Author’s response to reviews

Title: The effectiveness of the Inspiring Futures parenting programme in improving behavioural and emotional outcomes in primary school children with behavioural or emotional difficulties: study protocol for a randomised controlled trial

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Author’s response to reviews:

We are very grateful to the three reviewers for their helpful comments and provide a response below to those items requiring action (see paragraphs with the heading 'RESPONSE'). As regards progress of the study, data analysis is almost complete and we are in the process of drafting the main outcomes paper. (When the paper was originally submitted it was in the data collection phase.) We have not submitted any papers on the trial besides this protocol article.
Reviewer reports:

Geoff Lindsay, MEd (Ed Psych) PhD (Reviewer 1): The protocol relates to a UK developed parenting programme. The research is underway, indeed due to end in October 2017.

The evaluation of parenting programmes, especially those developed in the UK, is important in identifying both those programmes that are effective for the purposes specified, and under what conditions.

This protocol indicates that the study is well thought through and has many strengths. This review focuses on the design of the study as reported in the protocol, recognising changes in the protocol itself may be too late to have effect.

There are two preliminary points:

1. I note the study has received ethical approval by the Warren House Group Research Ethics Committee. This protocol reports the use of an implementation group and a non-intervention group who will be asked to provide data. This design, therefore, offers no opportunity for the control group to receive the intervention, e.g. waiting list control. How is this justified?

RESPONSE: Prior to testing the intervention, we were uncertain about its effectiveness, and owing to timescales and resources it was not possible to test effectiveness rapidly and then, if found to be effective, allow control arm parents to receive the intervention. A related point is that some control group children would have aged out of the intervention by the time it could be offered to them. Further, control group children had access to all services as usual and we have no reason to believe that services were withheld. There is also evidence that waiting list control design may exacerbate intervention effects in a trial because the control arms feel ‘compelled’ to report poor outcomes at post-treatment/follow-up in order to ensure they are still eligible for the intervention (e.g. Sedgwick, 2013; Furukawa et al., 2014).


2. There is a logic model but no reference to the handbook for the programme - what are the publication details and description? Has there been any previous research, in particular a feasibility study to support this RCT?

RESPONSE: We have added a reference to the handbook (p.5). We have also added a paragraph on small earlier study (p.6). It was not possible within the confines of Realising Ambition to conduct a feasibility study for the trial of this intervention, although we recognise the importance
and value of such studies and will refer to this in the results paper. Regarding intervention feasibility, it was an established intervention when the trial commenced, although additional support was provided to Malachi prior to and during the trial, notably with recruitment and fidelity measurement.

In terms of the protocol itself:

Adequacy of testing the hypothesis

3. The study comprises an RCT design. This is explained clearly. The aims and three objectives of the research are clear and appropriate. There are several challenges to the likelihood of success of the study.

4. The planned attrition rate is 20%. Attrition rates vary and may be relatively low in studies such as this where the data collection is conducted face-to-face (normally) and at home. The choice of this estimate is not unreasonable.

5. A total of c100 schools/children's centres would provide a large sample to access eight parents per school - the children will be 6-11 years, Year 2-Year 6. This could mean most groups from Key Stage 2 (Y3-Y6) and some of Key Stage 1 (Y2), and depending on the school/organisation, infant and junior, or combined schools.

6. The 2-phase design is attractive in terms of parent need: some parents requiring more/longer support will receive this. This could lead to parents undertaking a 24-week course. This raises practical issues regarding attrition. A feasibility study would have examined this. Furthermore, the longer period will include most 'needy' parents, which is likely to lead to higher attrition. These factors may seriously reduce the number of parents in the intervention arm rendering the 20% rate estimated as an under-estimate.

RESPONSE: We now know that the attrition rate at Time 3 was 26% and will discuss this in the results paper. We will also compare demographics and baseline scores for participants who are lost to follow-up and those who are not.

7. The measures are appropriate with both child and parent foci covered. These will take a not insignificant amount of time during the session which will be challenging, but other studies have overcome this. I assume, p12 line 52, that the 'additional' baseline data, comprises the measures? Please clarify.

RESPONSE: This is correct – we have clarified accordingly.

8. The use of the SDQ Total score promotes a higher level of reliability. Examination of the scale scores is important as the SDQ includes scales that are not directly susceptible to change because of the intervention.

RESPONSE: We can confirm that the analysis does this.
9. The methods for data collection, recruitment and retention, randomisation and blinding are appropriate.

Replication

10. The protocol generally provides a full account of the study which facilitates its replication. The less clear parts include the programme itself (no references) and the transition from Phase 1 to Phase 2 for selected parents. However, the latter depends on judgements at the time and the basic approach will allow replicability.

RESPONSE: We have added a reference to the programme manual (p.5). We have faithfully reported the criteria that Malachi apply for determining who is selected for transitioning from the group element to the one-to-one sessions, and recognise that to some degree it is a matter of judgement on the part of the facilitators. In the analysis we will explore if and how this group is different to other programme recipients.

Planned statistical analysis

11. The Intention to Treat method will be appropriate depending on the level of attrition. As this rises, the missingness factor can be measured but its salience and validity decreases.

12. The use of clinical cut-offs as well as continuous score results is reasonable.

13. The analytic plan is reasonable, however the sample sizes make some analyses problematic, e.g. ethnicity (explain categories).

RESPONSE: We have clarified that these analyses will be subject to having sufficient numbers in the relevant sub-groups (p. 23). In the analyses the ethnicity categories used are likely to be ‘White’ and ‘Non-White’ but this is to be confirmed.

Writing

14. This is appropriate; clear and well presented.

Summary

This is an interesting study. Given the fact it is almost ended, there is little change of protocol that is possible, other than clarifying the document.

Oana Alexandra David (Reviewer 2): This topic is of importance and there is a high value in researching the efficacy of parenting programs. The strength of the study is the statistical power offered by the sample size. However, the enthusiasm is limited by the following shortcomings in the methodology proposed:

- The program needs to be described in details for each session.
RESPONSE: We have amended the description of the programme content but are reluctant to spell it out in more detail because (a) we have checked and believe that we have fulfilled the criteria specified in the TIDieR checklist (Hoffman et al., 2014) and (b) the level of detail about the intervention provided is commensurate with that provided in many other protocol articles.


- While authors present in the intro data regarding the efficacy of cognitive-behavioral group based parent programs, then they choose to build a new one based on „A combination of child development education and psychodynamic, transactional and solution-focused therapy is used to improve parenting skills.". The rationale for doing so is not provided.

RESPONSE: We should clarify that the intervention was developed by the Malachi Trust, not the research team, and that it was already an established intervention prior to the trial. Nevertheless, we have sought to clarify the issue raised (see p.10). The psychodynamic and transactional approaches are designed to increase parent awareness of how (a) past experiences influence current behaviour, (b) maladaptive coping strategies affect parenting behaviour and (c) parenting behaviour affects child behaviour. Child development education and solution-focused approaches are used to further help parents improve their parenting skills.

- Authors mention research on the strategies found to be more effective in such programs but they do not seem to be part of this program.

RESPONSE: The majority of these elements are contained in Malachi’s programme (p.5) but the emphasis in the programme is on a more on the approaches described above.

- It is not clear why CWQ is used since it is a general measure and other measures are available for parent specific emotion-regulation.

RESPONSE: The programme does not focus particularly on parent-specific emotion regulation but rather on a range of different strategies that parents might employ to cope with stressful events. The WCQ is a tried-and-tested measure that is suitable for this purpose.

- Follow-up is used incorrectly here and this is misleading since it suggests that long term results are registered for the program. Follow-up is actually post-test since some of the sample will receive intervention in the meantime. Week count should be made from post-test not from the beginning of the intervention. It would be useful to follow participants at least 3 months after the termination of the intervention.

RESPONSE: There are three data collection points in the trial: baseline, after the group-based intervention (received by all intervention participants), and after the one-to-one sessions (received by some intervention participants). We think it is confusing if we use the term ‘post-test’ (or similar) because of the two-part nature of the intervention. For that reason, we have used
the term ‘follow-up’ and specified clearly what it means (i.e. relative to date of randomisation). Although the term ‘follow-up study’ is commonly used to mean studies with a follow-up several months (or more) beyond the end of the intervention, we think it is common in trials to use the term ‘follow-up’ to refer to any data collected post-baseline, including at the end of the intervention.

- clarification needs to be made in terms of intent to treat analyses and definition of drop-outs.

RESPONSE: Participants will be analysed according to the trial arm to which they were randomised, regardless of whether or not they received the intervention. The use of multiple imputation means that all participants will be included in the analysis, even if they dropped out of the trial (refused to provide data, or unable to find) before Time 2 or Time 3 data were collected. We have added a sentence to make this clear (p.23): “This means that, unless they withdraw consent completely, all randomised participants will be included in the analysis – even if they drop out (refused or unable to contact).”

Sophie Havighurst (Reviewer 3): This trial describes a sound study of good clinical practice. Use of a randomised controlled trial of an intervention will enable an evaluation of the practice of this service to be evaluated well. It would have been strengthened by also gaining evaluation data from other sources - currently the primary outcomes is limited by use of parent-data only (other than implementation data) that is subject to expectancy bias. However, this is a pragmatic trial and will still provide useful information about group differences.

RESPONSE: We will acknowledge this limitation in the results paper.

From the beginning there was a sound theoretical rationale provided. Great to see attention to family of origin and broader issues that impact parenting rather than just offering behavioural aspects of parenting which are usually limiting for a clinical service. The broader theoretical origins of the intervention provide an eclectic intervention (therefore being difficult to discern the key components of the intervention) that perhaps better reflects what is often delivered in services.

The inclusion of a partner is clinically sensible but may mean the study is compromised by have some families getting a more optimal (and different) dosage than those with only one parent involved.

RESPONSE: We will acknowledge this limitation in the results paper.

I was surprised by the exclusion criteria of parent mental health difficulties which will occur at a much higher rate in this sample - and are likely to be casually related to the problem. For example anxiety and depression might occur in 20-30% of parents and should not prohibit group involvement. In addition how does one rule out those with low self-esteem which again is likely a part of the cause of the child's problems? These criteria seemed in-exact as exclusion criteria.
RESPONSE: It is important to clarify that these are not exclusion criteria per se i.e. the qualifying phrase in the sentence in question is important; these become exclusion criteria when they “would seriously affect their ability to participate in the group sessions” (p.9), in other words difficulties of a significant severity. We have italicised this phrase for emphasis. These are the criteria applied by the service delivery organisation, who assure us that mental health problems in themselves are not a reason for excluding parents.

The Intervention was well explained. Origins of the intervention components were not always clear - and seemed more generic.

RESPONSE: We have elaborated a little, partly in the light of comments from other reviewers (see above).

Measures matched model and hypotheses and were well described.

Design clear. Figures describing Participant flow were also clear.

Power analyses seem appropriate and accurate. Proposed statistical analyses comprehensive. Randomisation clear.

Overall, a well described RCT trial of a clinical service delivering a parenting intervention.

ADDITIONAL CHANGES

In line with the recommendation of Flight et al. (2016), we have changed text on page 23 from:

“Linear mixed effects models (for continuous outcomes) and generalised estimating equations (for binary outcomes) will be used with group as a random effect in the intervention arm”

To

“Linear mixed effects models (for continuous outcomes and the binary outcome) will be used with group as a random effect in the intervention arm”


We have also made some minor cosmetic changes to the text.