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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18th November 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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Response to peer review of CHAMPS Revision 5

It is clear that there is still a difference of opinion here about what a feasibility trial is. I can see that the authors have labelled their study as a feasibility trial...
throughout the paper. Fine. At least that is clear. But I do think we need to be moving towards an agreed used of nomenclature here for categorising studies that precede a definitive study - international consensus is vital to aid comparison between trial designs and to assist with evidence synthesis. This trial still reaches beyond what most trialists would describe as feasibility if we take this definition as a starting point:

http://www.nihr.ac.uk/CCF/RfPB/FAQs/Feasibility_and_pilot_studies.pdf

I don't think it would be too much of a stretch for the authors to respond to my previous request to add a line or two in the discussion to explain why in their iteration a feasibility trial includes a power calculation, measurement of the primary outcome and only partial analyses of the kinds of feasibility parameters expected in a trial of this kind.

Response We have removed the power calculation from the manuscript and explained how the study is a feasibility RCT estimating standard deviations for a larger more definitive trial. We also outline parameters collected as part of the feasibility, such as acceptability, attrition, recruitment, and appropriateness of our suicide protocol.