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 randomised 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)

Version: 5 Date: 27 January 2014

Author's response to reviews: see over
The Editor
Trials Journal
15th January 2014

Dear Sir,
Thank you for your additional comments and suggestions for this protocol. We appreciate your feedback and have addressed each of the comments. We have “tracked” all changes as requested.

Editorial request;
1. A legend section has been included after the reference section.

Reviewer Comment 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)

Response:
In general research shows that independent predictors of poor treatment outcomes fall into 4 categories that include family demographics such as maternal age; child variables (e.g. severity of child behaviour); parent variables (e.g. parental mental health, family violence); participation and adherence; and family variables (for example poor parental education/occupation, life
stressors, substance use, poverty and so on). We have therefore used these criteria as a guide to select “high risk” families for this study. We have had to be pragmatic in choosing factors that could be easily implemented if this program is to be scaled nationally. The behavioural scale will allow us to identify children at increased risk of non-response. While we agree that an alternative would be to track response and enhance the programme once families have been shown to have a poor response, we believe that this approach would be difficult to implement widely and consistently. There is also a potential negative impact on the families, who would be offered the enhancement while continuing to attend a group in which families are doing well, and are not deemed in need of further intervention. This has the potential to increase a sense of failure, in an already vulnerable population. Additionally, having the intervention in place during the first part of the programme is important because the content focuses on building a positive parent child relationship and promoting positive behaviours. The first 6-8 weeks of IYP cover such topics as child directed play and special time, social emotional and persistence coaching, praise and rewards. It is during this part of the programme that parents need to make cognitive shifts in the way they conceptualise their child, make behavioral changes in how they interact and react, and learn ways to promote positive behaviours. This change in parent-child interaction and relationship needs to be established before the programme content shifts to cover the discipline strategies such as limit setting, ignore and consequences.

While parental age could be used as a screen, we are concerned that this would be unduly restrictive, as we have many high risk families of all ages. Family violence is indicative of major interpersonal difficulties and indicates a high likelihood of poor and coercive parenting, one of the major risk factors for non-response.

To make these arguments clearer in the protocol we have re-ordered the introduction and added a section on page 6-9 to justify the criteria for selecting families at greater risk for non-response to treatment.

**Reviewer Comment 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)*

Response:
Our statistician (CF) is aware of the paper you quote but has commented; “I'm reluctant to abandon our proposed strategy of analysing the change score while also controlling for baseline level. This is not an uncommon strategy despite the article, which focuses on social*
science contexts, rather than those with 'clinical' issues.” He has revised the text describing the analysis as follows:

The primary outcome measure, the change in the parent scores on the ECBI total problem score from pre- to post-intervention will be calculated for each individual and will be compared between randomised groups using ANOVA with randomised group and strata as fixed factors. Additional sensitivity analyses will be undertaken using an ANCOVA model and including the baseline level of the change score as a covariate. See page 18

This will allow us to address the points you raised while also carrying out analyses we believe to be more robust.

**Reviewer Comment 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)

Response: As above

**Reviewer Comment 4.**

*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)

Response:

We have considered the potential ‘contamination’ of the IY group by the EIY group but do not think this is likely to be a major issue. Sharing with each other in the group is part of IYP learning process which we can not limit but the overall time spent sharing experiences is small compared with the in-home coaching provided. We believe the main active ingredient of the enhancement is in vivo practice, thorough revision of the material from the group, tailoring the strategies to meet the unique needs of the family and addressing specific barriers for implementation. We believe the possible effect of the control group learning from the intervention group is therefore likely to be minimal compared to the personalised coaching.
We appreciate your feedback and hope these changes have adequately addressed your comments. We look forward to hearing back from you.

Dianne Lees