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
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Reviewer: Helena Länsimies-Antikainen

Reviewer's report:

The manuscript aims important and timely research area because there is a continual need to evaluate and develop the ethical quality of scientific research. In addition, it is important to widen knowledge about effects of ethical aspects in research. The main goal is to protect individual's autonomy and human rights.

Major Compulsory Revisions (Comments are expressed in order they turn up in the manuscript):

Main question: What is the novelty value of this study?

The aim of this study is described a little differently in abstract, background and discussion. Based on the results the description in background is more precise.

The pilot test of the questionnaire translation is described quite cursory. In addition, at page 10 (line 1 and 2) is a confusing amount of participants (21 and 7). There is need to know how and where these participants were selected? Was the only result test-retest reliability? etc.

The ‘Factors associated with low objective understanding’ results (page 13-14) are written quite inaccurate. It would be nice to read easily how these associations are interpreted (directions).

The authors state in discussion (page 15) that ‘Our study will provide degrees of objective and subjective understanding of the IC process among RCT’. Is this really so?

The authors’ have mentioned some limitations of this study. The quite low amount of participant in this accompanying research is a limitation especially when the main group is so huge (over 75 000 women). The discussion of study reliability and validity is missing.

Minor Essential Revisions:
Table 5: p-value is missing at A4 title column

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

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.