Author's response to reviews

Title: School based intervention to reduce anxiety in children: study protocol for a randomised controlled trial (PACES)

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Author's response to reviews: see over
Dear John Norrie

MS: 1869072230731713

School based intervention to reduce anxiety in children: study protocol for a randomised controlled trial (PACES)

Thank you for the referee reports regarding the above. I list a point by point summary of how we have attended to the issues raised by the referees below.

Referee 1

1. Study design
   Minor revision: We confirm that our study is not powered to detect differences between the two FRIENDS arms (School and Health led) although we do intend to undertake an exploratory analysis of differences between these arms. This has been clarified in the power calculation section on page 10 and in the statistical analysis on page 11.

2. Replication of the work
   Minor revisions
   a) Time points for secondary prevention (comparison baseline and 6 months) and primary prevention (comparison baseline and 12 months) have been added (page 5).
   b) Definition of "high" levels of anxiety and depression has been added page 5 i.e. top 10% of highest total RCADS in each group at baseline.
   c) Content of PSHE. The content of the comparison group (PSHE curriculum) will be assessed through semi-structured interviews with school staff (stated on page 8). This is a pragmatic trial and the interviews will be analysed to determine any overlap with FRIENDS.

Statistical Analysis – discretionary revision

   a) The point about ceiling effects is well made. We considered this when calculating our sample size and believe that we will be able to detect the difference (3.6 points) as stated in our power calculation on page 10.
   b) We have already stated in our statistical plan on page 10 that we would analyse children with high and low baseline symptoms. In view of earlier comments we have also added our description of high (top 10% of highest total RCADS in each group at baseline) and low symptoms (remaining 90% children).

Writing acceptable – discretionary revisions

   a) We thank the referee for the suggestion about including a statement about the potential implication of our findings. This will obviously form a major part of our outcome paper and we would prefer to discuss it in more detail once our results are known.
   b) Plans for dissemination. Whilst this might be of interest we would prefer not to include our dissemination plans in this paper.
   c) We thank the referee for the typo (Ethical approval and consent) which we have corrected.

Referee 2
a) Thank you for pointing out the typo which has been amended (page 7)

Suggestions for clarification/discretionary revisions

1. Aim of the study. We thank the referee for requesting clarification of the population. We hope that the amendments to the aims section detailed above address this point (page 5).
2. Ethical approval - this typo was also identified by the referee above and has been corrected
3. We have referred to an opt-out parental process (page 5) which I believe is the usual terminology for our approach.
4. We have rewritten the section on school recruitment (page 6) which we hope makes our sample clearer.
5. We have added the total number of children (1448) involved in the project as suggested (page 6).
6. PSHE is explained in full on page 8.
7. This project is externally funded via the NIHR and was subject to competitive review. The power calculation has therefore been subject to rigorous examination. The power calculation was based on a difference between FRIENDS (School and Health led) and usual PSHE. This has been clarified in the power calculation on page 10.

The study is not powered to detect a difference between the two FRIENDS arms although we will undertake an exploratory analysis of this. This exploratory analysis has been clarified on page 11.

Referee 3

Major revisions.

1. Although no hypothesis have been specified the aims of this project are clearly stated on pages 4 & 5. We do not feel that any further clarification is required.
2. As mentioned earlier our primary question and analysis is to compare FRIENDS (School and Health) versus usual PSHE. We will undertake an exploratory analysis of differences between the FRIENDS groups but this is not our primary question. We have however added a sentence in the background to highlight that trained school staff and psychologists are equally effective when delivering FRIENDS (page 4).
3. Study arms. We thank the referee for their comments about study arms and the need for clarification. In terms of specific questions
   a. This is a pragmatic trial and as such we do not know how many school staff will be involved in each session. Some children may for example have additional educational needs and have a support worker with them in the classroom. This worker will however be focused on the individual child and will not be a wider resource for the class. Therefore we believe our description that at least three adults will be present for session delivery is accurate.
   b. We have clarified on page 7 that health staff will be supporting the school staff who will lead the session. They do not have an active leadership role but are there to support the teacher’s leadership. As mentioned previously our primary analysis is not between health and school staff. If there was any effect when health staff supported teachers (which we do not expect) this will not confound our results.
4. Treatment as usual. As stated on page 8 semi-structured interviews will be conducted with school staff to determine the content of treatment as usual. This will be conducted after they have delivered their PSHE rather than before and so will not influence what the teachers do. This has been clarified on page 8.

5. We thank the referee for pointing out the process for completing assessments and have added a sentence to describe how child data is collected on page 8.

Minor essential revisions

1. Background. We provide a summary of treatment components of the intervention on page 6 but have added some information about how they will help reduce anxiety as suggested.

2. Percentage has been added on page 6 as suggested

3. The health professionals were recruited via open advert and competitive interview. We have not added this to the paper since we consider the key issue to be a description of their training and experience.

4. As stated on age 10 a further complete case analysis will be undertaken if we discover evidence of bias arising from missing data

Discretionary revisions.

1. We have amended the abstract as suggested.

2. We have clarified this as point prevalence (page 2)

3. We have clarified that this is an emotional disorder (page 2)

4. Amended as suggested (page 2)

5. Amended to say childhood and adolescence ([age 2]

6. Clarified as effecting everyday functioning (page 2)

7. We have removed “In terms of content” from the first part of this sentence which makes it less awkward (page 3).

8. We consider all those we cite as mediating variables.

9. We have added “reduction in symptoms of low mood” (Page 4)

10. We have now defined PACES at the start of the design section.

11. The typo has been amended (page 6)

12. The typo has been amended (page 7)

13. Comma inserted (page 9)

14. Comma inserted (page 9)

15. This sentence has been broken up (page 10)

We feel that we have adequately addressed the referee’s comments and hope that you will be able to make a speedy decision about whether our paper is now suitable for publication in TRIALS.

Yours Sincerely

Paul Stallard