Reviewer's report

Title: A centralised public information resource for randomised trials: a scoping study to explore desirability and feasibility

Version: 1 Date: 11 March 2005

Reviewer: Hazel Thornton

Reviewer's report:

General

This is an important scoping study. The authors have used this opportunity (constrained though they were) to successfully demonstrate that a centralised information resource for participants and potential participants about ongoing trials is not only desirable and feasible, but has wider benefits. As they suggest, the potential impact of undertaking a more detailed investigation is likely to be considerable.

Unmet information needs not only hamper research but are a cause of frustration for patients and potential participants.

Major compulsory revisions

1. It is important the title of a paper clearly reflects the content. Might I suggest that this title could be improved? As it stands, it could mean that it is a resource to find out what trials are, and/or what they are for. Perhaps something like: "A centralised public information resource for participants about ongoing clinical trials: a scoping study to explore desirability and feasibility."
2. Abstract: The methods section, second sentence, does not mention refusers, although we are advised (p.5 4th line up from bottom, and page 7 line 5.), that refusers were approached.
3. Introduction p.4. The first sentence of a paper is very important. It is not just 'new' health care interventions that require testing. Many interventions currently in use have not been evaluated. Interventions (old and new) need to be compared prospectively in trials to produce evidence about their benefits and harms.

Minor essential revisions

1. Abstract: Results. Suggest (line 3): "relating to the purpose of the trial, and the interventions etc."
2. Conclusions: Last words - perhaps a firmer recommendation - "is required" rather than "should be considered."
3. Introduction. P.4. 2nd sentence. Should it not be 'small' proportion, rather than 'low' proportion?
4. Line 8. "some peopleâ€¦do not thinkâ€¦." There is evidence to show that the quality of information leaflets is poor. (Lees N, Dixon-Woods M, Young B, Heney D, Thornton H CaTLET: Evaluation of information leaflets for patients entering cancer trials. . PSYCHO-ONCOL 10 (3): 266-266 MAY-JUN 2001)There is also evidence (other than the ProtecT trial referred to) to show that the 'framing' of information, and the way it is presented can affect the way that potential participants remember it, or understand it. This sentence needs re-phrasing to reflect this evidence, rather than this subjective way of describing information provision.
5. Line 9. Sentence beginning "People who agree to participateâ€¦" This sentence also needs
re-phrasing. It is not just people who agree - refusers can also highlight shortcomings, challenge the quality of patient information leaflets, and the quality of trial protocols. (See: Thornton HM. "Breast cancer trials: a patient's viewpoint." Lancet. 'Viewpoint' 1992; 339:.44-45) Suggest something like: "Some people who are asked to participate in trials may struggle to make sense of the proposition, and whether to participate or not." Randomisation is a particular stumbling block.

6. Page 4. last paragraph. Suggest, rather than:"none have been designed" replace with "although none were designed.". For example, Current Controlled Trials (www.controlled-trials.com <http://www.controlled-trials.com>) are currently investigating expansion of the number of data items it publishes for each trial, to include a brief summary including study hypothesis. Pressure for lay summaries of trial hypotheses is being taken notice of.

7. Methods. P.5. This section begins: "We recognised that different types of people would have different perspectives on information needs relating to clinical trials." This is unclear - which 'people'? It would be more usual to describe, and cite, what a literature search had shown, to demonstrate that a review had been done, and to enable readers to access this material. (E.g. research by Fallowfield; Cox; ECRI and others.)

8. Page 6, paragraph 2. It is not until the second paragraph that we are advised that topic guides were used. Might it be better to begin the first paragraph: "Using topic guides, we used semi-structured interviews etc." It would also be interesting and informative to provide the prompt list as an appendix. It would be interesting to know, for example, if participants were asked whether trial question was one that he/she wanted an answer to - did they feel it was relevant to their needs, or would have been of benefit to other similar patients?

9. It would be useful to know if the researchers felt that saturation point was reached, or did the time constraints and other limitations they referred to prevent this?

What next?: Accept after minor essential revisions

Level of interest: An article of importance in its field

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

Statistical review: No

Declaration of competing interests:

I declare that I have no competing interests