Author's response to reviews

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

Authors:

Phillip Tully (phillip.tully@adelaide.edu.au)
Deborah A Turnbull (deborah.turnbull@adelaide.edu.au)
John D Horowitz (john.horowitz@adelaide.edu.au)
John F Beltrame (john.beltrame@adelaide.edu.au)
Terina Selkow (Terina.Selkow@health.sa.gov.au)
Elizabeth Markwick (Elizabeth.Markwick@health.sa.gov.au)
Bernhard T Baune (bernhard.baune@adelaide.edu.au)
Shannon Shannon Sauer-Zavala (shannonezavala@gmail.com)
Harald Baumeister (harald.baumeister@psychologie.uni-freiburg.de)
Gary A Wittert (gary.wittert@adelaide.edu.au)

Version: 4
Date: 25 September 2015

Author's response to reviews:

Response to peer review of CHAMPS Revision 3
Reviewer: Suzanne Richards
Reviewer's report: Major revisions

Please update the abstract 'methods' section. The design is currently described as a "randomized, controlled, prospective feasibility study". In addressing my earlier peer review comments, you elected to drop the term feasibility study and this needs to be consistent throughout. I would also make reference to the cohort study running alongside the trial in the abstract.

Response Thank you for pointing this out we have revised the abstract referring to the study as; "This is a randomized, controlled trial with a single centre design."

We refer to the non-randomized comparator cohort in the revised abstract methods section as follows; "Parallel to the main trial, a non-randomized comparator cohort will be recruited comprising 150 persons scoring below the pre-determined depression and anxiety severity thresholds."

You have elected not to describe this study as a 'pilot' trial and will still test effectiveness. I am still not clear that you will have the power to do this in your sample size calculation: is 50 ppts enough to compare intervention and control groups? I don’t understand why you are putting the sample from the cohort study into this figure as this isn’t a randomised comparator. Can you review your sample size text to be sure this is clear - removing any reference to the observational cohort study from the sample size of the trial data (although by all
means retain the separate description of why this cohort group was formed and a sample of 150 people deemed sufficient for your proposed analysis).

Response We point out that only one RCT testing the unified protocol has been performed to date and recruited a modest number of participants to the intervention arm (n=26) and used a wait-list control (n=11). Since the previous RCT was performed outside of cardiology settings the current study if successful will provide the largest sample size to date. A larger study is not within the current grant funding budget unfortunately. With regards to a clearer explanation of the study power and not confuse the randomized sample size, we have deleted the text referring to the 150 persons in the non-randomized cohort (formerly page 12), and also added a sentence on the statistical analysis with the non-randomized comparator cohort.

Notwithstanding the latter point, if you are describing this as an RCT (not pilot), then the first paragraph of the methods section should be clearer: you state you are recruiting 200 participants, however as only 50 if these will effectively be randomised this is somewhat misleading. The first paragraph of the methods section needs to refer to an RCT (n=50) and also the observational cohort running alongside it (n=150) as this isn’t clear enough. Then the subsequent structuring of the methods section is coherent.

Response this section has been clarified to make it more explicit that 50 persons are randomized to the intervention or EUC. We have added a sentence stating that a non-randomized group is being recruited parallel to the main trial on page 9 as follows. “Parallel to the main trial, a non-randomized comparator cohort will be recruited comprising 150 persons scoring below the pre-determined depression and anxiety severity thresholds.”

Minor revision

Can you please describe the participant recruitment procedure in a little more detail. Who is scanning medical records to identify participants and get their permission to pass information onto the study team? What type of information will they be provided with, and how/by whom will written consent be obtained.

Response We have elaborated on the recruitment procedures raised by the reviewer. Since the literature has raised the possibility that similar interventions have been performed too soon after a cardiac event, we will re-contact participants in the 2-8 week period after a cardiac event and determine eligibility. Further details have been added to the revised manuscript page 16;

“The potentially eligible patients are identified at the hospital one to four days after their CVD admission by an authorized hospital staff member employed as a trial coordinator in the cardiology department. A pool of eligible participants will be determined by the trial coordinators review of cardiology admissions and medical records if required. In the first instance, persons will be approached on the hospital ward by the trial coordinator and provided with the study information sheet and an opportunity to discuss any aspects of the study with the trial coordinator. The potentially eligible patients are re-contacted by the study’s trial coordinator two to eight weeks after their CVD admission. Eligible and
consenting participants will provide written informed consent at the baseline appointment.”

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 have no competing interests