Author's response to reviews

Title: A randomised controlled trial of a community-based group-guided self-help intervention for low mood and stress: Study protocol.

Authors:

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

Thank you for the opportunity to respond to the editor’s and reviewers’ comments regarding the manuscript: MS: 1136170377913945, ‘A randomised controlled trial of a community-based group-guided self-help intervention for low mood and stress: Study protocol’. We found them very helpful and have responded to each point in turn and amended the manuscript accordingly.

**Reviewer 1**

**Major Compulsory Revisions**

- It would be helpful if the authors could provide a bit more information about the intervention. For example, in the keywords I see the term ‘bibliotherapy’, and I am wondering if there is a workbook or similar that accompanies the LLTTF classes? Are the sessions didactic or interactive? Are there activities to complete between sessions?

Additional information about the intervention has been added on Page 9, paragraph 1.

- Within the methods section, there should be a section that describes each of the measures used in the study. This should be followed by a section that describes the study procedure.

We have re-ordered, added subheading and added text regarding the measures used (starting on Page 18).

- The statistical analysis section refers only to the PHQ-9 outcomes, it would be helpful if you could briefly describe the planned analysis for the other measures used.

Since the other outcomes are continuous measures, we have simply stated in the statistical methods section that similar methods will be applied as for the primary analysis.

- I’m a bit concerned that the study sample size isn’t chosen to answer the primary research question. I think this needs to be clarified or reconsidered.

Our reasoning with the sample size calculation was that if we ensure sufficient numbers within the subgroup of participants with a baseline PHQ-9 score of 10 points or more, then we will automatically have enough in the sample as a whole. The only way this will not be the case is if there is little or no effect of the intervention within the subgroup with PHQ scores of 5-9 at baseline. If this effect
is observed, and the primary analysis consequently fails to detect an intervention effect, we will at least have sufficient power within the more severely depressed subgroup and may be able to demonstrate a diminution of the intervention effect amongst the less severely depressed subgroup.

**Minor Essential Revisions**

- **The described focus of the intervention is inconsistent across the paper. In the title, it appears that the focus is low mood and stress, but the primary DVs are measures of depression and anxiety. Neither low mood nor stress are included as keywords. The LLTF course is described as CBT for depression. Etc, please clarify.**
  The focus of our research is levels of depression, anxiety and social functioning. A key feature of the intervention is that common everyday language used. Therefore terms that people can relate to such as ‘low mood’ and ‘stress’ are used instead of ‘depression’ and ‘anxiety’. The paperwork for the project including the participant information sheet also use this language in order to engage these individuals who are self-referring from the community and may be more comfortable with this more informal language, rather than more clinical mental health terms. The project is a community based initiative and the classes are framed as life-skills classes, not a ‘treatment’ for depression. The trial has been registered with the current title so this cannot be changed. However, we have added the terms ‘low mood, distress, anxiety’ to the list of keywords.

- **Under the heading ‘Cognitive behavioural therapy’ – the authors state that NICE recommend CBT for ‘moderately low mood’ – it would be more accurate to say ‘NICE recommend CBT for mild to moderate depression’.
  Thank you, this has been amended on Page 6, Para 1.

- **We have recently reported the successful implementation of a LI CBT intervention in the voluntary sector is described in this paper, and it would seem useful to refer to this highly relevant study:**

  This reference has been added on Page 6, Para 1.

- **The participants section mentions an ‘interview’ – its not clear what this refers to.**
  Thank you for highlighting this error. First mention of the interview has been moved to Page 15, para 3, a further detailed description of the interview is included in the ‘Measures’ section on Page 17.

- **I wondered if there are any exclusion criteria regarding comorbidity, severity or risk?**
  This has been clarified on Page 14, Para 4.

- **Its not clear what the MINI is used for in this study, as confirmed diagnosis isn’t necessary for inclusion, nor is clinically significant**
change (e.g. moving from meeting diagnostic criteria to not) mentioned as an outcome metric – please clarify.

The MINI is being used with consenting participants. We are not including it as a mandatory measure due to the community based population being recruited. However, this measure will be helpful in describing the population being studied. This has been clarified on Page 16, Para 1.

- It is not clear how the information about a drop in PHQ-9 scores found in the pilot RCT relates to the calculation of sample size needed to detect a between group effect?

The reviewer is correct in that the sample size calculations depend only on the standard deviation of the primary outcome, and the magnitude of the intervention effect that we wish to be able to detect. However, we felt that adding the information about changes in mean PHQ-9 scores from the pilot helps to put the target intervention effect upon which the sample size is based into context.

- It would be helpful to clarify how adherence to the LLTTF class manual will be measured (e.g. what level of adherence is considered ‘acceptable’?), and how will this information be used in this study?

Additional information regarding the consistency checks has been included on Page 17, Para 3.

Reviewer 2

Major Compulsory Revisions

- It is stated that ‘participant safety and wellbeing is paramount’ however there are potential risk implications associated with asking participants to complete the eligibility measures by post. The participants are asked to complete the PHQ-9 on their own and return in the post to the researcher. Whilst any identified risk may be addressed at the point at which the questionnaires are returned if the risk is considered immediate then the time delay between participants completing the PHQ9 (question no9 regarding thoughts that they would be better off dead or hurting themselves in some way) may be too long. This is of particular importance for those participants who self-refer and are not separately seeking NHS help. An adequate explanation of how this could be managed e.g. by completing the PHQ-9 on the telephone when completing the MINI is required. The procedures for addressing risk issues throughout the trial should be detailed clearly in the protocol.

Participants are given information on how to seek immediate help for their emotional problems in the participant information sheet which accompanies the eligibility questionnaire. Although we are not recruiting from the NHS, many potential participants will be in contact with their GP and will be on anti-depressant medication for their low mood. Additionally, contact details of the research team are outlined on the participant information sheet to allow the potential participant to get in touch more quickly if required. It is not possible for the PHQ9 to be completed on the telephone at the same time as the MINI interview as this interview is not a mandatory measure so a proportion of individuals will not take part in this. As recruitment has started, we cannot
change the protocol regarding the collection of PHQ9 data. A statement regarding this has been included on Page 15, Para 1.

- An explanation needs to be provided to explain why only ‘those who complete baseline measures but fail to attend classes or fail to return follow-up measures’ will be invited to take part in a qualitative interview. Whilst it is advantageous to understand why people fail to engage with the intervention it is also of benefit to invite those who did engage.

We originally planned to interview those who did not engage in order to gain a different perspective than gained previously from interviews of attendees in the pilot study. However, due to low levels of drop-out to date, this element of the project has been removed from the protocol. The funders have agreed to this amendment.

**Minor Essential Revisions**

- In the participants section the sentence starting is either incomplete or the last word ‘using’ needs to be deleted.

Many thanks, this has now been amended.

- The participant section is the first place that an interview is mentioned ‘We anticipate that most, if not all, participants will agree to the interview’ and as such it is unclear what this refers to. This is explained later in the protocol in the follow-up section. Some explanation earlier in the protocol is required. It is unclear if a confirmation of diagnosis (using the M.I.N.I) is required for the participant to be included in the trial. If it is then this should be stated clearly and added to the inclusion criteria.

First mention of the MINI interview has been re-located and a full explanation included. Please see response above for more detail.

**Discretionary Revisions**

- The population statistics provided (5th paragraph of CBT section) are useful in determining that a self-referral approach has been used successfully previously to obtain mental health samples but it would be useful to determine if this method engages service users who may not engage in mental health services via traditional NHS methods e.g. minority groups. It would be useful to include any relevant literature within this section.

We feel this issue is best placed in the discussion section of the paper with reference to future research. Therefore, a paragraph relating to minority groups has been added to Page 26, Para 2.

- The LLTTF Classes section briefly describes the sessions included within the intervention and states that a ninth session takes place 6 weeks after the final class but it is not clear within the protocol the reason why the ninth session is conducted at this time point. An explanation of this would be beneficial.
The purpose of the 'Revision and planning for the future ' class is to revise the 8 week course content and also to deliver some advice on how to stay well by using various tools such as 'checking in days’ in which participants are encouraged to review their progress. The class takes place 6 weeks after the core 8 week course as it is thought that this is an appropriate duration for participants to integrate/apply the skills they have learned in the course in their everyday lives. The revision class therefore serves as a booster session to keep participants on track with the intervention, as they are advised to continue using the resources after the groups support ends for optimal benefit. This has been outlined in Page 9, Para 2.

- **It is highlighted, prior to the aims section, that the primary end point for the current RCT is 6 months (rather than 12 weeks). A discussion about the impact that this may have upon the outcomes would be useful – participants during this time may have engaged with/accessed a number of different interventions or services during this time, although it is understood that these will be identified through administering the CSRI at follow-up.**

In the pilot study the primary end point was 12 weeks. However, based on advice from the funders, we have extended this to 6 months for this substantive RCT. This will allow the long-term impact of the intervention to be assessed and groups can be compared at this 6 month follow-up point whilst the DAC remain a control group. It is true that this may increase the risk of contamination in the sense that participants may access other forms of support. However, this may be less likely in this community based sample than in a study based in primary care for example. Data on services accessed during the study will be collected at 6 months using the CSRI. This issue has now been discussed on Page 11, Para 2.

Finally, can I please request that all future correspondence is sent to Professor Christopher Williams (chris.williams@glasgow.ac.uk) as I am going on maternity leave on 2nd August.

I look forward to hearing your final decision.

Yours sincerely,

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