Reviewer’s report

**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 randomised controlled trial.

**Version:** 2

**Date:** 1 November 2013

**Reviewer:** Michael Hurlburt

**Reviewer’s report:**

1. Will the study design adequately test the hypothesis?
   *The hypothesis still does not precisely match the study design. This has to do with whether the sample targeted really represents families “who typically have poorer outcomes”.

2. Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing?
   *Yes, sufficient details are provided

3. Is the planned statistical analysis appropriate?
   *Yes, in general the analytic approach is appropriate. A few minor suggestions are provided and the authors are encouraged to consider the benefit of somewhat more sophisticated modeling techniques.

4. Is the writing acceptable?
   *Yes, but it would benefit from a further editorial pass to fully meet professional standards.

The authors have made efforts to respond to each of the concerns in the initial review and to provide clarification about some issues that were potentially not entirely clear. A number of the responses provided address and substantially resolve issues raised in the first review round.

For example:

1. The authors have now given considerably more attention to justifying the potential value of a home visitation based enhancement of the IY program.

2. The authors have streamlined some unnecessary components of their study rationale that previously raised questions.

3. The writing style and presentation of the manuscript have substantially improved. In this reviewer’s opinion, the manuscript could still benefit from a further editorial pass just to resolve some minor issues around use of commas, hyphenation placement, and a few areas of wording structure. Depending upon
whether the journal handles these small editorial issues, the authors may wish to address this once more for overall presentation purposes (discretionary).

4. The arguments about efficiency and potential cost savings have been moderated somewhat to a level appropriate to the proposed research.

5. The purpose and structure of proposed qualitative work is now more clearly described.

However, there are still remaining issues that the authors will likely want to spend time considering in advance of the conduct of the proposed trial.

1. The authors clarified that they intend to target the EIYP home visitation support to families with the highest levels of risk, presumably to try to reduce the lack of response among families found in the past not to respond to the IY program entirely by itself. The authors outline research in the introduction that suggests that they might be able to identify in advance which families might not benefit from the IY program by itself. However, a review of the studies cited on page 5 of the introduction does not provide great confidence that the criteria to be used to select high-risk families are criteria that will actually strongly predict IYP non-response. Presumably the authors are most interested in non-response among families in which behavioral issues are already of concern, so selecting based on the presence of elevated behavioral problems doesn’t seem to add a lot in determining what it means to be high risk in this particular situation. Presence of a parental mental health disorder and CYFS involvement also do not seem specific enough to really identify families at high risk of treatment failure, especially when these are included with an OR rule. One wonders again why the decision to initiate the EIYP program is not predicated more directly on evidence of lack of benefit at some point during the program (e.g., possibly halfway through) when it is possible to begin to see which families are having difficulty with program benefit and which are not. This would seem to be one of the implications from one of the key references cited in the introduction (Beauchaine, Webster-Stratton, and Reid, 2005), which argues that changes in targeted parenting behaviors actually mediate the program outcome. As designed, the study proposed seems largely to ask the question of whether adding the EIYP will result in benefit to all families where need for the IY program is identified. The initial argument seems to make the case that the economic benefit of the EIYP program is likely to come from being able to better serve families with the greatest risk of program non-response. It is not clear that the current design efficiently targets families at greatest risk of non-response. If this is not the intent, it would simply be more appropriate to say that this is a test of an enhancement to the IYP for all families where need for IY is present. (major)

2. With respect to the analytic approach described, the authors clarified that they would utilize change scores on the dependent variable (ECBI, for example), while also controlling for the initial baseline level on the dependent variable. As described by Allison (1990) [http://www.statisticalhorizons.com/wp-content/uploads/Allison.SM90.pdf], there are really two basic analytic options for examining change over time. The first is
to use the dependent variable at post, controlling for its initial level prior to intervention, or simply to analyze change scores as the dependent variable, not to do both. Allison provides an extensive discussion of how to think about which option makes the most sense for a particular study situation. The authors are likely not to want to both use change scores and control for the initial level of the dependent variable in their analyses (minor)

3. The authors clarified that they planned to conduct analyses separately for changes from pre to post and from post to follow-up in order to make clearer different patterns of potential change over these different time periods. Although this is an acceptable approach to analysis, it is still quite possible, and even desirable to model post and follow-up in the same model. One model can accommodate explanation of pre-post change and post-follow-up change, and aid in addressing the presence of missing data. It is not necessary to approach data analysis in this manner, but it certainly has advantages that are worthy of further consideration. (discretionary)

3. Given the randomization plan outlined, which involves parents in the same parenting group being randomized to either IYP or to IYP + EIYP, one needs to be aware of the possibility of social threats to the study’s internal validity. Parents in the same groups will become friends with one another and may talk about their different experiences with involvement in the program. There is always the potential risk that parents not in the EIYP condition will try to learn from what is happening in that condition, which could undermine the intent of the study to some degree. The authors will want to consider have methods for observing/understanding the degree to which this occurs. (discretionary)

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

**Quality of written English:** Needs some language corrections before being published

**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.