Reviewer’s report

Title: Participants' understanding of randomized controlled trial (RCT) through informed consent procedures in the RCT for breast cancer screening, J-START

Version: 2
Date: 4 July 2014
Reviewer: Julia Wade

Reviewer’s report:

Thank you for the opportunity to review this paper. It describes a quantitative evaluation of participants’ understanding following informed consent processes during recruitment to the J-START trial using a Japanese translation of the QuIC (Joffe et al. 2001) and purpose-designed questionnaires to collect data on personal characteristics and patient impressions of the informed consent process.

Please note that review of the quality of the research was impeded by the English used in this written report. The English will need correction in many places in the text (abstract and main body) in order to make the message clear. However, generally the meaning can currently be inferred and my sense is that this is a language problem rather than a problem with the quality of the research.

The question is new and the subject clearly deserves investigation, for the reasons the authors state in the background: the authors have undertaken a translation into Japanese of the QuIC in order to carry out the first evaluation of the quality of understanding following informed consent consultations for an RCT involving healthy volunteers.

However, findings mostly confirm key concepts that participants fail to comprehend as demonstrated by previous investigations of informed consent processes during trial recruitment and stated in the discussion on p15. The question and findings may therefore be most relevant to a Japanese audience.

• Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)

1. The aim of the study needs describing more accurately in both the abstract (page 3) and the text (page 6) - current description of the study question is potentially misleading in the abstract, allowing the reader to misinterpret this as an RCT of informed consent within the J-START RCT whereas in fact this is a survey study of the quality of informed consent given by participants of an RCT).

2) It is not clear, how many participants were used to evaluate the Japanese translation of the QuIC, 21 or seven (page 10).

3) Questionnaires to collect data on patient characteristics and patient impressions of the consent process were presumably purpose-designed and
have not been validated or tested for reliability – it would be helpful if this is made explicit (p10).

4) Objective understanding of the QuIC Part A score p12 and Table 2: I was not clear why the authors did not highlight the relatively poor understanding of ‘A9 Benefits to self’ as this was only 1.6% higher than score for A13 and why this question was left out of the analysis shown in Table 5. ‘Therapeutic misconception’ arises frequently during the process of taking informed consent for trial participation (e.g. see Flory & Emmanuel 2004).

6) Page 13 states that ‘92% reported that their understanding had been confirmed by the research coordinator at the end of the oral description during the IC process’. I’m not clear what is meant by ‘confirm’ here. Does it mean the researcher asked the participant if they had understood. Are the authors assuming that if a patient answers ‘yes’ (or fails to ask further questions at this point) that they do understand? The authors’ own findings in this paper indicate differences between participants’ subjective (perceived) and objective (actual) understanding, so the latter assumption would not be supported by the evidence.

7) Page 13 Findings highlighted in the text p13 reflect data in Table 5 however, the text needs rewording to make the message clearer, e.g. the association is between responses to questions and evaluations made by the patient about information provision.

7) NOTE As a qualitative researcher I do not feel qualified to judge the statistical analysis. The statistics used, as far as I am aware, are suitable.

8) The discussion would benefit from being more concise. Findings reiterate previous findings that are already relatively well established in the literature (p15) so are not novel and fail to reference a key systematic review (Flory & Emmanuel 2004) which in common with Nishimara et al. 2013 found that extended discussion was the optimum method of improving understanding in informed consent for research - perhaps a reason why differences were found here between study centres?

9) Discussion p16 – whilst it is interesting to consider how these findings may arise in this particular context, it would be even more interesting to reflect on why these same failures of understanding arise across very differing trials.

10) The authors suggest that insufficient or variable use of information materials across study centres may explain observed differences in understanding between centres, but there seems to be no presentation of data as to whether such variation occurred between centres (p18).

Moreover current evidence suggests that face to face discussion is one of the best methods of optimising quality of understanding in informed consent (Flory and Emmanuel 2004, Nishimara et al. 2013). The literature suggests that the key to improving quality of understanding lies in the interaction between recruiter and patient rather than in adjusting content or presentation of patient written or video information. The authors might like to comment on the limitations of a purely
quantitative investigation as presented here and consider mixed methods approaches to future research which includes qualitative investigation of what is said during informed consent discussions.

- Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

- Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)

See final comment under 10 above.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Not suitable for publication unless extensively edited

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare I have no competing interests.