Author's response to reviews

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

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Version: 3 Date: 6 December 2010

Author's response to reviews: see over
Dear Editor

MS: 7400612654161362 - Involving users in the design of a randomised controlled trial of an intervention to promote early presentation in breast cancer: qualitative study

Thank you for inviting us to resubmit this paper. We have revised the paper accordingly. Here we provide our response to reviewer 2’s comments

Reviewer 2

Reviewer 2 has asked that we acknowledge the probable non-representativeness of the sample we included in our qualitative study and discuss the implications, which we have done. He believes that our discussion of the importance or otherwise of quantitative representativeness in a qualitative study is unacceptable, so we have omitted it.

Reviewer 2 remains concerned that we will not attempt to gain consent in our cluster randomised controlled trial in the control group. I would like to reiterate that we do indeed plan to request consent to participate and to be followed up from both control and intervention groups. Neither group will be asked to consent to be randomised (as is often the case in cluster randomised controlled trials). The control group will not be asked to consent to the actual intervention but that is because they will not be offered the intervention.

The reviewer has asked that we discuss further the rationale for choosing cluster over individual randomisation, which we have done, and we have attempted to clarify the point above further in the introduction where we describe the trial design.

I hope that these changes are sufficient.

Yours sincerely

[Signature]
Lindsay Forbes