Author's response to reviews

Title: Cardiovascular Health in Anxiety or Mood Problems Study (CHAMPS): study protocol for a randomized controlled trial

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Author's response to reviews: see over
18th August 2015

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Dear Editors-in-Chief,

Please accept the revised manuscript “Cardiovascular Health in Anxiety or Mood Problems Study (CHAMPS): study protocol for a randomized controlled trial” as a submission to BMC Trials. Below we outline our response to the reviewer comments.

Once again I thank you for your consideration of this manuscript. With best wishes, sincerely yours.

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Referee 1:
The authors clearly describe the rationale for their emerging intervention, and their intervention is certainly worthy of investigation. My comments relate mainly to the description of methods, rather than any fundamental problems with their proposals. I’ve listed some of the issues – most of which can easily be rectified with a little more description. The authors may wish to review the SPIRIT guidance just to ensure they have covered all the necessary descriptions.

Major revisions
Please can you explain the rational for the blanket exclusion of older people (aged 75 years or more) from an intervention targeting a CVD population? Why is this acceptable (as opposed to ageist) given the target population?
Response Since depression tends to be reported in younger patients the upper age limit was to reduce heterogeneity. We have removed the inclusion criteria upper age limit.

Study design – given the methods described, I wondered whether this might be best described as a pilot RCT rather than a feasibility study. However, the design is a little at odds with some of the analysis plan – which appears to be exploring effectiveness, rather than the primary focus of feasibility (or piloting) work which is to test procedures and derive data to support a definitive trial.
Response We have deleted the term feasibility in the revised manuscript, page 9.
In the revised statistical analysis section on page 13 we have outlined that we will assess patient preferences and patient recruitment retention/attrition and use this information to inform a larger more definitive trial. We also outline that we will assess the suitability of the enhanced usual care as an alternative and our suicide risk management strategy.

The randomisation/group allocation description in the study methods is very confused. Eligible patients are first described as those with depression/anxiety symptoms over certain thresholds. I am not sure I understood the ‘non-distressed control group’. This group appears to be people participants without emotional distress (you say below the depression/anxiety severity threshold for PHQ-9 and GAD-7). Where is the randomisation and how does this fit within the sample size of 50 patients? Looking at the flow diagram, it would appear that you have an RCT randomising distressed patients to intervention/control, then a non-randomised comparator group. I suspect the easiest way to clarify the methodology is to avoid the term non-distressed ‘control’ group’ and call them a non-randomised comparator cohort (or something suitable). The use of the phrase control group lead me to think they were the randomised comparator. You also need to clarify the sample size along these lines. I am assuming the n=50 refers to the distressed patients who are randomised, to EUC or UP – but you don’t actually state the allocations in the randomisation section. Just a little more detail would be helpful.
Response We have clarified the terminology and refer to the group as a “Non-Randomized Comparator Cohort” throughout the revised manuscript as suggested. Furthermore, we have clarified the sample size and statistical power section by more explicitly stating that n = 50 refers to the persons randomized to UP or EUC, and up to 150 persons in the Non-Randomized Comparator Cohort.

Statistical analysis plans – I mentioned earlier that this section appears to be testing effectiveness, although the authors don’t state that they will make causal inferences from the data. I also suspect they are missing a trick, in so much as this would be a perfect opportunity to report and test study recruitment/retention procedures etc. I would like to see more emphasis on trial procedural testing in this section. There is also no description of how the non-distressed comparator group will be analysed.
Response We have incorporated more information relating to the assessment of the trial procedures on page 13 of the revised manuscript. We also elaborate on the statistical analyses and outline the analysis plan involving the non-distressed comparator group, also page 13 of the revised manuscript.

Level of interest: An article of importance in its field
Quality of written English: Acceptable
Statistical review: Yes, and I have assessed the statistics in my report.
Declaration of competing interests: I declare that I have no competing interests'

Editorial requests:
1. Please ensure the title conforms to journal style for study protocol articles. The title should follow the format ?___________: study protocol for a randomized controlled trial.? Please note that the title in the submission system should match that of your manuscript.
Response Change made as suggested.

2. Please note that 'SSV' should be 'SSZ' in the Authors' Contributions section.
Response Change made as suggested.