Reviewer's report

Title: Decisions about participation in RCTs: The role of conditional altruism

Version: 2 Date: 29 June 2009

Reviewer: katie featherstone

Reviewer's report:

This is a well written and competent paper. However, I do have a number of reservations with the thrust of this paper that need to be dealt with.

Major compulsory revisions-
On reading – the title, introduction and discussion leads the reader to assume the paper is about ‘altruism’- however, when it gets to the results section, this doesn’t seem to be the case- this appears to be about perceived benefits and disadvantages of participation. I think the main issue with this paper is finding the focus and story- at present it doesn’t really tell us anything new.

I am not convinced the focus on altruism follows from the results section- to justify this the analysis needs to provide a more detailed account of its role. However, I am not convinced altruism plays a significant role in individuals decisions to participate in trials- and this paper doesn’t provide me with any evidence that it does. Having carried out a large amount of fieldwork and written in the field I have predominantly found that personal benefits and preferences for a particular treatment are key driving forces and I suggest that these are key motivations in this trial. This paper may also benefit from being a little more specific in focus- this trial looks at a preference trial- perhaps experiences of participation in this type of trial would be an interesting focus. It may also be useful to focus on participants or non-participants- this is a short paper and I think including all groups and data sets may be too much and has lead to a rather surface paper.

What is the aim of the paper- to provide ways to improve recruitment? Please set out aims of the paper more clearly – it seems to drift across a few interlinked themes. The authors discuss ‘non-altruistic as well as altruistic motivations as important’ –why divide altruism away from wider motivation?

Background

The review of the literature examining patients experiences of recruitment- particularly the qualitative literature is rather surface- I am not convinced that the authors have really tried to engage properly with this literature it is summarized to such an extreme that it doesn’t really tell the reader anything- if they engaged, I think they would achieve a better story.

The detailed qualitative studies in this field (some of which are cited here) are trying to uncover the complexities involved in understanding and participating in
clinical trials- the authors should do this literature justice rather than glossing over them. In addition, the authors have missed some key references- see Snowdon et al (social science and medicine) who is a key author in the field. The authors should also examine in more detail some of the papers already cited- particularly the papers by Donovan and Featherstone.

They say that ‘altruism’ is a clear theme emerging from research in the field- however, I would not agree- the authors need to examine the varying quality and methodologies employed by the studies in this field and engage in a more selective way with the literature.

More details of the trial and the condition are needed to enable the reader to put it in context. Is this a preference trial? If so, this needs to be discussed as a methodology and that this is an unusual trial and not standard – it is also a surgical trial, which has specific issues. Also perhaps a section on what information patients received about the trial. The observational data could be used here to provide the context- what happened in these consultations? This is also a key aspect of recruitment missing in the wider literature.

In addition, I didn’t really understand from the description what GORD is- please explain for a wider audience- life expectancy? Effect on quality of life? Treatment?

Results

Table 1- I am not sure what table one adds to the readers understanding- I would prefer the summary of participants in a sentence in the methods section.

Figure 1- I do not like this table and would like it removed- I don’t think that the complexity of patients experiences can be reduced to a flow chart and do not think that this is an appropriate representation of patients decision-making- do patients really divide ‘benefits’ and ‘disadvantages’ in such a systematic way. This is not consistent with the methodological approach.

I am not convinced by the themes- what is an ‘initial inclination to participate’? -is this about motivation and why is it important- and how do you know when this is recalled during a post-recruitment interview? Similarly, dividing the following sections into perceived benefits and disadvantages feels a little simplistic. The section on ‘benefits’- to me this reads as- They want access to better treatment/specialists and they want access to their treatment preference.

Generally there is poor integration of observational data- if you are using this data set- which I encourage you to do- you do need to provide extracts of field notes or provide a description of the encounter, not just refer generally to the observation findings, for example -‘Observation notes from this man’s and other’s trial recruitment consultation suggest that in practice, potential participants did not ask many questions about their own condition or current treatment, but none of them expressed disappointment with this consultation.’ It is not enough to give a general overview of the observational data, it reads a little like anecdotal evidence rather than data- so a more robust use of this method please. I would
also hope that this data set will add a more detailed context in which the interview results can be situated.

Generally, this is a rather ‘surface’ analysis- more analysis of the extracts- what does it mean? Also a little more detail- for example, statements like ‘a couple of interviewees’ is a little chatty in tone and not appropriate. I am not convinced that the themes presented here really tell us anything new- the authors need to look at the qualitative papers in the field already and see how they can develop or move on their findings- this paper fails to deal or acknowledge the complexity of peoples decision-making and their rationales for participation or not.

In addition, I would prefer longer data extracts that are analysed in more detail but less of them. A one or two line extract does not tell us anything.

I find the main thrust of this paper too simplistic- ‘The main findings of this study are that an inclination to help others or contribute to a collective general good can positively predispose people towards participation in a clinical trial, but that the formal decision about participation is then additionally influenced by considerations of the implications of participation for themselves personally.’ It feels as though the authors have referred to the literature, but haven’t engaged with it What does this tell us? Do people really have an ‘inclination’ followed by a ‘formal decision’?

Discussion and conclusion
Given the nature of the journal, the suggestions for trialsist at the end of the paper are a bit predictable and weak- I think some detailed practical advice- perhaps aimed at those running preference trials may be more appropriate and useful

In addition, given my above comments, I do not think they can justify the section on the gift relationship without a lot more work examining this within the analysis section.

minor essential revisions-

Methods
Details of the number of patients recruited onto the trial and for each of the trial arms, dates of the trial, how many centers? The sub-study examines patients from two centers, but how were they chosen and what were the other centers?

‘A combination of observational and interview methods were adopted [29-31]’- is this ethnographic? Why were these methods chosen- I think for a paper within a journal such as this, a justification of the methods- why they are used to explore this topic and details of how the data was analysed is vitally important- this allows readers from a wide range of audiences to judge the quality of the paper.

The methods section is already long so I would encourage the authors to focus on tightly summarizing the key features of the methods- numbers, sample etc and concentrate on providing readers with a robust description of the appropriateness of the methods and how they link to the aims of the study.
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