Reviewer's report

Title: Cardiovascular Health in Anxiety or Mood Problems Study (CHAMPS): protocol for a feasibility study for the transdiagnostic treatment of emotional disorders among cardiovascular patients

Version: 2 Date: 17 July 2015

Reviewer: Suzanne Richards

Reviewer's report:

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?

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.

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.

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.

**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'