Reviewer’s report

Title: A Randomised Phase II Trial to Examine Feasibility of Standardised, Early Palliative (STEP) Care for Patients with Advanced Cancer and their Families [ACTRN12617000534381]: A Research Protocol

Version: 0 Date: 14 Dec 2018

Reviewer: Michael Campbell

Reviewer’s report:

This is a protocol for research that is supposed to test the feasibility of standardized palliative care introduction based on illness transitions, and provide guidance on subsequent development of a Phase 3 study. It seems well designed and promises a fruitful outcome

1) The primary endpoint is a feasibility one, to determine whether they can recruit 90 patients in 24 months, with 60% completion, which is appropriate. It would be nice to link this with the main study. I assume the target relates to the main study using a larger number of centres likely to get ?X patients which would be a reasonable size for this type of a phase 3 study.

2) I am a bit concerned about the hypothesis testing aspects for a feasibility study. I would prefer estimates and confidence intervals of the secondary outcomes (say using ANCOVA) which would help decide whether the treatment has some effect, or whether it needs modifying. The problem with p-values is that, if they are significant and then the secondary endpoints promoted to primary in a subsequent paper, they may make the subsequent phase 3 study harder to justify.

Level of interest
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An exceptional article

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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