Author's response to reviews

Title: Brief oral health promotion intervention among parents of young children to reduce early childhood caries

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Author's response to reviews:

Miss Natalie Pafitis MSc

Senior Executive Editor

Address to reviewer’s report

Dear Miss Pafitis

Thank you for the reviewer’s comments regarding the manuscript entitled

“Brief oral health promotion intervention among parents of young children to reduce early childhood caries”.

We have responded to the reviewer’s comments in the order of the queries raised.

1. Details about what the brief counselling sessions will entail is included in the M&M section (rapport establishment, agenda setting, exploration of issue of concern and presentation of option menu and development of behaviour change plan and follow-up plans). Additional information on the expected duration of the counselling is now included.

2. The recruitment of study participants and the randomisation protocol is further explained in the M&M section. Study participants will be recruited from parents/children attending the community/child health clinics in metropolitan Perth and Bunbury/Busselton area and individually randomised, stratified on city location only (Perth or Bunbury/Busselton). This is not expected to have an impact on estimation of sample size nor in the planned analytical strategies.
3. Information relating to the training of counsellors in basic oral health messages and the evaluation of the MI training and monitoring of the intervention is now further expanded in the M&M section.

4. Information relating to the preliminary evaluation of the effectiveness of the training is now included in the M&M section.

5. The questionnaire will collect information on various psycho-social factors posited to be of importance in oral health, possibly as mediators, as well as socio-demographic and oral health behaviours. The theoretical rationale underlying the psychosocial factors is well developed and whilst the measures may not be tested in this study they have been tested in other settings (referenced in the manuscript). The strength of the randomised controlled study design as used in this study is its ability to control for potential unmeasured confounding variables and bias. The questionnaire is used to collect for those measures felt to be potential mediators for the outcome of interest, namely oral health knowledge, behaviour, attitudes, self-efficacy, social support and parental stress, and their potential impact will be evaluated and the causal pathway tested, through mediation analysis, (this is expanded further in the Background and M&M section).

Exposure to related protective factors will be collected via a questionnaire at 12, and 36 months; dietary information for the child will collect fluid consumption and exposure to communal water fluoridation and oral care behaviours, principally toothbrushing and toothpaste use, and use of professional services including professionally applied fluorides (this information is now included in the M&M section).

There is no specific behaviour that is targeted in the intervention, the topic/s for discussion between the counsellor and the study participant will arise during the counselling session and at the instigation of the study participant, in keeping with the MI approach, which eschew “expert” delivery of information which may not have been requested (the approach is further detailed in the M&M section).

6. The standard care program will continue throughout the study and all children (intervention and control) will continue to be provided with the screening program as currently applied, this is made clearer in the M&M section.

7. The collection of DDE data is now excluded. Procedures to maintain reliability throughout the study is now included in the M&M section.

8. The analytical plan will commence with presentation of baseline data to determine adequacy of randomisation. Primary endpoints will be analysed using
parametric and non-parametric statistical procedures as appropriate, accounting for likelihood of skewed carious outcome data. Primary analysis will use the two-group assignment to determine the effectiveness of the intervention. Subsequent multivariate analysis will use logistic regression and Poisson regression to estimate the effects of measured factors on the carious outcome and mediation analysis to discern causal pathway were the intervention found to be effective; this is further expanded in the M&M section. Information on the variables to be used in the analysis is now presented more fully in the M&M section and explained in an added Table 1.

Please note that the changes made to the revised manuscript have not been "tracked". If tracked version is required please advise.

Yours sincerely

Peter Arrow

Joseph Raheb

Margaret Miller