Author's response to reviews

Title: Advancing the evidence base in cancer: Psychosocial multicentre trials

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To the Editors-in-Chief, Trials,

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**Title:** Advancing the evidence base in cancer: Psychosocial multicentre trials

**Authors:** Robert Sanson-Fisher, Lisa Mackenzie, Phyllis Butow, Nicole Rankin and Christine Paul

We would like to thank you and the reviewers for the comments on our manuscript “Advancing the evidence base in cancer: Psychosocial multicentre trials” dated 30th August 2012. Below we address each of the issues raised:

1) **Clarification of familial gatekeeping as a barrier to increasing the number of recruitment sites**

As requested by reviewer 2, in paragraph 7 (page 6), we have clarified that whilst professional gate-keeping may limit the ability to collaborate across different recruitment sites, familial gate-keeping may limit access to some patient and carer populations. We have then pointed out some ways in that an established collaborative could overcome this on page 12, including having resources for involving and engaging family members in the research process, to ensure family members are aware of the voluntary nature of research participation, and that the patient has the right to withdraw from the research at any time, without any consequences to the provision of their health care.

2) **Clarification that the non-exhaustive nature of listed assessment alternatives**

As suggested by Reviewer 2, we have amended paragraph 8 on page 7 to “Three of the most commonly used assessment alternatives include the Hospital Anxiety and Depression
Scale (HADS), the Depression Anxiety Stress Scale (DASS), and the more recently developed ultra short screening tools such as the Distress Thermometer (DT).

3) Challenges in selecting outcome measures and underlying psychological constructs for assessment

In response to Reviewer 2, we have added some content to paragraph 8 on page 6 to address the challenges in identifying appropriate constructs for assessment, before having to select measures to assess a selected construct. We have also included reference to the need for linkage between constructs, measures and intervention mechanisms. This is now linked to a “lack of agreement on critical research questions” being a fundamental barrier to obtaining the high-level evidence for psychosocial interventions, as described on pages 9-10.

4) Comment on the use of CONSORT guidelines

The authors have now introduced the CONSORT guidelines in paragraph 9 on page 7. We have also included reference to psychosocial oncology reviews assessing research design, noting that few RCTs assessing the impact of psychosocial interventions of psychological distress meet CONSORT guidelines.

5) Clarification of psychosocial clinical trial registration

Following page 8 paragraph 10, the authors have now included some discussion of the largely voluntary nature of psychosocial trials registration with clinical trials registries, low rates of trial registration in the behavioural sciences and the potential impact that this may have on publication bias.

6) Introduction of external sources for moderating overburdening of small patient populations

In paragraph 14, page 10, we have included some comment about the need for consensus on topic areas to avoid overburdening small patient groups. On page 14, we
have also mentioned how the consultative priority setting process could be used as an external mechanism to determine which studies will be carried out with which populations.

7) **Clarification of individual gains to be had from such a collaborative**

In the last paragraph of the Results and Discussion section we have now included a more balanced argument as the potential professional gains that might be had from taking part in the collaborative.

We hope this revised manuscript meets your approval, and we look forward to receiving your response.

Yours sincerely,

**Associate Professor Christine Paul (PhD)**

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