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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Author's response to reviews: see over
Dear Sir/Madam,

I would like to thank the reviewers for their positive feedback and helpful comments regarding the above manuscript. I have addressed each issue as detailed below.

Reviewer: Lara Ebenfeld

Reviewer's report:

Major Compulsory Revisions:

1. Abstract: Primary and secondary outcome measures: Please state what exactly is primary outcome (it is usually only one measure); what are secondary outcomes.

   The main aim of this pilot study was to test the research design. We aimed to determine our ability to recruit from the community and retain participants, collect data and deliver the intervention. The primary outcome in the future substantive study will be Patient Health Questionnaire (PHQ9) score (depression) so PHQ9 scores in this pilot will be used to inform a sample size calculation.

2. Abstract: Results: In this section you mention 2 x 25 participants. In the study flow you randomized 53 participants. Please use the correct number.

   Fifty-three participants were recruited (29 in Scotland and 24 in Northern Ireland). Of these, there were no baseline PHQ-9 data recorded for 7 patients, these individuals were excluded from analysis. The final analysis was therefore based on data from 46 participants who entered the study, were randomised and provided baseline data. This has now been clarified in the abstract and in the results section.
3. Abstract: Results: If you report a p-value, please add the test method where it is based on (e. g. t-test etc.). Check this in the whole manuscript and be sure to use the style the journal proposes. (Also lines 331, 338, 339, 343, 344 etc and tables).

   Thank you for this comment. We have ensured that the test used has been stated when necessary and added information in footnotes and titles on the tables but do not believe it should be stated for every result since there is a full explanation of tests used in the methodology section and we have been advised to limit the length of the results section since it is a pilot study.

4. Methods: Recruitment and participants: In the abstract you mention the duration of depressive symptoms for one year as inclusion criteria. Please make sure to state this here as well and mention how it is measured. State this also in the discussion when you summarize what you have done.

   Duration of depressive symptoms was not part of the inclusion criteria and is not listed in the Methods or the Abstract section.

5. Methods: Outcome measures: lines 215, 237: I guess that reference number 15 is not correct. You mean 18, right?

   Thank you for highlighting this mistake, it has now been amended.

6. Methods: Outcome measures: line 244: Reference number 18 might be 17. Please check and make sure that you use sequential numbers in your manuscript.

   This has now been amended.

7. Discussion: lines 417/418: Here you say that an adherence of 50% is "high". In the conclusions line 456 you describe adherence as "reasonable" what is more appropriate to my mind. Please be consistent. If you choose for "high adherence" please explain where this is based on and how you define adherence.

   We now refer the adherence at ‘reasonable’ in both the discussion and conclusion sections.

8. References: Please check all references carefully regarding formal errors and be sure to use the guidelines provided by the journal. Especially have a look at reference numbers 2, 3, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22 (it is not in your manuscript), 23.

9. Overall: The whole manuscript should be checked carefully regarding correct presentation of reference numbers (e. g. lines 103, 104, 107, 108, 109, 161, 184, 215, 216 etc.. Mention reference before punctuation, e. g. line 119: no punctuation).
Re. points 8&9: Thank you, all references have been checked and amended.

10. Overall: Choose either British English or American English (e.g. 'randomized' vs. 'randomised').

   We now use 'randomised' throughout.

11. Overall: Please make sure to report statistical numbers in the same style. For example you use for standard deviation "+/--" vs. (sd=...)".

   Thank you. We now use sd throughout.

Minor Essential Revisions:


   Thank you for this suggestion, we now state this is a depression measure.

13. Abstract: Results: Explain abbreviations of IA and DAC when used first.

   These abbreviations are now explained in the abstract.

14. Background: line 111: Why does one to one contact by phone or face to face result in a delay? It would be good to make this point clearer.

   The issue here is the advantages/disadvantages of one-to-one and group based support. Group based support means that 10-15 people can be supported in a relatively short space of time, during a 1.5 hour session for example. When support is delivered on a one to one basis, only 4 people can be supported in this time (based on 20-30 minutes per person). Therefore, class based guided self-help has the potential to increase capacity and reduce waiting times. This is now explained in the background section.

15. Background: line 111/112: I am not a native speaker but you should check if "deliver a resource" is correct language. To my mind it is possible to deliver a training in order to activate/manage resources.

   This sentence has been amended to aid understanding.

16. Background: line 128: What exactly do you mean with "make-up of surrounding community"?
17. Methods: Recruitment and participants: line 150/151: Where is your assumption of sufficient sample size based on?

As this is a pilot study, we were unable to carry out a power calculation to determine appropriate sample size. However, we realise justification for the sample size we chose is needed, this has now been added to the methods section. The aim of the pilot was indeed to obtain an estimate of clinical effect to inform the power calculation for the substantive study.

18. Methods: Intervention: I would prefer if you state it earlier that the intervention is CBT-based (maybe in the first sentence).

Thank you for this suggestion. “CBT” is now mentioned in the first sentence of this section.

19. Methods: Intervention: line 193: Why do you use capital letters for “Revision” and “Reunion”?

This sentence has been amended; the name of the revision session has been added.

20. Methods: Intervention: line 197: Please mention by whom the sessions were manualised/scripted.

This has now been clarified in the intervention section.


I think you may have meant line 224, the reference has now been added.

22. Methods: Outcome measures: line 240: Make sure to report the original paper in the first sentence like you did it with the other questionnaires as well.

Thank you, this has been added.

23. Methods: Outcome measures: line 251: I would advise to use "The results of the interview of the study will be published separately" because you use the class feedback form (what is qualitative as well, if I understood correctly) in your results in this paper. Please check.

Thank you. This sentence has been amended.

methods "Statistical Methods"? Please be consistent with other parts of the manuscript.

This heading has been changed to: “Statistical methods”

25. Methods: Why do you only choose for an intention-to-treat analysis? Particularly, in a pilot study it would be interesting to perform a per protocol analysis in order to get an idea of the efficacy of your intervention. Regarding the meaningfulness of a pilot paper, I would suggest to add such an analysis.

Intention to treat analyses were carried out as this approach gives more conservative results which we believe is more appropriate for a pilot study since the data will be used to estimate required sample size for the future large RCT. Per-protocol analyses were carried out and the results do not differ greatly from the ITT analyses. These can be added to the results section if required, although we may be concerned about the increased length of the paper.

26. Results: You choose to compare significant differences in mean scores of the different outcome measures at different times. That is okay, but if someone is not familiar with the questionnaires it would be great to add Cohen's d to get a better impression of the progress of the participants.

Thank you for your suggestion. We had not considered this necessary for this pilot study paper, however these can be added if thought to be essential to aid understanding.

27. Figures: Title figure 2: line 562: Please add full stop (like in title figure 1).

Full stop added.

28. Figures: Title figure 3: line 567: Please add full stop (like in title figure 1).

Full stop added.

29. Tables: Table 1: line 572: Full stop is not common at the end (like in table

Full stop removed.

30. Tables: Table 1: Add your test statistic (where is the p-value based on?).

A footnote has been added to explain the p-values in Table 1. The other tables report within- and between-group difference estimates, with 95% confidence intervals and p-values derived from missed effects regression models as described in the table titles and statistical methods section.

31. Tables: Table 3: Add your test statistic (where is the p-value based on?).

Please see above.
32. Tables: Table 4: line 581: Full stop is not common at the end (like in table 2).

   Full stop removed.

33. Tables: Table 4: Add your test statistic (where is the p-value based on?).

   Please see above.

34. Tables: Table 5: line 586: Full stop is not common at the end (like in table 2).

   Table removed.

35. Tables: Table 5: Add your test statistic (where is the p-value based on?).

   Table removed.

36. Tables: Table 6: line 591: Full stop is not common at the end (like in table 2).

   Table removed.

37. Tables: Table 6: Add your test statistic (where is the p-value based on?).

   Table removed.

38. Figure 1: Make sure that you use either British English or American English consistent with the rest of the manuscript (analyzed vs. analysed, randomized vs. randomised).

   We now use “randomised” throughout the manuscript.

39. Figure 1: Please have closer look at the layout (line width, boxes should be in line, consistency among whitespaces when reporting n’s).

40. Overall: Please be consistent with "3 months" vs. "12 weeks" for reporting your follow-up assessment (have also a look at figure 3).

   “3 months” is now used throughout the manuscript.

Reviewer: Harm van Marwijk

Reviewer's report:
This is an interesting and sympathetic study on group-based guidance support for a bibliotherapy approach for anxiety and depression in community settings, I assume versus usual care although this is not stated in the objectives. Delayed access controls were the comparison condition. This should be made clear, in the abstract and introduction (that reads well). The many results suggest that inference is possible in some way and I disagree with that.

Major compulsory revisions:

First a few important overall points/questions that need to be answered:

- Why was the PHQ9 score of 5 their inclusion criterion (mild depressive symptoms) an inclusion criterion and was their mean sample score over 14?

  We chose to include those with a PHQ9 score of 5 or above as this is the cut off for mild depression. The aim was to recruit individuals with mild, moderate and severe depression. The mean PHQ9 score of the sample was 14.5 (sd = 6.5). It is possible that those with mild depression (PHQ9 scores nearer 5) did not consider themselves in need of help as their symptoms were mild. We believe that the high scores of those recruited highlights the need for such community recruitment approaches as it shows that there is an unmet need for psychological interventions for depression in the community.

- The authors mention depressive and anxiety symptoms as outcomes and potential treatment focus but include only on PHQ9 depression symptoms, why? What does that mean for inference purposes?

  Efficacy relating to both depression and anxiety are investigated in this study. Although the course is expected to be useful for both anxiety also, depression is the focus of the intervention. Therefore, we chose the PHQ9 as our primary outcome and used PHQ9 data in the power calculation for the future substantive RCT.

- The paper is generally written well but has an overly English/British perspective for an international journal. NICE does not make guidelines for the whole world. To add a bit on the specifics of the UK situation (IAPT) would help international readers on the other hand to better place results. I saw several typo's in the references.

  Thank you for this suggestion, a short paragraph has been added in the background section to give context.

- The paper is a bit long and has much detail for relatively small samples. The number of tables is also rather large. Table 1 and 2 could be combined and table 3 could go in the text. Table 4 is reasonably easy to read although I prefer to read intervention and controls in columns rather than in rows. Tables 5 and 6 seem a bit much for such a small study and could perhaps be put in appendices.
Thank you for these comments. Tables 2 and 3 have been removed, the information is now in the body of the manuscript. We feel it is important to keep tables 3&4 (previously 5&6 in the main manuscript if this is acceptable).

We agree that intervention and controls in columns is often the best presentation of such data, we feel that our use of rows for treatments works better since we are presenting data at different time points.

- The paragraph on how the pilot would inform a subsequent trial I found difficult to understand. Was that preconceived? Was the design published beforehand? Why not if not?

The pilot study was carried out in order to gain information regarding the feasibility of recruiting from the community, delivering the intervention and collecting data from participants. The study also aimed to provide data concerning efficacy of the intervention and the outcome data was used to carry out a power calculation to determine the sample size required for a large RCT. These aims were outlined in the trial protocol (Current controlled trials. Ref: ISRCTN84893887); however the protocol was not published in a journal.


- Most psychological or psychotropic treatments work better for people with higher symptom scores. I am not sure such a stratification is needed for practice purposes.

Stratification for age, gender, use of medication and order to aid equal distribution of these factors across the two groups.


Thank for suggesting the inclusion of these references, they have been included in lines 478-483.
Yours sincerely,

Professor Chris Williams
Professor of Psychosocial Psychiatry and Honorary Consultant Psychiatrist