Reviewer's report

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

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Reviewer: Ursula Sansom-Daly

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General Comments:
This is a well-written, clear manuscript that describes and addresses an issue of utmost importance to the development, evaluation and dissemination of evidence-based psychosocial interventions in cancer. The authors do an excellent job of summarizing common barriers to researchers conducting rigorous intervention-based research, and discuss how their proposed collaborative trials group (for multicentre psychosocial trials) might address each of these barriers.

Although in its present form the manuscript constitutes a useful and important contribution to the literature, a number of suggestions/comments emerged which are addressed below. (These all fall under the category of Discretionary Revisions; see below).

Major Compulsory Revisions:
NIL.

Minor Essential Revisions
NIL.

Discretionary Revisions

BACKGROUND.
- In paragraph 7 (page 6) the authors discuss the notion that professional and familial gate-keeping may limit recruitment sites. Although the link between professional gate-keeping and the ability to collaborate across different recruitment sites is clear, it is less obvious how familial gate-keeping would directly impact upon recruitment site pathways. It seems more likely that familial gate-keeping may impact upon the types of patients able to be recruited (e.g., breast cancer patients not passing on a recruitment package to their spouse/partners) and/or also the pathways through which these patients might be recruited (e.g., rather than relying on family members to pass on information, researchers might need to rely on fliers around a hospital to attract partners and family members of a cancer patient). Perhaps this point could be clarified or elaborated upon.

- In paragraph 8 of page 6, the authors mention that there is a “large number of assessment alternatives” but then go on to name only three. It seems that the three mentioned are likely three of the most commonly used across cancers/trials
etc, however it is unclear why they have been singled out. Could the authors clarify this? (e.g., “Three of the most commonly used include…..” or similar?)

- Relating to this same paragraph (no. 8, page 6) it also seems that a second point remains unsaid – that is, although there remains a lack of consensus on which actual outcome measures should be used, beneath this lies a second difficulty, which is determining which psychological constructs or outcomes should be measured (or are most likely to show change). This point relates to your later paragraph about the “lack of agreement on critical research questions” (pp. 8-9) and is a fundamental barrier to obtaining the high-level evidence for psychosocial interventions that the authors desire. For example, there has been discussion in the literature that too often there is a poor linkage between the mechanisms targeted in a psychosocial intervention, and the outcomes measured, and this significantly reduces the likelihood of observing effects. This issue most likely ties back to the other points regarding many sites having a lack of multidisciplinary expertise (e.g., which might better ensure that an intervention has a theoretical basis and clear linkage to outcome measures). Perhaps the authors could elaborate upon these points, noting that there is not only a lack of consensus on which measures should be used (e.g., HADS versus DASS) but also which psychological outcomes should be focused upon (e.g., post-traumatic stress symptoms? Fear of cancer recurrence? Depression? Etc).

- Para 9, page 7: the authors make some important points regarding gold-standard research design, however they make no mention of CONSORT trial procedures, which has been one initiative to ensure the dissemination of and adherence to such gold-standard trial methodology. Can the authors comment upon the use of and/or adherence to CONSORT type guidelines in the psychosocial intervention literature? Are any reviews available that note what proportion of RCTs adhere to these? Certainly in the adolescent and young adult (AYA) literature a recent review was published which noted that few trials did so (Sansom-Daly, U.M., et al, 2012, Health Psychology) however this may also have been commented upon in other recent reviews in the adult and pediatric literature.

- Related to the points about “Appropriateness of Research Design” (Background Para 9, page 7) the authors might also discuss whether psychosocial trials are currently being registered with clinical trials registries. For example, do we know what proportion of local, (non-NHMRC) grant-funded psychosocial trials in recent years have been registered with the Australian and New Zealand Clinical Trials Registry (ANZCTR)? It would be interesting to know how widespread this practice is when it is not compulsory (as is the case with NHMRC-funded trials). This relates to your later points about publication bias, and your recommendations about registering trials might be even more compelling following on from clear indications that this is not current practice.

- Paragraph 13, pp. 8-9: the authors’ make some excellent points regarding the importance of achieving consensus regarding the critical research questions to be addressed. It seems that another, somewhat related motivation for prioritizing research questions (and hence studies) is also to reduce the burden on small populations (e.g., pediatric/AYA cancer, rare tumours, etc). Given that concerns
about their own patients being overburdened can often be a significant barrier to multi-site collaboration (i.e., the ‘professional gate-keeping’ mentioned earlier in the article), it seems that having some external mechanism to determine which studies will be carried out with which populations (and at which sites) may also be an effective way of reducing this barrier. The authors might mention this point also, if there is space.

RESULTS AND DISCUSSION.

- In the last paragraph of the Results and Discussion (p. 17) the authors discuss the risks/costs to the individual researcher in taking part in their proposed collaborative. It seems that it might also be beneficial at this point to have balanced this with the potential personal/individual gains that might be had from taking part in the collaborative. Of course, the whole article up until this point is very convincing in terms of the benefits to the quality of research and to wider, evidence-based practice, but the authors could address a little more specifically the potential benefits to individuals wishing to join. For example, how is authorship negotiated, and are there any benefits here in terms of being part of the collaborative? Are there any good models from medical clinical-trials collaborative groups (in Australia or overseas) that could be used to inform how individuals might be incentivised to take part in the collaborative, or how the broader benefits might be constructed to outweigh the personal/individual risks involved?

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.