Author's response to reviews

Title: Group cognitive behavioural therapy for women with mild to moderate depression: pilot and feasibility study for a randomised controlled trial using mixed methods.

Authors:

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Author's response to reviews:

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1st April 2011

Re: Group cognitive behavioural therapy for women with depression: pilot and feasibility study for a randomised controlled trial.
Authors: Helen Cramer, Chris Salisbury, Joel Conrad, James Eldred and Ricardo Araya

Dear Sir/Madam

Please find below our point by point response to the BMC editorial board's concerns with respect to the above paper. Please get in touch if you need any further clarification.

Yours sincerely,
Helen Cramer

Editorial request

ANS: In response to this editorial request we have inserted a statement about the
study's ethical approval in the methods section and removed this statement from the acknowledgements section.

Reviewer 1:

1. The baseline measures and the 3 and 6 months measures should be in the same table so that the reader can compare the results between groups and time points more easily.

ANS: We do not agree that it would be appropriate to have the baseline data in the same table as the follow-up results for three main reasons: (1) baseline values are needed to compare the groups at baseline and to make sure that the randomization worked. It is the usual convention to present results of baseline values in an initial table for this purpose as we did in our paper in table 1; (2) all regression models in Table 2 are adjusted for baseline values so baseline values are less informative; (3) the table would be very large and complex to read.

2. The statistical tests described as "descriptive statistics" (p10) need to be defined, e.g. as t-tests and chi-square tests.

ANS: We have changed the wording on page 11 to make it clear that we described the characteristics of the intervention and control arms at baseline using simple descriptive statistics such as means and proportions. As is made clear in the CONSORT guidance, it is inappropriate to conduct statistical tests such as t-tests for differences between groups at baseline in a randomised controlled trial.

3. The measure of anxiety symptoms is referred to as "Beck Anxiety Scale" (p6). This measure is properly called "Beck Anxiety Inventory". The authors should spell out Beck Anxiety Inventory or BAI in the text and the tables.

ANS: We have removed the word ‘scale’ and inserted ‘inventory’ into the text box 1 on page 6. In table 4 we have now included details of each measure of each outcome.

4. A mean of about 45 on the BAI indicates high anxiety levels among the participants. The authors should comment on this and I'd like to see a discussion on whether the participants really presented depression as their primary problem.

ANS: We had scored the BAI from 1 and 4 rather than from 0 to 3, which is the usual convention. This does not alter the comparison between groups, but it does have an impact if one wants to compare the characteristics of our sample with other studies. We have now re-scored the data using the 0 to 3 system and changed the results accordingly in Tables 1 and 4.

The re-scored results still suggest a moderate (rather than high) level of anxiety in our patient population and we have now commented on this in the description of the sample in the results. As to whether or not the participants presented with depression as their primary problem this is more difficult to establish and of doubtful relevance. In usual clinical practice, many people with depression do not present it as their primary problem. The participants in our study all responded to
an invitation to take part in an intervention designed to help women who were having problems coping. We deliberately did not use medical terminology such as depression. We used an established cut-off point of 10 in the PHQ-9 as an inclusion criteria which is consistent with a diagnosis of at least moderate depression – women with lower scores on the PHQ9 were excluded.

Minor Revisions:
1. Some double spaces are left in the text and should be removed.

ANS: The whole text has been scanned. After a comma there is a single space and after a full stop there is a double space. This has been made consistent throughout the text.

2. The reference list contains some errors, e.g. missing or unnecessary spaces,

ANS: thank you for spotting these errors. They have now been corrected.

Discretionary Revisions:
1. Reporting of effect sizes (e.g. Cohen's d) would make the results easier to interpret.

ANS: We acknowledge that there are different ways of reporting effect sizes. We used a standard way of reporting which is in line with CONSORT guidelines. We therefore have not made any changes in the text.

Reviewer 2 –
1. The title of the paper may be misleading. It would be more appropriate to indicate this by naming the paper e.g. Group CBT therapy for women with many symptoms of depression rather than mild to moderate depression.

ANS: We presume this reviewer is questioning our description of our sample of patients as being depressed because we did not conduct a formal diagnostic interview to confirm the diagnosis. However our study was a pragmatic one, and it is normal practice for primary care doctors in the UK to use the PHQ9 as a basis for treatment decisions, without these patients having a formal diagnostic interview. We believe it is reasonable to describe our sample of women as being 'depressed'. However, thinking about our title again in the light of our inclusion criteria, we have revised the title to be 'women with depression' rather than 'women with mild to moderate depression'.

Minor essential revisions:
References
Minor issue not for publication; References #2-3 and 20-26 are printed in italic rather than bold.

ANS: The references are based on the BMC’s house style as set out on the website so that book titles are in italics, while journals are in bold and italics. Therefore no changes have been made.
Results

Minor issue not for publication; A sentence at the bottom of second paragraph in results needs revising “The short period of intensive (recruitment?) also meant that community organisations had little time to plan or invite people to join the groups.”

ANS: Thank you for spotting that error. The word ‘recruitment’ has now been inserted (please see page 13).

Please also note, I have added all the tables at the end of the document rather than as additional files. The tables are all now in portrait as requested. However I was unable to understand the website instruction to use ‘table format’ and so have thought it better to leave the tables at the end of the document rather than directly in the text where they are relevant. Please get in touch if you required me to change the tables if this is a problem.