Reviewer’s report

Title: School-based strategies for oral health education of adolescents- a cluster randomized controlled trial.

Version: 1 Date: 22 July 2012

Reviewer: Donald Chi

Reviewer’s report:

This manuscript describes results from a cluster randomized trial that examined oral health outcomes related to a classroom-based intervention targeted at 10-11 year olds in Pakistan. The study tests an interesting set of hypotheses. However, there are a number of concerns: 1) lack of concordance between the stated behavioral theory, the intervention, and the questionnaire used to measure changes in knowledge and behavior; 2) inadequate details on the active ingredients in the intervention; 3) no a priori hypotheses; and 4) no details on fidelity of interventions led by dentists, teachers, and peers. These omissions make it difficult for a reader to take what the authors have done and attempt to replicate the study in another setting. I would also suggest that the authors obtain the CONSORT checklist and ensure that each piece of required information is included in the manuscript. Additional details are listed below.

Major Compulsory Revisions

1. The Study Design and Study Population subsection in the Methods section is difficult to follow. It does not include information on the exclusion or eligibility criteria (which were used to identify schools that could be allocated to one of the five arms) and there is insufficient information regarding randomization and allocation methods. Please include this information.

2. Details related to the intervention are missing or unclear. How often was the 1-hour OHE implemented (e.g., once, twice yearly, multiple times over the 2 year study period)? What specific educational elements were included in the OHE? How were social cognitive theory constructs of self-efficacy and social support operationalized through the intervention? How was fidelity ensured across the different intervention arms and clusters?

3. The sample size and power estimates were based on a 50% reduction in gingivitis but all of the study outcome measures were not disease-related, but rather knowledge-based and behavioral. Studies intended to change behaviors rarely achieve such large changes. In fact, results presented in Table 2 suggest that the largest change in behavior was a 37% change. Thus, I have concerns that the study is underpowered for the presented outcomes. In addition, from the ISRCTN website, it appears that changes in oral health knowledge and behavior are secondary outcomes – these concerns need to be addressed and any related limitations need to be included in the manuscript.
4. Please report confidence intervals for % change over time (Table 2) to provide the reader with information on whether the changes over time within each intervention arm were significant.

5. How clinically meaningful are the measured changes in oral health knowledge? For instance, one of the survey items asked students about how many teeth are in the mouth and another asks about when the first molar erupts. How relevant are these pieces of knowledge in improving behaviors or clinical oral health? This raises the question of face validity of the measures adopted for the study.

6. Given the vast number of statistical comparisons that were made, did the authors consider adjusting the adopted alpha level for multiple comparisons by Bonferroni corrections?

Minor Essential Revisions

1. The original trial on the ISRCTN website states that the intervention was directed at 10-13 year old, but the study states that the intervention was for 10-11 year old. Please explain discrepancy.

2. I am unfamiliar with reliability coefficients greater than 1.0 (e.g., 7.9 and 8.7). Please make sure these are correct.

3. Rather than citing a previous publication, please report intra-rater reliability estimates for the single examiner.

4. As written, it is not clear from the Data Analysis subsection in the Methods section that mean percentage change from baseline to end of study is the outcome. Please clarify this in the text.

Discretionary Revisions

1. It is unclear to me as to how large distance between the schools could be ensured based on the randomization protocol described. Were the schools randomly allocated by geographical area?

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests.