Reviewer’s report

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

Version: 1 Date: 12 Sep 2017

Reviewer: Geoff Lindsay

Reviewer’s report:

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?

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?

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.

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.

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.

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.

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).

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.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

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