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: 9 February 2011

Reviewer: Andrew Vickers

Reviewer’s report:

This is a well reported protocol for a feasibility study. The authors’ overall objective – the effects of vocational rehabilitation on work status – is laudable and the feasibility study carefully developed to help address specific design issues.

I have several comments. All of these should be considered major compulsory revisions.

First, I have grave doubts about the sensitivity of the FACT questionnaire to effects resulting from the intervention. It seems likely that patients who return to work earlier due to vocational rehabilitation will have a better quality of life than women who don’t, but I doubt whether the FACT will pick it up. The authors are advised to read each and every question on the FACT instrument and ask themselves whether they believe that the intervention will lead to a large difference in responses (small differences are very hard to pick up). For example, is it plausible that vocational rehabilitation will lead to detectable differences in responses to items such as “I feel close to my friends” or “I have difficulty in eating heavy foods”. At the very least, the authors might consider adding evaluation of the outcome questionnaires as a study aim. The authors do list as an objective determining whether the outcome measures are “appropriate”, but do not state how this will be done.

Second, the statistical analysis section is inadequate. Yes, this is only a feasibility study, but that doesn’t mean “anything goes”. In particular, even if just a feasibility study, the authors will undoubtedly report an estimate of treatment effect, and the statistical methods used need to be specified in the protocol so that they can be compared with those reported in the trial report. For example, the authors state “The differences from baseline values to 6 month and 12 month follow-up for primary and secondary outcome measures will be compared using appropriate paired and independent sample tests”. This is extremely vague! The protocol for comparison of outcomes between groups should be precise enough so that two competent statisticians reading the protocol would conduct identical analyses and report identical statistical results. As a general word of advice: use of paired tests is irrational for a randomized trial; outcomes for which baseline and follow-up measures are taken should be analyzed by ANCOVA (see Vickers Altman BMJ); the main endpoint is a time-to-event variable and so should be
analyzed using Cox regression. On this point: there doesn’t appear to be a statistician listed as an author; might it be wise for a statistician to be included on the study team?

Third, the investigators state as an aim that “response rates” will be evaluated. It is unclear what is meant by this term.

**Level of interest:** An article whose findings are important to those with closely related research interests

**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'