Reviewer's report

Title: Impact of a web-based treatment decision aid for early-stage prostate cancer on treatment choice and satisfaction: Study protocol for a pragmatic, cluster randomised controlled trial

Version: 1 Date: 23 February 2015

Reviewer: Andrew Vickers

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Major comments

1. I am fully aware that decisional conflict, treatment satisfaction and decisional regret are pretty standard outcomes measures, but they actually do an extremely poor job of distinguishing good from bad decisions. See, for example, Fagerlin Medical Decision Making http://www.ncbi.nlm.nih.gov/pubmed/17873251. In brief, it is not at all clear that lower conflict indicates better decision-making (e.g. a very biased decision aid would lead to lower conflict, because patients would be more sure that they had made the right decision). And regret is extremely time sensitive (e.g. a man may have no regrets 12 months after choosing active surveillance compared to a surgery patient enduring incontinence after surgery; 10 years later, when the active surveillance patient is dying from metastatic disease, things may be very different). At the very least, the authors need to acknowledge the very important limitations of these endpoints and to discuss how interpretations of the study may be accordingly difficult.

2. The statistics section is confused and vague. This is a cluster randomized trial, and so analysis must take account of the design. However, the authors have a long section describing a number of different possible analyses (e.g. t-tests or non-parametric equivalents) that do not reflect the cluster design. They then briefly describe a multilevel modeling approach without giving many details at all. The general principle of a statistical section in a protocol is that two statisticians working independently would write a similar results section on the basis of the protocol alone. The statistics section should describe each hypothesis tested and then give a clear and unambiguous description of the statistical methods.

3. The EORTC30 includes questions such as “Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?”; “Have you vomited?” and “[Have you felt] irritable?”. On what possible grounds would we expect patients to answer such questions differently depending on their group assignment?

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:

none