PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Deliberative democracy and cancer screening consent: a randomised control trial of the effect of a community jury on men's knowledge about and intentions to participate in PSA screening.
AUTHORS	Thomas, Rae; Glasziou, Paul; Rychetnik, Lucie; MacKenzie, Geraldine; Gardiner, Robert; Doust, Jenny

VERSION 1 - REVIEW

REVIEWER	Peter Elwood Cardiff University Medical School, Institute of Primary Care & Public Health
REVIEW RETURNED	17-Jun-2014

GENERAL COMMENTS	This paper describes what I know as a Citizen's Jury in which the effect of instruction affects the views of people with no vested interest, in a medical procedure. We conducted a similar study with the title: My Health – whose responsibility [J Epidemiol Comm Hlth. 2010;64:761-4]. It was one of the most stimulating studies I have been involved in. My general reaction is that far more studies of this kind, in which the public are involved, and their opinions are obtained, should be conducted. Government reports such as 'Securing good health for the whole population' (Wanless 2004); 'Choosing health: making healthier choices' (DoH 2004);), 'Equity and Excellence: Liberating the NHS' (Secretary of State 2010) all emphasise the need to establish an effective partnership between the health services and citizens Furthermore, Lenaghan et al.(1996) urged that decision makers at a local and national level should take time and make an effort to obtain informed comment from groups representative of the general public, and actions by health services should be guided by the voice of the public. Frequently there are discussions about screening procedures, and often the professionals are divided. Rarely however, are the view of the public sought. I therefore find this study of great interest and value, and clearly screening for prostate cancer is an excellent topic as the evidence is complex and professionals are seriously divided. A particular value in this study is that standard fact sheets and general information were given to all the subjects, but only some were given addition information by expert witnesses. In fact, I am surprised at the relatively small differences between the groups (Figure 2) but probably that simply shows my own bias

	against the test! Having said all that, I find the study far too long and containing far too much detail on aspects of little interest. I also find that important facts are sometimes lost in a wealth of details. I would recommend that a very short report is given very wide publicity. Originality - does the work add enough to what is already in the published literature? If so, what does it add? If not, please cite relevant references. A new evaluative approach * Importance of work to general readers - does this work matter to clinicians, patients, teachers, or policymakers? Is a general journal the right place for it? Yes, the specific findings are of relevance to all males, but the jury approach is of very wide importance. However, I think it would be best published in an epidemiological of a public health journal. * Importance of work to general readers - does this work matter to clinicians, patients, teachers, or policymakers? Is a general journal the right place for it? Yes, the specific findings are of relevance to all males, but the jury approach is of very wide importance. However, I think it would be best published in an epidemiological of a public health journal.

REVIEWER	Paul Ward Flinders University, Australia
REVIEW RETURNED	04-Jul-2014

GENERAL COMMENTS	This is an excellent paper using a novel approach. There have been a number of citizen juries, but the use of this method within an RCT is wonderful. The authors should be commended on the study and the paper on which it is based.

REVIEWER	Ries Kranse IKNL (comprehensive cancer center), The Netherlands
REVIEW RETURNED	03-Sep-2014

GENERAL COMMENTS	I have one major problem with this paper. I agree with the authors that it very is important to inform men prior to PSA testing about harms and benefits. A community jury seems a possible instrument to achieve that goal. But the information the researchers provided to the jury participants was probably not what they intended to provide. Question 2 in box 1

	reads : "Out of every 1000 men, about how many do you think will be diagnosed with prostate cancer some time in their life?". The correct answer, according to the authors is 15-25 (in fact it is 150-250). Question 3 reads : Out of every 1000 men, about how many do you think will die from prostate cancer? *. The correct answer, according to the authors is 1-5 (in fact it is 10-50). The reason for this mistake may be that in the Fagerlin paper which is the source for these questions (Table 3) the results refer to 100 men instead of 1000 men. In view of the aims of this study (to correctly inform men prior to PSA testing) I consider this a fatal mistake (since it cannot be corrected for in retrospect). In addition the authors very likely carried out their calculations using the wrong answers as being the correct ones. So the estimates of the increase in substantive knowledge related to participation in the jury were very likely flawed. As a second minor comment I doubt if the p-values that are reported are correct (due to the small numbers of participants in the control and the jury group and given that they are probably derived on the assumption of normality). This is a minor issue since the effects are obvious, irrespective of the precise p-value. If I am correct about the "question 2 and 3 issue" this is a very unfortunate mistake. The subject is very important! and the outcome (a decrease in the number of men considering PSA testing after jury participation) is interesting.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1 suggested the study was too long with some details of little interest.
Response: Our manuscript fulfils the word limits of BMJ Open and the requirements of both CONSORT and TiDIER guidelines. We believe it is important to provide detailed information regarding the study recruitment and process to facilitate further research.

Reviewer 1 also suggested that if the manuscript was shorter it could be more heavily publicised.
Response: We agree with this comment. Our dissemination plan was to publicise the abstract using infographics, text and hyperlinking to any media interviews or publications. We would also comment on the manuscript in relevant blog posts and provide short interviews. In this way we would simplify our manuscript for general use without making the current study unreplicable.

Reviewer 3 correctly pointed out the error made in the answers of two knowledge questions.
Response: We have removed these two questions from the paper and have consequently made changes to appropriate sections in the manuscript. As previously stated, the knowledge questions were secondary outcomes and were not used to inform men in either group. The correct information was provided by the expert witnesses as can be seen in the available youtube videos. Professor Frank Gardiner's presentation can be found here http://youtu.be/9vPt3NAcG8g and Professor Paul Glasziou's here http://youtu.be/nifkjdZKmsU. These are cited on page 7 of the manuscript. The results of the knowledge questions do not change our primary outcome or the main findings from the study.

Reviewer 3 also had a minor comment that he considered the p values in analyses may be incorrect possibly because analyses were based on an assumption of normality.
Response: The statistical analyses conducted for continuous data were ANCOVA and Fisher's exact test for categorical data (page 8). An ANCOVA is robust to departures from normality and we used pre-test scores as covariates. The Fisher's exact test was used due to small frequencies in some cells. To check for typographical errors, we have rerun the analyses and the results are unchanged.

VERSION 2 – REVIEW

REVIEWER	Prof Paul Ward Flinders University, Australia
REVIEW RETURNED	16-Oct-2014

GENERAL COMMENTS	I really liked the first version of this paper, and it seems that the authors have appropriately responded to the minor suggestions from reviewers.

REVIEWER	Ries Kranse Comprehensive Cancer Center, Utrecht, The Netherlands
REVIEW RETURNED	28-Oct-2014

GENERAL COMMENTS	In the original manuscript the authors assumed the wrong answers as being the correct ones for questions 2 and 3 (box 1 in the original paper). The data processing for these two questions was based on these incorrect answers. The issue of these two questions in box 1 (about the life time prostate cancer and lifetime prostate cancer death risk) could have been dealt with in two ways. 1) simply delete the questions (and all related discussions) from the manuscript. This is what the authors did. Their motivation being that the information obtained by these two questions is relatively unimportant . 2) See what comes out if the correct answers to these questions were used (after all, these are valid and relevant questions and they were answered by all participants). I.e. : is the community jury group still better in identifying the correct answer for the life time risk to die of prostate cancer? And w.r.t. the comparison for the life time prostate cancer risk, is there still no difference between the arms? What are the conclusions of the authors in view of the correct processing of these two questions? Is it fair to simply leave out these questions as if they have never been asked and answered? Depending on the outcomes of this processing it may not be necessary to deal with this issue in the paper. For question 2 the correct answer was > 25, for question 3 (life time risk to die of the disease) one may argue that the correct answer was not in the list, but the life time risk to die of prostate cancer for the Netherlands (and the USA) is roughly 3%, Therefore I think >20 is the best answer for question 3 (is the life time risk to die of prostate cancer < 2% in Australia?). Two, different issues (that are related): On page 4 line 12 it is stated that the results of the ERSPC and PLCO (prostate arm) were equivocal. That is not true. ERSPC showed a 20% prostate cancer specific mortality reduction. PLCO (prostate arm) did not. line 42 page 11 It is stated that ""Neither the ERSPC Neither the ERSPC nor PLCO trials has a median follow-up long enough to reliably address prostate cancer mortality". Same issue, the ERSPC showed a 20% disease specific mortality reduction (papers in NEJM 2009 and 2012).

VERSION 2 – AUTHOR RESPONSE

Reviewer 1 was very positive about the manuscript and had no suggested revisions.

Reviewer 2 commented:
1) In order to address the knowledge question error, we could have either deleted them from the manuscript or rerun the analyses constructing a “correct answer” by using closest approximation from the answers provided.
Response: In the first revision of our manuscript, we chose the former to simplify the issue. The questions and therefore answers were incorrect. These questions were not central to our study. Once the error was pointed out, we believed it most appropriate to delete these questions from the results.

2) The statement made in the manuscript that the results of the ERSPC and the PLCO trials were equivocal was incorrect.
Response: We have clarified this sentence. It now reads, “The results of two large randomised controlled trials of population screening (the ERSPC trial in Europe3 and the PLCO trial in the United States4) were much anticipated, but the differing methods and results have led to conflicting interpretations and recommendations from expert groups.5,6” (Page 4).

3) The statement “Neither the ERSPC3 nor PLCO4 trials has a median follow-up long enough to reliably address prostate cancer mortality..” was questioned due to ERSPC data at 11 years.
Response: We have clarified our sentence to now read “The median follow-ups of the ERSPC3 and PLCO4 trials (13 and 11 years) are not sufficient to reliably address long-term prostate cancer mortality…” (Page 11).