Reviewer's report

Title: A post-trial survey to assess the impact of dissemination of results and unmasking on participants in a 13-year randomised controlled trial on age-related cataract

Version: 1 Date: 4 February 2011

Reviewer: Conrad Fernandez

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The manuscript describes the return of results and impact upon participants of individual results and a brief description of effectiveness of masking. The clinical setting is novel although unclear that it is generalizable (as the authors acknowledge), the findings do add to the literature supporting the return of results and minimal impact upon participants. Some methodological limitations are suspected as the methods details could be better described (see below). A strength is the very high response rate for a survey.

1. The reading level of the lay summary is very high (by Flesch-Kincaid readability score = grade 18!). Given that only 25% of the cohort had completed high school, not clear that the level of understanding would have been adequate. This should be included in limitations of interpretation of the study.

2. How were these questionnaires and lay summaries developed? Was there any attempt at validating or piloting the lay summaries or questionnaires. If not this should be included as a limitation. If yes, this should be described in the methods.

3. Were the original results offered to participants or just sent to everyone? This should be explicitly described.

4. The questionnaire questions are often not provided as a balanced Likert response (eg potentially leading to biased responses). This should be described as a limitation.

5. Seems incongruous that half of those described as satisfied still needed more info./ Please discuss reasons for this further.

6. The authors state: “This caused some CTNS participants to complain about the delay in receiving the results”. How did they respond to this for this group? How many complained? How did they know there was a delay?”

7. The authors state: “It is critical to maintain contacts with the participants until provision of results”. In the methods please describe who was responsible for retaining contact (the participant or the researcher) and how was this done.

8. The authors state: “since 443 post-trial questionnaires were completed at home by the participants and 167 were administered to participants at the clinic”.
Did they analyze the responses to determine if these were different depending on the location for filling out the survey?

9. There are some Formatting issues in table 1. Not all the words are visible in my copy. Abbreviations in the title of the tables should be spelled out.

10. Limitations of generalization should be expanded as noted above – esp the trend to lower education levels in non-respondents and the high level of literacy needed to read the cover letter.

11. I presume the original supplementary documents were in Italian? Were these supplementary documents provided to the reviewer translated by a professional translator? This should be stated in the methods.

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

**Quality of written English:** Needs some language corrections before being published

**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.