about the timing of this evaluation. The methods state that the study was completed in April 2010, but also that control schools received the completed intervention in 2010. You report on the fidelity of the intervention in the control schools, which is quite interesting. Please clarify the timing of implementation and data collection.

Follow-up data collection for the main trial was completed in 2010. Resource packs were sent to control schools between September 2010 and March 2011. We have slightly reworded the Sample section of the Methods. Detail about the timing of data collection is also now included in Table 1.

- p13: the first time you report an estimate and CI, you need to spell out risk ratio (RR) and 95% confidence interval (CI).

This has been corrected.

- “A description of the observed delivery of the intervention in the four process evaluation intervention schools is provided in Table 3, indicating that not all schools provided all components to all classes.” This does not make complete sense, what is “indicating”, the table or the findings in the table?

These sentences have been reworded and the word “indicating” has been removed.
- In the dose section on page 13-14, percentages would be helpful for all univariate data, since keeping track of the overall N of the study is challenging. This is actually the case throughout the manuscript.

The first paragraph of the Dose section describes the observed delivery of the intervention in the four intervention schools selected to participate in the qualitative data collection. No quantitative data analyses are used in this section. Percentages have not been added because only four schools (8 classes) are referred to, as shown in Table 3. The second paragraph of the Dose section uses information from the log sheets from all 178 schools, but percentages have not been added here either because the log sheets were not designed to collect detailed information about the specific components of the intervention that were delivered. This second paragraph was added at the request of a previous reviewer who was interested in whether information from other schools (from the log sheets) supported what was observed in the four intervention schools that participated in the qualitative direct observations. The updates to Table 1 and the Methods section are designed to make it easier to keep track of the different schools that were involved in the various data collections included in this paper.

- Though shown in Table 2, there is no discussion as to why certain areas have higher fidelity in either the results or discussion sections.

The finding that the proportion of schools who delivered the educational package (fully or partially) varied by geographic area, the highest proportion being in Bath and North East Somerset (BANES), is described in the Reach section of the Results. We can only speculate about why the BANES area would have higher rates of intervention delivery than other areas. Education statistics show that BANES has a consistently higher proportion of pupils achieving Level 4 or above in both English and Maths (80% in BANES, 72% in Bristol in 2010), and therefore may potentially be able to accommodate and take advantage of interventions such as this one. We do not have any data related to the school ethos or culture that is likely to be related to their engagement with such public health interventions.

- p20: “Fidelity of delivery was also reportedly better…” compared to what? “…using this model.” What model?

This sentence has been re-worded: Fidelity of delivery was also reportedly better in intervention schools than control schools in the trial. This suggests delivery of the intervention beyond the trial is unlikely to be sustainable using this model of a centralised, non-research agency to coordinate intervention delivery.

- p22. “The quantitative and qualitative methods used in the process evaluation were an effective mechanism by which to measure and explore intervention reach, dose, fidelity, acceptability and sustainability.” By what measure? It would be useful to introduce this paragraph as the strengths and limitations section.

This paragraph has been reworded to introduce it as a discussion of the study’s strengths and limitations. Reference to “effective mechanism” has been removed.