Author's response to reviews

Title: A pilot study to evaluate 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.

Authors:

Dianne G Lees (leesdianne@gmail.com)
David M Fergusson Prof (dm.fergusson@otago.ac.nz)
Christopher M Frampton Ass Prof (chris.frampton@otago.ac.nz)
Sally N Merry Ass Prof (s.merry@auckland.ac.nz)

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Author's response to reviews: see over
The Editor  
Trials Journal  
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Dear Sir,
Thank you for taking time to review this protocol. We appreciate your feedback and have addressed the editorial requests and the reviewer comments. We have “tracked” all changes as requested.

**Editorial request:**
1. A title page has been included
2. Abstract has been formatted correctly
3. Ethical approval is in methods section
4. Competing interests statements is at the end of the manuscript
5. Acknowledgement section has been included
6. Authors contribution section has been included

**Reviewer Comment 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)*

Response:
We agree that the justification for adding a home visiting component to IYP was not adequately addressed. We have added a section at the bottom of page 5 (Background section, paragraph 6) to address this point.

**Comment 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)*

Response:
We agree with the reviewers comment and have removed this reference.

**Comment 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)

Response:
The protocol has been revised with particular attention to writing style grammar and format. The final paragraphs of the introduction have been rewritten to address these comments. The reference section has been formatted in an appropriate style.

Comment 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)

Response:
It may not have been clear in the protocol that all participants in the trial have risk factors that are associated with poorer outcomes with IYP on its own. We also realise that it was not clear that IYSS is the service that was set up to provide a targeted intervention for high risk families. The intervention provided by IYSS has been named EIYP to make this distinction. Appropriate changes in the protocol have been made. Our question is whether, in the high-risk group attending IYP, the addition of an EIYP improves outcomes. An open trial of EIYP showed high levels of satisfaction and excellent retention so that these families did not consider the additional home support onerous. We will check the satisfaction ratings in this study. Reference to this finding has been added at the top of page 7 (Background section paragraph 10).
Comment 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)

Response:
Some aspects of this comment are addressed in our response to comment 4, where we clarify that EIYP is for targeted high-risk families. It is accepted that not all those children with behaviour scores in the clinical are on a trajectory towards conduct disorder. However if we can show that a greater number of vulnerable families make more improvement with extra support, and if this changes their trajectory at follow up, then it is more likely they will have better outcomes and require fewer resources over time. The screening we used to identify families with high risk factors is based on findings from the literature that identifies both parent and child factors for developing conduct disorder. Page 5 (Background section paragraph 5).

Comment 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)

Response:
This study is a pilot study to determine the feasibility of conducting a larger randomised controlled study and to collect data to inform the design of a definitive randomised controlled trial of this intervention. However, we expect this sample size will be large enough to detect a large effect size. The issue of data nesting within IY groups is addressed in comment 7

Comment 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)

Response:
It may not have been apparent in the earlier draft of the manuscript but we intend to calculate the differences for each individual and then analyze these changes using the ANCOVA model with baseline level as a covariate and stratum as a factor in the analysis. In this manner the 'nesting' within strata is captured in the analytic approach. We acknowledge the utility of using a mixed model repeated measures analysis, we have chosen not to use these analyses for the following reasons: 1. we are focused on the change from pre to post intervention, and we have no intermediary sampling times between these points; 2. we expect that those we reassess at follow-up are likely to be a selective subset of the whole sample size and we are reluctant to include this change (post to follow-up) in the primary analysis; and 3, we expect the change from post intervention to follow-up to be very different from the change induced by the interventions and have chosen to separate these in the analyses.

Comment 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)

The qualitative analysis section has been expanded to include more details on the qualitative approach, the type of the questions included and the data that will be collected that will add depth to the analysis (page 15).

We hope these changes have adequately addressed your comments and look forward to hearing back from you.

Dianne Lees