PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	DISSEMINATING RESULTS TO CLINICAL TRIAL PARTICIPANTS: A QUALITATIVE REVIEW OF PATIENT UNDERSTANDING IN A POST-TRIAL POPULATION
AUTHORS	Darbyshire, Julie ; Price, Hermione

VERSION 1 - REVIEW

REVIEWER	Charles Fox, Consultant Physician, R&D Unit, Northampton General Hospital, NN1 5BD. I know and respect the authors and I was a PI in the 4-T study. However, I have no conflict of interest with respect to this submission to BMJ Open.
REVIEW RETURNED	26-May-2012

THE STUDY	The authors must have been disappointed in the very low response rate of 9%. As they mention in the text, this makes the questionnaires returned unrepresentative. Results on a simple database - no stats required. For the last question, the simple response should be NO which thus requires no explanation.
RESULTS & CONCLUSIONS	Because of the low response rate, no conclusions can be drawn from the questionnaires. A lot of work went into this project, which then foundered on the poor response rate to the questionnaires. The conclusions are accurate but I would like to suggest that the authors address the most striking finding of the study, namely the low response rate. This is an important negative finding which should be published and for which there is no obvious explanation. It would contribute greatly to the literature on patient views of research if there were a detailed and honest discussion on the possible causes of this disappointing result. Ideas that come to mind are: 1. Did patients find the questionnaire threatening? The first 14 items are closed questions (CQs) and we know that a series of CQs can feel like an interrogation. It would be interesting to speculate that a questionnaire made up of more open (softer) questions with scaled answers would have elicited a higher response rate, without reducing the value of the findings. 2. Did patients see this as an add-on? If I put myself in the shoes of a patient who had taken part in the 4-T study, I would probably have felt positive about the experience and

	felt happy to be told the results of the trial. If I then received a further questionnaire through the post, I might feel that this was an unexpected add-on. Having looked through the quesionnaire, I might feel that I had done my bit for this particular research project and might discard the questionnaire with a mild feeling of guilt. The fact that less that 2 out of 3 study centres took part in this project suggests that the add-on effect was an important factor. 3. Postal questionnaires often have a poor response rate. There is an extensive literature on methods of increasing the response rate to a postal questionnaire. Ref: McColl E, Jacoby A, Thomas L et al. Design and use of questionnaires: a review of best practice applicable to surveys of health service staff and patients. Health Technology Assessment 2001;5 (31). The authors may already be aware of this and more recent work on the subject but this is important advice to follow if you are sending questionnaires to patients. 4. Perhaps the authors can come up with other plausible explanations?
GENERAL COMMENTS	I welcome BMJ Open and am privileged to take part in this process, designed to make the results of research widely available, including studies where the results are negative. I am sorry to cause the authors more work but their submission as it stands is of limited value because of the low response rate. This could be turned into a virtue if they were to examine the possible causes and put forward solutions to help themselves and future researchers. Forgive me for recommending a paper written by a notable social anthropologist who investigated why patients join a clinical trial. Ref: Lawton J, Fox A, Fox C, Kinmonth AL. Participating in the UKPDS: a qualitative study of pateints' experiences. Br J of General Prac. 2003. 53: 394-398. This explains the motvation for joining a study. page 11: Reference 3 has no title.

REVIEWER	Helen Kirkby, PhD Student, The University of Birmingham, United Kingdom. I have no competing interests to declare.
REVIEW RETURNED	29-May-2012

THE STUDY	It cannot be decided whether the overall study design is appropriate and adequate to answer the research question because there is a lot of information missing as to how non responders were attempted to be followed up - please see the addition comments section below. Participants demographics are required and a comparison between responders and non responders. The patients are not representative of actual patients since the response rate was 9% and likely to be extremely biased towards those who are the most encouraging of research. Methods - see additional comments below for information that needs including.

	Statistical methods - no mention of how qualitative data was analysed.
RESULTS & CONCLUSIONS	The results do not answer the research question becuase of the extremely limited response rate (9%). Qualitative results need to be better presented. The message is not clear - the quality of the writing could be substantially improved.
REPORTING & ETHICS	A statement of ethical approval needs to be included.
GENERAL COMMENTS	1. The response rate to this study was extremelt low, at 9%. This will significantly bias results and I do not think you can draw any results from this sample at all. The sample is likely to be extremely biased and not representative of the whole study population. I would like further information on the efforts made to encourage return of questionnaires - i.e. follow up questionnaires and phone calls etc. 2. You state that trial centres were "asked to forward a copy of the letter to all trial participants as soon as possible". How did you ensure this was done by trial centres? If these were not sent out, it may account for the low response rate. 3. You do not present any demographics of the participants. This is especially important with such a potenially biased sample and I would like to see a table that compares the demographics of the study sample to the demographics of those in the 4-T trial (i.e the 455 invited to participate). It may be useful to look at the centre responders were from to see if a particular centre returned the majority of responses, for example. 4. I would like to see the qualitative results better presented - this is difficult to read as it is. 5. You do not describe how you analysed your qualitative results. 6. Further work is required in the writing style, which is difficult to follow at times. The message of the paper is difficult to pick out from the article itself. 7. You need to include a statement of ethical approval.

VERSION 1 – AUTHOR RESPONSE

We have substantially revised the conclusion to allow discussion of possible reasons for the low response rate and, in light of Dr Fox's comments on open/closed questions, we realised that we had not accurately reflected the questionnaire responses and have changed the format of the main results tables accordingly.

We took on board Ms Kirkby's comments about representativeness and have also included some basic demographics which allow us to demonstrate a comparison between our 40 responders and the 708 participants from the main study.

We are aware that the response rate was very low but think that the revisions have clarified the message that the results of this ancillary study can offer to the research community.