Author’s response to reviews

Title: Effectiveness of School Dental Screening on Dental Visits and Untreated Caries among Primary Schoolchildren: Study Protocol for a Cluster Randomised Controlled Trial

Authors:
Haya Alayadi (haya.alayadi@kcl.ac.uk)
Wael Sabbah (wael.sabbah@kcl.ac.uk)
Eduardo Bernabe (eduardo.bernabe@kcl.ac.uk)

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REVIEWER #1

The trial you propose is interesting and will increase the evidence base for referral methods for dental screening in SA schools for untreated caries. It presents some challenges given the limited resources available. I have made some specific points which I hope will improve the manuscript.

Comment: Funder - 'self-funded' is ambiguous. If the authors are funding the research this should be explicit (e.g. through substantive employment). See SPIRIT for guidance if required. The authors declare that they have no competing interests but are involved in the design of the research which may considered a conflict that requires stating.

Response: The trial is part of a PhD project carried out by the principal investigator (HA), under the supervision of the co-authors (WS and EB). The project is funded by the Saudi Cultural Bureau in London (covering HA’s tuition fees, living expenses and research consumables). The Competing Interest and Funding sections of the protocol have been revised to reflect these changes. The role and responsibilities of all authors have been clearly stated under the contributions section.
Comment: The sponsor or the contact details are not specified in the manuscript and are listed as not applicable in the submitted checklist. This should be justified as it contradicts the NCT registration which lists KCL as the Sponsor.

Response: The trial is sponsored by King’s College London. This is now stated in the 2nd paragraph on page 6.

Comment: There is no details about any Trial Management Group or independent oversight committee. This may not be required but it is a SPIRIT checklist requirement so justifying why there isn’t a TMG, TSC and DMEC is advised.

Response: The trial will be closely monitored by a PhD committee (acting as a Trial Steering Committee), including the principal investigator, the two supervisors and two independent external examiners. This is now stated in the 2nd paragraph on page 6.

Comment: There is no consideration of risk/harm. The manuscript acknowledges (from the review) that there is no conclusive evidence regarding the harms or benefits of school-based screening. Are there any safety issues? Are false positives or incorrect referrals possible? If so, how will these be handled?

Response: Given the training and calibration of examiners in caries assessment, the probability of having false-positive cases is minimal. Upon referral, a standard dental check-up is always conducted as part of the treatment plan where any false-positive cases will be identified. If that occurs, the dentist will inform parents that upon further examination no treatment is required. This information is now presented in the 3rd paragraph on page 11.

Comment: Data management - the manuscript doesn’t specify who will collect the data and be responsible for it in each cluster/site as appropriate. Only the abstract mentions that dentists will collect the outcome measures, so it would help to be clear who is doing what.
Response: There will be 12 examiners (all dentists) doing the fieldwork for the trial under the supervision of the principal investigator. This is now stated in the 3rd paragraph on page 10.

Comment: It is unclear whether 'separate fieldwork teams' will have access to data (previously the manuscript states that only the authors will have access).

Response: The fieldwork teams will only be responsible for data collection. Only the principal investigator will be responsible for data entry and management. This is now stated on page 12.

Comment: It is unclear if the 'recorder' will be blind as it reads like they both send referral letters (page 10) and record the primary outcome. I found it difficult to unpick this section. It may aid the reader to describe the roles of those in the fieldwork team/s e.g. the field team (in each cluster?) consists of a recorder who will do x and an examiner who will do y. Individuals will switch roles to minimise visual fatigue.

Response: We have clarified the role of the examiner, the recorder and the site organiser in the last paragraph on page 10. Examiners and recorders will be blinded to group allocation by sending separate fieldwork teams to schools in each trial group. This has been described under Blinding on page 9.

Comment: Accounting for 11% attrition would require a sample size > 1000.

Response: The exact sample size required after accounting for 11% attrition rate is 1010 (505 each group). This has been stated in the 1st paragraph on page 13.

Comment: Page 7 ("Trial Outcome") - wording implies there are two primary outcomes.

Response: The text in the above section (page 8) has been changed as suggested.
Comment: Page 15 (para 1) - consider revising, it is unclear in parts.

Response: We have rephrased the 2nd paragraph on page 15 to improve clarity.

Comment: Page 15 (para 2) - please add a reference for 'robust design'. Also, I am not sure how collecting and analysing sociodemographic data reduces bias - it allows you to compare the groups and consider how balanced the groups are. Later in this paragraph the authors go on to mention limitations of the proposed trial which is important; however, the wording could be improved.

Response: The word ‘robust’ has been erased from the above paragraph. Collecting data on covariates will help accounting for any baseline differences between the trial groups that might affect uptake of dental services (in the event the trial groups are unbalanced after randomisation). The entire paragraph has been rephrased to improve clarity (3rd paragraph on page 15).

Comment: Given the potential impact of gender segregation on the study design and implementation the team may want to consider (if you have not done so already) whether it is feasible to engage a male co-PI to help ensure the ratio is representative of the target population.

Response: As the trial is part of a PhD project for which HA must show she is leading the project, the inclusion of a male co-principal investigator is not feasible. However, we have added a male organiser for boys-only schools, under HA’s supervision. This is described in the last paragraph on page 10.

Comment: Figure 1 does not include when assent/consent will be obtained.

Response: This item has been added to Figure 1.
Comment: Typos: Page 9 (line 2) - taking part *in* (rather than 'of') a trial. Page 9 - "For schools that agree*d* to participate"

Response: The text has been revised as recommended.