Reviewer's report

Title: Patient Recruitment In a Behavioral Intervention Randomized Clinical Trial of Chronic Heart Failure Patients in the VA

Version: 1 Date: 4 February 2004

Reviewer: Nicola Mills

Reviewer's report:

General:

This was an interesting and coherent paper that explored patient recruitment to a trial of behavioural therapy for chronic heart failure. The problems of trial recruitment in general are well documented, so it is important to explore reasons for this in different research contexts.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached): None

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct):

Abstract:
1. The study methods are not clear from the abstract. More detail is required, for example, it would be helpful to have a sentence explaining how patients for the qualitative sub-study were recruited and how patient data were collected.

2. The following extract, “approaching potentially eligible patients in the VA clinics and by telephone”, should appear under ‘methods’ and not ‘results’.

Methods:
3. There are no methodological details of the qualitative sub-study and statistical analysis under the ‘Methods’ heading. A single sentence with regard to the statistical analysis will suffice (as per the Abstract) but more detail is required with regard to the qualitative sub-study, for example, who was approached and how, numbers refused/accepted interview, what were patients asked, how were data recorded and how was it analysed). Some of the information under “…Results from qualitative study” covers the above but should be moved to the methods section of the paper.

4. Detail is also required with regard to how reasons for non-participation were ascertained (for example, were pre-defined response categories given to patients – and if so how were they generated - or did patients give reasons unprompted).

5. The font size for two sentences beginning “The education group…” in the first paragraph of the methods section is smaller than the rest of the text.

6. Under the sub heading “Clinical Sites” the phrase “by helping identifying potentially…” should be changed to “by helping to identify potentially…”.

Results:
7. The key to Table 2 should be dropped, as (presumably) there were no statistically significant differences between the two groups.

Discussion:
8. The authors should discuss their study findings in light of previous research, for example, have other trials of CHF looked at problems with recruitment, or how do these study findings compare with other studies on trial recruitment in different fields? The authors may be interested in review papers, such as Lovato LC et al. Recruitment for controlled clinical trials: literature summary and annotated bibliography. Control Clin Trials 1997;18:328-357, or Ross S et al. Barriers to participation in randomised controlled trials: a systematic review. J Clin Epidemiol 1999;52:1143-1156, which reviews barriers to trial recruitment.

Discretionary Revisions (which the author can choose to ignore):

Title:
9. The term “VA” should be written in full or dropped, as it is not an obvious term to non-American readers. An alternative title could be: “Patient recruitment to a randomized clinical trial of behavioural therapy for chronic heart failure”.

Introduction:
10. It would be useful if the authors explained what is meant by “VA clinics” for non-American readers.

Results:
11. It is very useful to present a flow diagram of patient recruitment, as the authors have done in Figure 1. However, this diagram only presents patients recruited through the clinics and not those recruited by telephone. It would be useful to extend this diagram to include the number of patients approached and recruited by telephone and thus present the total number of patients enrolled in the study. This would make it much easier to see how the numbers of patients presented in Tables 1 and 2 are derived.

12. In Tables 1 and 2, it would be useful to present actual P values of all comparisons rather than just those that were found to be statistically significant.

Discussion:
13. The study’s success in recruiting beyond its projected number of patients lies in its investigative and flexible approach to the recruitment protocol. The authors may want to refer to a study that also took this adaptable approach and succeeded in increasing recruitment to a trial of treatments for prostate cancer from 40% to 70% (Donovan JL et al. Quality improvement report - Improving design and conduct of randomised trials by embedding them in qualitative research: ProtecT (prostate testing for cancer and treatment) study. BMJ 2002; 325: 766-70).

What next?: Accept after minor essential revisions

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

Quality of written English: Acceptable
Statistical review: No

Declaration of competing interests:
None