Reviewer’s report

Title: Calcium and vitamin D supplementation and/or periodontal therapy in the treatment of periodontitis among Brazilian pregnant women: protocol of a feasibility randomised controlled trial (THE IMPROVE TRIAL)

Version: 0 Date: 03 Dec 2018

Reviewer: Susanna Dodd

Reviewer’s report:

Thank you for submitting this interesting trial protocol. I have a number of suggestions for improving the flow and structure of the protocol:

1) The authors should offer some benchmark or threshold levels for each feasibility outcome, which in turn would inform the authors/reader if a future study is indeed feasible (for example, what does "acceptability" mean in practical terms for the feasibility outcome? And what % threshold would be required to determine acceptable recruitment, adherence and retention?)

2) Analysis of pilot studies should focus on confidence interval estimation rather than hypothesis testing, as pilot studies are not powered to determine treatment effects with any confidence. Therefore, all inferential statistics should be treated with caution. I would suggest that the authors rewrite the statistical analysis section, stating that analysis will focus on confidence interval estimation, and that all hypothesis testing/regression modelling will be viewed as entirely exploratory. Useful references relating to this issue include:


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