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

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Reviewer: Edwin van Teijlingen

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This RCT protocol ‘Behavioral and psychosocial effects of rapid genetic counseling and testing in newly diagnosed breast cancer patients: Design of a multicenter clinical trial’ has been written three of not four years ago. The funding was awarded early 2007 which means the application to the funding body was made probably late 2006. This is probably the reason why this protocols for a randomized controlled trial does not mention the CONSORT guidelines (http://www.biomedcentral.com/1471-2288/1/2) as BMC journals expects it to do.

The qualitative research element in this largely quantitative trial is poorly described, and probably conceptualized. This study protocol of a RCT which incorporates an element of qualitative research describes the qualitative element of the results very poorly. The statement in the Abstract on qualitative research is a throw-away sentence “A subset of the participants will be interviewed to obtain qualitative data” which would be criticized in an undergraduate essay. This statement is unsophisticated. Why else would one conduct research interviews other than to generate qualitative data? It’s as simplistic as saying: “A whole battery of questionnaires will be administered to the women to generate quantitative data.”

The Methods section is not much more informative, on page 9 it simply states: “A subset of women will be interviewed to obtain supplementary, qualitative data about the RGCT experience.” The section on analysis is not much clearer about how the authors will analyse the qualitative dataset. Page 17 states “Supplementary, descriptive analyses (both quantitative and qualitative) will be used for reporting the patients’ experiences with RGCT.”

The authors should consult some basic qualitative methods papers, such as Pope et al. (2000), who explained clearly that “transcripts and notes are the raw data of the research. They provide a descriptive record of the research, but they cannot provide explanations. The researcher has to make sense of the data by sifting and interpreting them.”

The qualitative analysis van be a basic thematic analysis, since a “thematic analysis may be undertaken as the initial phase of data analysis, or when a study has limited resources, or as an introduction to analysing qualitative data (Forrest Keenan et al. 2005). For possible improvements to the qualitative analysis in the
genetic counseling field, the authors should look at relevant papers such as, for example, Grant et al. (2006).

Possible extra references:

The authors seem very prescriptive in their outcomes. They see genetic counseling as very directive, i.e. there are only certain outcomes which are ‘good’. Thus in this RCT as given on page 9 “The primary clinical outcomes include: the uptake of direct BLM or of delayed CPM.” Have the authors considered how the statement on page 5 “The objectives of cancer genetic counseling, in general, are to improve knowledge and understanding of the possible genetic basis of the disease, of personal risks of developing cancer, and of the possible consequences of undergoing genetic testing,” sit with assertion on page 3 by the authors that: “The primary behavioral outcome is the uptake of direct bilateral mastectomy or delayed prophylactic contralateral mastectomy.” Some genetic counselors would argue that genetic counseling should not be directive, but the authors here obviously have another view, and genetic counseling at is best is directive.

For example, Hines and colleagues in qualitative study of 15 HD counselors found that their most common ethical challenge was testing prenatally for HD which also results in presymptomatic testing of minors. Participants were divided about how directive to be in response to this ethical issue and about termination of a gene positive pregnancy
Hines KA, Veach PM, LeRoy BS. Genetic counselors' perceived esponsibilities regarding reproductive issues for patients at risk for Huntington disease, J Genet Couns. 2010 ;19(2):131-47

Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)

• Make appropriate reference to CONSORT guidelines in this protocol (www.biomedcentral.com/1471-2288/1/2)
• Add detail to the qualitative data collection, analysis and reporting. Also describe the link between the expected qualitative data and the main quantitative data in this study.
• The authors should consider the nature of genetic counseling as portrayed in their study. There is no need to change their position, but there is a need to reflect on their very directive approach with very medical outcomes as positive expectations.
• The authors have not convinced me as a non-clinician that the extra time gained by the rapid genetic counseling and testing is in itself beneficial, am I missing a point here? Just because we have tests that take shorter to get a result does not mean that we have to use them.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

• Page 12 Would like to see some evidence (reference) for the statement “However, in current practice, this occurs rarely during the pre-surgery period.”
• Page 15: et al should read et al. (with full stop & italics);

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

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests