Reviewer's report

Title: Behavioral and psychosocial effects of rapid genetic counseling and testing in newly diagnosed breast cancer patients: Design of a multicenter clinical trial

Version: 2 Date: 29 November 2010

Reviewer: Edwin van Teijlingen

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There is one serious discrepancy left:

I still have some reservations about the way qualitative methods have been used (or will be used).

The slightly rephrased text in the Abstract is acceptable, but the following text on page 10 is not acceptable:

“The interview data will be transcribed, but will not be submitted to formal content analysis. Rather, they will be used to illustrate quantitative results (e.g. use of direct quotations).”

The explanation in the cover letter by the authors does not give me confidence either that they know where they are talking about:

“Description of the qualitative research element of the study.

We appreciate that reports on qualitative studies need to adhere to the standards outlined in

the RATS guidelines. Our study, however, is predominantly quantitative in nature. The more

qualitative interview data that we are collecting will be used for illustrative purposes only; that

is, to highlight and illustrate results that emerge from the quantitative data (e.g., by using direct

quotes). It is not our intent to conduct formal qualitative analyses using structured coding

systems. This was not part of the protocol as submitted for IRB approval and to the trial registry.

We have added some information on the topics covered during the interview, and the way the

data will be used on page 9 of the manuscript.”

This reads still very much as: “We are looking for a few nice quotes to make our paper sexier.” Either the authors drop the qualitative interviews altogether or they do it well. There are different ways of conducting and analysing qualitative
methods, and I am very happy to discover that the authors will be using a very simple thematic analysis/content analysis, but they do have to do the analysis systematically. What is the use of using a scientific method if it is not systematically?

In the cover letter the sentence: “It is not our intent to conduct formal qualitative analyses using structured coding systems. This was not part of the protocol as submitted for IRB approval and to the trial registry” can be read in two ways. First, in the protocol submitted to the IRB we did not mention qualitative methods and now we are adding them through the back door. Secondly, in the submission to the IRB we had an equality ambiguous statement about qualitative methods and they did not notice / comment on this. If the first case is true, the authors need to go back to the IRB with an amendment and ask ethical approval to do the interviews properly. If the second case is true, the IRB did not do its job properly (which is in itself questionable, as allowing poor research to go ahead is unethical), but no way to try to convince an academic journal to publish a protocol with a flaw.