Reviewer's report

Title: Changing case Order to Optimise patterns of Performance in Screening (CO-OPS): A Research Protocol for a Randomised Controlled Trial

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Reviewer: Sarah Damery

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This was an interesting protocol which outlined a simple yet potentially effective intervention to assess whether changing the order in which mammography results are read in breast screening assessment centres can reduce the impact of vigilance decrement and increase rates of breast cancer detection.

My specific comments on the protocol are outlined below. All have been numbered for ease of distinguishing between them.

Major compulsory revisions

1. Title: I would suggest changing the title to explicitly refer to the focus on mammography screening i.e. “Changing case Order to Optimise patterns of Performance in mammography Screening (COOPS): A Research Protocol for a Randomised Controlled Trial”

2. Background (3rd para): I think an extra sentence of description/justification is needed here – why is keeping interval cancer detection rates to 2.3 per thousand considered difficult to achieve whereas 3 per thousand is considered realistic?

3. Background (existing knowledge section, para 1): This paragraph states that readers assess 120 mammograms per 1 hour session. However, the abstract states that readers assess 30-50 women’s mammograms per session. The text needs to be consistent and to clarify which is correct i.e. be clear exactly what is being described when talking about reader workloads – is it the case that there is more than one image per woman, thus a batch of 50 women’s mammograms may equate to c.100 images being read. Please clarify this in the text.

4. Background section: No evidence is given that there is currently an observable vigilance decrement in the field of breast screening. The only example is that observed in the similar yet different field of radar operation. What is the evidence that such decrements exist in the field of breast screening? It is important to present some evidence from breast screening itself as this is crucial for providing a rationale for undertaking the study and justifying the need for the work in the first place.

5. It would be useful to reiterate how many breast screening centres will be participating in the trial in the ‘trial summary’ part of the methods/design section.

6. How might the differences between centres in their stated procedures for
mammography assessment (to be determined from the pilot survey of unit practice) have an impact on the trial design? Could it cause certain units to be removed from eligibility for the trial, or are differences in routine practice simply something that will have to be borne in mind in the statistical analysis of the trial results i.e. the purpose of the survey ascertaining routine practice of different centres is not clear in terms of the potential effect on the study.

7. In the methods/design section the authors mention a pre-pilot. Is this a phase prior to a pilot before the main study, or does ‘pre-pilot’ actually refer to a pilot that will be done shortly before the main study gets underway? I suspect the latter, so better to call it a pilot phase rather than a pre-pilot.

8. In the methods/design section, the protocol talks about “The first 12 months data will be collected...” It would be useful to clarify here exactly what data items will be collected. If the data will only be rates of cancer detection in intervention and control arms at this stage, then make this clear. If you intend to collect other data e.g. sociodemographics, cancer staging data, types of cancer e.g. DCIS, then these data items need to be mentioned.

9. It is not clear in the protocol whether the mammographies being assessed will all be first mammograms (rather than imaging following recall subsequent to a previous mammogram that may have pre-dated the trial itself). Can the authors clarify this point?

10. Linked to the previous point, in the assessment of cancer detection rates, will the diagnostic process be taken into account? What I mean is that presumably the main outcome of mammograms being read is to assess whether there are potential abnormalities in the imaging that would need further assessment. These further assessments may entail further imaging being produced (which will need to be read later down the line), or may entail a woman being recalled for a biopsy etc. So, whether or not a cancer is eventually detected is not likely to be directly as a result of the mammogram being read at a breast screening centre; reading the mammograms is most likely to result in a woman being recalled for further investigation, and diagnostic decisions will follow at a later date, perhaps after further rounds of image reading. Will this be allowed for/picked up on in the trial design?

11. I think more detail is needed on the way that the cost-effectiveness element of the work will be undertaken. The authors mention using a model which can calculate lifetime cost of the outcome/implications of the control or intervention group results. What sorts of data items are taken into account in this model and how does it calculate the lifetime cost?

12. I think the trial aims/secondary aims section (page 5) and the trial outcomes/secondary outcomes section (page 6) could usefully be amalgamated as they essentially say the same thing and currently seem slightly repetitive as the outcome list directly follows the aims list in the protocol.

13. The statistical considerations section (3rd para under ‘Secondary analysis’)
mentions comparing ‘the recall and cancer detection rates for the two reading groups which make up the control arm’. This is the first explicit mention of there being two reading groups although it is implied elsewhere. I assume this refers to the fact that the control group is split between those where both practitioners read their batches in either forward or reverse order, but this is not clear in the text and could introduce unnecessary confusion.

14. Following from point 13, I wonder whether the study should more correctly be referred to as a four arm study, since the intervention and control groups are in effect each broken down further into two groups. Figure 1 in particular does not make this clear, and gives the impression that there will be a single control group and a single intervention group.

15. Again in reference to figure 1, the ‘allocation’ box on the right hand side is confusing since the text in this box talks about participants in the control group ‘receiving allocated intervention’. Technically, the ‘control’ arm should not receive an ‘intervention’. This needs rephrasing/rewriting to remove confusion.

Minor issues not for publication

16. Background section, paragraph 3 (3rd sentence): Do not start a new sentence between ‘...de novo between screening rounds” and “Or are not seen”; this should be one sentence. Also, in the same sentence, the text should read “not seen or picked up by the programme” (rather than ‘pickled’!).

**Level of interest:** An article of importance in its field

**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.