Reviewer's report

Title: An evaluation of the efficacy of adding a structured home visiting intervention to improve outcomes for high-risk families attending the Incredible Years Parent Programme: study protocol for a randomized controlled trial.

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Reviewer: Michael Hurlburt

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The manuscript “An evaluation of the efficacy of adding a structured home visiting intervention to improve outcomes for high-risk families attending the Incredible Years Parent Programme: study protocol for a randomized controlled trial” directly address the issue specified in its title. It summarizes the rationale and design for a proposed randomized trial that involves an extension of the Incredible Years Parent Program.

At a broad level, the manuscript is clear and succinct in explaining the question being addressed, data to be collected, and the general approach to analysis. In some areas, details that might be desired were absent and often there was room for improvement in the writing and presentation format, but overall this reviewer had a clear sense of the purpose and approach for the proposed trial. This is the broad impression I was left with after reading the manuscript.

Without dwelling on specific aspects of presentation, I will attempt to summarize some of the key issues that could benefit the overall presentation of this study protocol, labeling each as major, minor, or discretionary.

1. In its rationale, the study protocol emphasizes the value of parent training programs for reducing early conduct problems, including information about the percentage of children/families not benefitting from programs such as the Incredible Years Program (IYP). What is not given much attention, despite its being the primary intervention component of interest in this trial, is the rationale for why a home visiting approach would potentially be an effective adjunct to the existing IYP program. It seems as though it would make sense to have further justification, either through reference to other effective home visiting programs (e.g., Nurse Family Partnership; SafeCare), or through an argument based on the authors’ relevant experience/knowledge, as to why the added home visiting component is likely to be a particularly effective method for enhancing IYP outcomes. (major)

2. The authors cite research suggesting that conduct problems are on the rise (references 1 and 2). It is not clear that this is a necessary argument for this study protocol. If it is, it would be preferable to cite primary rather than secondary sources for this claim. (minor)

3. Throughout the manuscript, the authors could afford to give more attention to
writing style, grammar, and presentation. I often found myself stumbling over misplaced or missing commas, missing words, and sentences that could use proofreading. The final few paragraphs of the introduction, where the principal hypothesis is stated, is one clear area where writing could use further attention, although I also felt there were many others. Although Trials does not call for a specific formatting style, the single spacing of the text throughout seemed out of step with Trials' basic requirements. When looking at the reference page, I found similar need for attention to detail in reference consistency and completeness. Issues that I found throughout the document in writing crispness and completeness detracted notably from the professional quality of the manuscript in my opinion. (major)

4. At a gross level, I was struck by a seeming mismatch between the argument in the introduction and the ultimate design of the study presented. The authors argue initially that a subset of children/families do not show improvement back into the "normal" range (about 1/3rd). I was expecting, based on this argument, and the way it was presented, that the trial would end up offering the IYSS extension to families who seemed to be experiencing difficulties (or the need for additional support) during delivery of the IYP, or toward the conclusion of the IYP. The design presented proposes offering the IYSS to all families receiving IYP, which seemed at odds with the study rationale presented, and with the strong emphasis placed on the importance of (a) focusing on those families with high levels of risk and (b) maintaining cost effectiveness. Without further justification for the rationale for the home visiting program generally, I actually wondered how many parents would want to take part in effectively almost a doubling of the requirements associated with the IY program, when it already is a long and intensive program. Further discussion and reconciliation of this issue would be helpful. If the authors already have experience with delivery of the IYSS and how parents react to it, this would be helpful. (major)

5. In a number of places the authors make the argument that prevention is bound to be cost effective, arguing that children with conduct problems are likely to have much greater costs across the lifespan than those without conduct problems. There is some truth in this claim, but the authors should be careful not to present the claim that all of the children taking part in the IYP already have conduct problems at a level that will result in much higher costs to society. In fact, we know that at this early age range it is possible to predict with some, but imperfect accuracy which children will develop more extensive conduct problems. Prevention is certainly worthwhile, but the authors should take care to be sure that their claims regarding potential cost savings are in keeping with what we know about our true ability to predict future delinquency among very young children. (minor)

6. With regard to sample size, I found myself asking whether it was likely that one would observe a moderate to large effect size if the intended benefit of the IYSS extension is principally directed toward families where children and families are not already experiencing substantial benefit from IYP. A sample size of 126 is actually reasonably large, but if the effect of interest is principally hypothesized to
appear among 1/3rd of the sample, then I wondered whether the sample size where it mattered would be large enough.

At a purely technical level, the data in this trial are nested within IY groups and analyses most appropriately should be prepared to take this nesting into account, both from an analytic standpoint and from the effect it could have on study power. (minor)

7. With regard to the analytic approach discussed, it is relatively straightforward. The authors discuss examining differences in treatment groups from pre to post using ANCOVA. Technically, ANCOVA does not examine pre-post differences. It examines group differences at post, controlling for levels of the baseline variable (and possibly others) at pre. The authors may wish to be a bit more precise in their statement regarding the analytic approach to be used. Furthermore, the authors may benefit from considering whether there are repeated measures modeling approaches (e.g., PROC MIXED in SAS, or something similar) that would allow the authors to examine outcomes (e.g., the ECBI) at post and follow-up in the same model, controlling for the baseline level. When conducting intent-to-treat analyses, such modeling approaches could allow for inclusion of more cases in the model while allowing for the presence of some missing data. Such an approach could provide a more robust and streamlined approach to intent-to-treat analyses. (minor)

8. Finally, the qualitative analysis portion of the protocol could use further elaboration. In its current form it is quite short. It could benefit from further specification of the kinds of questions that will be included in qualitative interviews or questions and the kind of data that the authors hope to extract from those questions. (major)

In summary, as a reviewer I clearly understood the purpose and design of the study protocol. The procedures described were replicable and comparable with other similar types of studies. Attention to some specific issues could clarify the full potential of a study that may make an important contribution to existing knowledge.

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

Quality of written English: Not suitable for publication unless extensively edited

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests