Reviewer’s report

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

Version: 2 Date: 18 September 2012

Reviewer: David Heyne

Reviewer’s report:

The authors are to be commended for their work in establishing what is clearly a very important trial.

Major Compulsory Revisions

1. No hypotheses are specified.
2. Evidently an important aspect of the study design is the comparison of outcomes between school-led and health-led FRIENDS, but the Background to the study does not develop a strong case for comparing these two groups.
3. Study arms: Given the design of the study, it is important to be clearer about the similarities and differences between school-led and health-led FRIENDS. The paragraph starting “At each session …” needs to be clearer. How many school staff will be involved per session. Is it just one, or might it be more? When health staff assist school staff, what will the health staff be doing / not be doing? Will they be involved in delivery in any way? If they are involved in delivery, this would be a major confound for the comparison between school-led and health-led groups with respect to outcome.

4. Treatment as usual: How will the information derived during the semi-structured interview be used? Will it sometimes influence what happens during treatment as usual, during the study?
5. There is no description in the method of the process used to gather data at pre-intervention and at follow-ups (by whom? where? under what conditions, etc.)

Minor Essential Revisions

1. Background: The Introduction would be enhanced by including more description of how the intervention components are expected to prevent/reduce anxiety and depression in young people.
2. School recruitment: 45 schools out of 268 schools expressed interest; this can also be represented as a percentage (17%).
3. Health led FRIENDS: How are the health professionals recruited?
4. Statistical Analysis: “A further complete case analysis may also be undertaken …”; what does this hinge upon?
Discretionary Revisions

1. Abstract: “need to investigate alternative preventive approaches” could be changed to “need to investigate preventive approaches” or “need to investigate alternative approaches in the form of prevention”.
2. Background: “indicating that 4-8% of children”; helpful for the readership to specify what kind of prevalence rate is being reported here.
3. Background: “criteria for a severe disorder”; meaning anxiety disorder / depressive disorder, or meaning severe anxiety disorder / depressive disorder; or something else?
4. Background: “which fall below (i.e., sub-threshold) criteria required for a formal diagnosis” might better be written as “which fall below criteria required for a formal diagnosis (i.e., sub-threshold)”
5. Background: “that during childhood” meaning childhood and adolescence? Or specifically childhood?
6. Background: “but are nonetheless significant”; specify in what way they are “significant”.
7. Background: “In terms of content …” is a long and awkward-sounding sentence.
8. Background: “... mediating variables such as”; are these all mediating variables?
9. Background: “FRIENDS also had a positive effect upon mood in the high anxiety group”; it’s helpful if this is a bit more specific.
10. Design: PACES is referred to in the Table heading, but it has not yet been spelled out for the reader.
11. Ethical Approval and Consent: “required to provide signed assessment” is probably meant to be “required to provide signed assent”
12. Study arms: “insure” is probably meant to be “ensure”.
13. Secondary Outcomes: comma required after (SDQ), before “a brief”
14. Outcomes for the economic evaluation: comma required after “use data”
15. Statistical Analysis: the sentence including “will be assessed and using” reads rather awkwardly.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**
'I declare that I have no competing interests'