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: 17 February 2011

Reviewer: Victoria Blinder

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Major points

Too many aims

Nine is too many aims for most studies, especially a pilot study. Some of the aims, such as aims 1 and 3, both of which address determining the number of potentially eligible patients, could be combined into a single aim. Others belong in a different study, such as aim 8, which addresses the suitability of patients with other tumor types for a study of vocational rehab and return to work.

Unnecessarily complex design

It is unclear to me why a feasibility study needs to be designed as a randomized trial. The randomized design does nothing to advance any of the stated aims. If the overall goal is really to assess the feasibility of undertaking a larger study designed to assess the impact of a vocational rehabilitation intervention on return to work after cancer, then the pilot could be done as a single arm, with all participants receiving the intervention. The only aim that could benefit from a randomized design is aim 7, which addresses estimating an effect size for the purposes of power calculations for the future larger study. However, the investigators could estimate the effect size to inform sample size calculations by looking at some of the published studies addressing vocational rehabilitation and return to work. With respect to the sample size calculation for the pilot study, I do not understand how the authors arrived at a standard deviation of 100 days. Is this taken from the study by Drolet et al. that is cited in the preceding sentence? This should be stated explicitly.

Lack of standardization of the intervention

The authors state that “the intervention is referral to a VR service.” Will all participants be referred to the same vocational rehabilitation provider? Will there be any standardization of the intervention? It seems that someone not involved in the study (the “case manager”) will determine the kind of services each participant will receive, but it is not at all clear that this person will follow a predetermined standardized system to assign services. On what will they base these important decisions? How will the investigators keep track of the specific intervention that is received by each participant? All of this needs to be explained.
clearly. If the authors plan to study an intervention that is not standardized, then they should explain their rationale for doing so.

Qualitative methodology

When undertaken correctly, qualitative research can be extremely valuable and informative, particularly when undertaking a program of research in which there is scant existing data. The semi-structured interview format is appropriate for this study, but these interviews should be done until a point of saturation is reached. The decision to interview 5 participants in the treatment arm and 5 in the control arm seems arbitrary. Instead, the researchers should interview 3-5 in each arm and then analyze the data, with a plan to do additional rounds of interviews (of new participants) until no significant additional information is learned from the interviews. This is also the case for the interviews of lung and prostate cancer patients, although, as I explained above, I believe this part of the study should be undertaken separately (see “too many aims” above).

Minor points

• The names of public figures should be stated completely (see the second paragraph of page 2, “Dame Black’s recent review of the health . . .”)
• In the last paragraph of page 4 the researchers alternate between the future and present tenses. This needs to be revised to be consistent throughout the paragraph (and the entire section describing the study methods).