Reviewer's report

Title: Vocational rehabilitation services for patients with cancer: design of a feasibility study incorporating a pilot randomised controlled trial among women with breast cancer following surgery

Version: 2 Date: 10 January 2011

Reviewer: Charlie Goldsmith

Reviewer's report:

In general, this protocol is well done. However, the following are a few suggestions for continued improvement.

1. P(age) 1, p(aragraph) 2, l(ine) 3. Suggest dropping [old].
2. P 1, p 2, l 7. Suggest including the name of the QoL measure.
3. P 1, p 4, l 1. Include the date of registration and the date the first patient was randomized, if that has happened.
5. P 2, p 1, l 5. Since incidence is a time related rate, what is the time, is it [annual]; if so, insert it.
6. P 2, p 1, l 8.9. Delete [old]. Also P 4, p 1, l 1.
7. P 2, p 3, l 2. Since [or] logically includes [and], drop [and/].
8. P 4, p 3, l 7. Rewrite as [... with 5% level of significance and ..]. It is not proper to use its compliment.
9. P 5, p 1. There is no need to repeat the wording for those that are ineligible or refuse. Why not state it once?
10. P 7, p 1, l 2. Replace [ranges] by [varies].
12. P 7, p 1. Did you consider adding something like the EQ-5D to get utilities as well as a disease specific measure? This would make the results easier to compare to other diseases other than Breast CA, and allow for a cost utility analysis after the main trial is completed.
13. P 7, p 5, l 1. Provide a citation for why you think 5 patients per group for a total of 10 will be adequate for the qualitative analysis. Similarly P 8, p 2.
14. P 8, p 3, l 2,3. Provide references to the two software packages.
15. P 9, p 1, l 1. There is no need to test for comparison of the two groups after they are randomized. It is much more important to measure the randomization integrity. Comparison should be done clinically as all the differences are expected to be due to chance. See Altman DG & Dore CJ: Randomisation and baseline comparisons in clinical trials. Lancet 1990;335(8682):149-53 and a letter in Lancet also 1990;335(8703):1476 and another paper by them: Baseline

A random sample of 10 references was checked for accuracy of citation.

16. R(eference)s 1,8,9,10,13,19 seem accurate.
17. P 10, R 4 should have location of an organization to help find it. This reviewer could not locate it. Is this part of the Scottish government?
18. P 10, R 7, l 2. Insert [(6)] after [14].
19. P 10, R 1 1. Delete [.] after the initial of the first author.
20. P 11, R 12, l 2. Insert [(7)] after [173].