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: 2 October 2010

Reviewer: Anthony Miller

Reviewer's report:

Major compulsory revisions

This qualitative study suffers from the disadvantage, as the authors realize, that the participants may not be representative of those who may eventually participate in their trial. Further, there seem to have been major differences between the breast cancer patients and the non-breast cancer subjects. In particular, there were few women with breast cancer over the age of 65, and few of them lived in London.

Although it may be comforting to the authors that these subjects provided support for the “opt-out” consent process they propose to use in the trial, and even though this could mean that the proportion of women who elect to accept this option will be few, it does not overcome the fundamental flaw of the cluster randomized design they propose to use, namely that this option will only be available to those in the intervention arm, not to those in the control. Permitting the option therefore, will inevitably introduce bias in their trial. If the authors decide to proceed with cluster randomization, therefore, they will have to introduce procedures to permit opt out in the control arm. However, the present study has not evaluated the extent that women will opt out if they are told they are part of a group selected as controls. An important need for completing the design of their trial has therefore not been evaluated.

The other striking issue about their proposed trial is that what they are essentially evaluating is the effectiveness in improving survival (preferably expressed as reducing breast cancer mortality) of a mechanism to promote breast self-examination among women who have completed the planned screening in the NHS screening program. This is clearly an important endeavour and it is important that the design of the trial is valid, and that it is understood what is being evaluated.

Level of interest: An article of limited interest

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