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

Authors:

Lindsay JL Forbes (lindsay.forbes@kcl.ac.uk)
Carol McNaughton Nicholls (Carol.McnaughtonNicholls@natcen.ac.uk)
Louise Linsell (Louise.linsell@npeu.ox.ac.uk)
Jenny Graham (Jenny.graham@natcen.ac.uk)
Charlotte Tompkins (Charlotte.tompkins@natcen.ac.uk)
Amanda J Ramirez (amanda-jane.ramirez@kcl.ac.uk)

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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. Our response to the reviewers’ comments are:

Reviewer 1

Major revisions

1. Informed consent

The reviewer notes that we debate in this paper two departures from the norm in randomised controlled trials in relation to informed consent: opt-out and verbal consent.

She suggests that we

- discuss the National Centre for Social Research Ethics Committee requirements for consent. As it happens, The National Centre for Social Research Ethics Committee does not provide consent for trials such as the one described. Ethics approval for the trial described in our report would be obtained from a National Health Service Research Ethics Committee.
- Provide a view as to whether verbal consent sufficiently represents informed consent.
- Support further the statement about the Bengali group’s comments that verbal consent was better.

She notes also that the impact of the opt-out approach on patient autonomy should be addressed and that we might suggest that a woman might opt out at any time in the future.
She also suggests that we consider creating a section on informed consent in the methods and including a paragraph in the discussion on all the issues outlined above. We have done so.

We have addressed in the discussion:
- NHS Research Ethics Committee guidance
- Whether verbal consent sufficiently represents informed consent.
- The impact of opt-out consent on patient autonomy.

We have clarified the statement about the Bengali group in the results section and added in a sentence on this in the discussion.

2. Potential harm to participants

The reviewer expressed concerns that we stated that taking part in the trial was not painful or intrusive given that we planned to collect data on women with breast cancer which may uncover negative emotions. She suggested we acknowledge this.

We agree and have amended this.

Minor revisions

We have corrected the typos and added the connecting sentence as suggested.

Discretionary revisions

We have provided further information about what the follow up interviews in the trial are about; in fact the outcome data are nature and duration of symptoms.

We take the point that that the woman being asked about opt-out consent stated that she might “…. happily tick a box and say “Yes if I get cancer I’ll talk to you””, implying that she had thought the question was about opt-in consent, which is what she describes. We believe that what the woman was trying to convey was that any consent (opt-in or opt-out) at the time of recruitment may not be relevant much later when a woman had developed cancer. We have clarified this in both the results and the discussion.

Reviewer 2

Reviewer 2’s concern about the study design is that the opportunity to opt-out will not be available to the control arm and that this will introduce bias.

We can be completely clear about this: the same methods to obtain consent to participate (initial opt-out consent to participate and for long term follow up using routine datasets) are proposed for both control and intervention arms. The only difference will be that the control arm will not be asked to provide verbal consent to receive the intervention itself.

The trial design, therefore, will not introduce the bias he suggests.

We have clarified that both intervention and control arms will be offered the opportunity to opt out of participation and of long term follow-up in the introduction and clarified what it is the trial intends to evaluate.

The reviewer also noted that few of the women with breast cancer lived in London. We are not sure whether this is a criticism or not – it seems reasonable to us, as most people in the UK do
not live in London. We take the point that few of the participants were aged over 65 and therefore the group is not quantitatively representative of women with breast cancer; we have now acknowledged this in the discussion. However, we also make the point that quantitative representativeness is not of prime importance in a qualitative study.

Yours sincerely

Lindsay Forbes