Author's response to reviews

Title: A community-based pilot randomised controlled study of life skills classes for individuals with low mood and depression.

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Version: 4 Date: 1 December 2014

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A community-based pilot randomised controlled study of life skills classes for individuals with low mood and depression.
Carrie-Anne McClay Katrina Collins Lynsay Matthews Caroline Haig
Alex McConnachie Jill Morrison Pat Lynch Louise Waters Ilena Day
Grainne McAnee and Chris Williams

Dear Dr van Ballegooijen,

Thank you for your feedback and suggestions concerning the above manuscript. We have addressed each issue as outlined below.

This is a pilot study and the study aims, hypotheses, description of outcome measures and conclusions should unequivocally be described in this context. If I understand correctly, this study will indicate the feasibility of a large-scale RCT. Primary outcome measures are rate of recruitment, retention, acceptability and adherence to the intervention (as stated in the Abstract). However, the description of outcome measures (page 8 and 9), the analyses (page 10), and the included tables appear to be focussed on efficacy. Overall, in this paper, I miss a consistent emphasis on the primary outcome measures.

Thank you for raising this issue. As suggested, we have reviewed all aspects of the manuscript to reflect the focus on the primary outcomes of the pilot study – recruitment, retention, adherence, satisfaction and ability to collect data coupled with establishing an estimate of clinical effect to inform the power calculation for the substantive study.
The abstract, results/outcome measures’ section have been edited to reflect this. Much of the efficacy analyses in the results section has now been removed (including accompanying figures and tables) and the discussion has been edited and re-structured to emphasise the key findings of the pilot study.

On page 13, the paragraph ?Informing the power calculation for the future substantive study? intuitively seems out of place and belonging to the Discussion section.

Information concerning the power calculation has been moved to the discussion as advised.
You base the power calculation for the future RCT solely on proving a difference among a severe subgroup. Is that subgroup this interventions target group? If so, why do you not exclude milder depressed patients? If not, then I assume your target group is supposed to include milder depressed patients as well. In that case I'd expect the power calculation to be based on the entire sample, including the milder cases. If you expect less effect for milder cases, your future RCT might not have enough power to prove it, because the power calculation is based on the large effect within the severe group.

The aim in the future large RCT was to deliver the intervention to individuals with at least moderate depression (scoring 10 or more on the PHQ-9), therefore only data from those scoring at this level in the pilot were used to inform the power calculation. We have now included an explanation for this choice (bibliotherapy is known to work for this group and not for those with only mild scores). The inclusion on those scoring under 10 allowed us to more quickly recruit and fill the classes in order to provide efficient delivery of the intervention and limit any delay in beginning the classes. This has been clarified in the discussion section (sub-heading: Power calculation).

Limitations?

This was a small pilot study, designed to test whether such a trial is viable, and as such was not powered to demonstrate efficacy. The data collected from this pilot study however has been valuable in calculating the required sample size for the future RCT. This is too negative. This study was not aimed at demonstrating efficacy. The question for the limitations is whether this study has been able to draw conclusions about the primary outcome measures.

A final limitation of this pilot study is that the primary follow-up point was 3 months, meaning that the longer-term impact of the intervention could not be assessed. This is not a limitation in my opinion, because you did not aim to assess the longer-term impact.

Thank you – these limitations have been removed.

Thank you for your comments, we feel they have improved the paper.

Yours sincerely,

Professor Chris Williams
Professor of Psychosocial Psychiatry and Honorary Consultant Psychiatrist