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: 2 Date: 5 November 2010

Reviewer: Anthony Miller

Reviewer’s report:

The authors defence of the non-representativeness of samples selected for qualitative research is unacceptable. Rather, the authors should acknowledge the probable non-representativeness of the sample they have studied and discuss the implications.

This study was done to help in the design of consent procedures to use in a cluster randomized trial. Given the fact that in such trials the consent is one sided (i.e. from the intervention group but not the control) it must be acknowledged that cluster randomized trials have this major disadvantage (in addition often, in the difficulty in confirming there is balance in the compared groups) Although this may not be the place to discuss this in full, it could have been expected that this would at least have been discussed, and the reasons given for not selecting individual randomization.

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.