Reviewer’s report

Title: Involving users in the design of a randomised controlled trial of an intervention to promote early presentation in breast cancer: qualitative study

Version: 1 Date: 18 August 2010

Reviewer: Ruth Heisey

Reviewer’s report:

In general I would like to commend the authors for involving age appropriate women to assist in refinement of the research protocol. They have acknowledged that these women are likely more “pro research” than others and that this is likely to limit the generalizability of their findings. Nonetheless it is wonderful to see user involvement to refine protocol development.

Major compulsory revisions:

1. Informed Consent

My greatest concern is that the authors are proposing two significant departures from the norm with respect to the nature of informed consent. Firstly, the issue of “verbal” rather than written consent and secondly that of “opting out”. I think it is essential that there is some discussion of your current National Centre for Social Research Ethics Committee requirements and a statement regarding your view as to whether or not verbal consent sufficiently represents informed consent. Your statement that, “The Bengali group noted that verbal consent was better for people who did not speak good English and also those with a low level of literacy,” needs to be supported. Is this because they understand verbal communication better than the written word or is it that they don’t really understand?

While there is evidence for the “opting-out” approach in low-risk studies, this is not standard of care and I think this need to be further addressed with respect to the impact on patient autonomy. Perhaps you could also include a statement ensuring that the woman is allowed to opt-out at any time in future.

You provide a quote regarding women’s desire for informed consent in the “Identification of women with breast cancer through routine datasets”. I think you might consider a section on “Informed Consent” including this quote then provide a paragraph in the discussion section to cover off the above issues.

2. Statement acknowledging potential harm to participants

I have some concerns about your statement that taking part in the trial was “not likely to be painful or intrusive”. You are planning to interview women and ask the duration of breast cancer symptoms prior to presentation. We know from your work and others that likely 30% will have delayed 3 months or more and there
may be many negative emotions uncovered during this interview. I think a statement acknowledging this is necessary.

Minor essential revisions:

Introduction: Trialists – typo, symptomatic presentation “of” breast cancer, Perhaps a connecting sentence between the second and third paragraphs for improved clarity e.g. “The hope is that this increased awareness will translate into earlier presentation of women with breast cancer symptoms.”

Initial opt-out consent: The women felt the only reason they might wish to opt out was the because… (suggest delete “the”)

Conclusions: …acceptable to potential research participants “and” should be considered…

Discretionary Revisions:

Methods of ascertaining, contacting and interviewing participants with breast cancer: It would be clearer if you discussed here what these interviews are about. I am still a bit unclear- you say in one place to collect outcome data and in another to discuss nature and duration of symptoms.

Your quote under the Initial opt-out consent section seems to refer to a woman who has opted-in by stating: you might quite happily tick a box and say, “Yes if I get cancer I’ll talk to you”… Please clarify this.

If the issues under major compulsory revisions are addressed then this is definitely worthy of publication.

I have no competing interests. This manuscript does not require review by a statistician.

Thank you for the opportunity of reviewing your manuscript.

Sincerely,

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

Declaration of competing interests:

I have no competing interests