Author's response to reviews

Title: Patient Experiences in Retinal Trials: a Cross-sectional Study

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Author's response to reviews: see over
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Timothy Shipley, Executive Editor

BMC Ophthalmology

Dear Dr Shipley and editors,

Thank you for considering our manuscript titled ‘Patient Experiences in Retinal Trials’ (Au, CP., Fardell N, Williams M, Fraser-Bell S, Campain A, Gillies M) for publication in BMC Ophthalmology. We appreciate the comments from the reviewers. Please see our responses to the reviewers’ comments (italicized) as follows. The changes are tracked in the revised manuscript.

Reviewer 1

Interesting study and I have little to add to improvement other than to advise to discuss the limitations of the use of a questionnaire designed by the authors only without e.g. focus groups, and the scoring method.

We have included in the discussion section some of the limitations of our questionnaire design. The questions in our survey were formulated after a literature review of previous surveys, and after discussion with medical, nursing and paramedical staff, to ensure face validity. Content validity could have been enhanced with a pre-study for selection of questions and response options [1-4]. This could include focus groups in addition to the literature review which we performed, to ensure that all appropriate items were included.

References:

Reviewer 2

Please provide a reference to support the method of reaching the sample size calculation. Provide a discussion of how the survey questions were tested or refined and whether any face or content validation was conducted before fielding the survey. In the Discussion section, address how the absence of a negative response option in the “benefit” questions might have impacted the results.

We did not perform sample size calculations for this exploratory, non-comparative study. Rather, we approached 80 consecutive patients in the research clinics during a set period.

We have added to the methods section that face validation was conducted through discussions with medical and nursing staff.

We have addressed the reviewer’s comment that the absence of a negative response option in the question “How did you benefit from participating in the study?” could have positively skewed the results.

The authors do not comment on the potential undue influence of being handed the survey by research staff and the expectation to complete it on site.

Our survey’s response rate was very high at 96%. We acknowledge that there might have been undue influence on patients to complete the survey on site as staff handed the paperwork to them at the clinic. Furthermore, patients could fill out the survey while waiting to see the doctor. Although this survey administration method might have introduced positive bias, asking patients to complete the survey off site would cause inconvenience and would yield a lower response rate. We have included this in the discussion.

Please provide a table or sentence illustrating the distribution of survey respondents across the 14 retinal studies.

The questionnaire was filled out anonymously and did not allow respondents to indicate which retinal/macular trial they were part of. We did, however, confirm that they were from at least one of the listed studies. Thus, we are unable to provide information on the distribution of patients across the trials. Nevertheless, our population was a consecutive sample and would include patients from a number of different trials. Our clinics are not differentiated based on which clinical trials the patients are part of.

Further, the purpose of our study was to investigate patient experiences in retinal trials, and to identify sources of satisfaction and dissatisfaction. We believe that the items in the questionnaire provided information on these associations that would be important to improve the clinical trial process.
Figure 1 appears twice in the manuscript, both before and after the Appendix. The duplication should be eliminated.

We have deleted the duplication of Figure 1.

The authors might do well to review the literature of the past 5 years concerning the participant experience studies more broadly in the context of translational research, and in the development of validated instruments.

Increasingly, participant experience studies are undertaken as part of clinical trials to help inform recruitment, trial delivery and improve the conduct of future trials [1]. Most of these studies, not in the field of ophthalmology, have focused on patients’ understandings and experiences and how these might affect recruitment, retention and adherence to the treatment being investigated in the trial [2-5].

As we mentioned in our article, ophthalmology patient satisfaction studies have mainly been in the areas of cataract and refractive surgeries [6-9], as well as in for oculoplastic and glaucoma surgeries [10,11]. Our study provides insight into patient experiences and satisfaction in clinical trials in the context of translational retinal research.

We have incorporated more references regarding the development of validated instruments to assess patient reported outcomes [12-14].

References

9. Schein OD. The measurement of patient-reported outcomes of refractive
The finding that 14% of participants did not understand that they could withdraw requires additional discussion beyond the comment that it is important to stress participants’ rights.

In the discussion, we have suggested that participants might have been more focused on the actual treatment and side effects or visit scheduling information and decision making of whether to enter a clinical trial and less on other issues such as withdrawing. We have added the reviewer’s suggestion that the conduct of verbal consent, the conduct of the survey on site, and the signing of the consent for retinal studies all in one day may all be unintentional subtle sources of undue influence. Nevertheless, this highlights the importance of clearly explaining to patients their rights when entering the study as well as their obligations, and not ‘flooding’ patients with too much information simultaneously.

Thank you for considering our article for publication and we hope to hear from you soon.

Yours sincerely,

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