Reviewer’s report

Title: A heart failure self-management program for patients of all literacy levels: A randomized, controlled trial [ISRCTN11535170]

Version: 2 Date: 20 November 2005

Reviewer: Robert N Doughty

Reviewer’s report:

General

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

See comments below regarding the adjustment in the results for the differences in baseline characteristics. I think that this may overstate the results and the authors should tone down this result and acknowledge that these results may be overstating the results just based on this one study.

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

1. The primary end points are described as combined death/all-cause hospital admission and quality of life (with Minnesota Living With HF Questionnaire, that was modified for people of low literacy). These outcome measures were assessed at 6 and 12 months: which time interval was the primary outcome time measure? (minor essential revision)

2. A major point is the statistical presentation of the primary outcomes with adjustment according to differences in baseline characteristics. The method of randomisation was by concealed random number generation and with the proposed sample size of 150 small differences in baseline characteristics may have occurred but should have been due to chance. From Table 1 the only meaningful (and statistically significant) baseline differences were that in the control group there were:
   a. fewer men,
   b. more receiving beta-blocker therapy, and
   c. patients had a higher mean QoL score.

   However, the authors have described multiple factors associated with higher hospitalization rates from prior studies and then adjusted for these if the relationship between the variable and the study group or outcome was <0.3. With this analysis the odds ratio for the outcome of death or readmission changes from 0.69 (non-significant) to 0.53 (significant). While the pros and cons of this sort of statistical adjustment can be argued the issue that I see is that there were not marked clinical differences in the baseline characteristics to start with. This is a fundamentally important part of this manuscript as whether the study holds a positive or negative result hinges on this analysis. My sense is that this sort of programme may well result in important reductions in clinical events, but I am concerned that with this statistical adjustment that the true magnitude of these benefits is over emphasized.

3. Further to the above discussion of the statistical adjustment, the authors should also bear in mind that the original sample size was 150 subjects, but the study was stopped after 127 due to funding constraints. The primary end point for which the study was powered was the QoL score which was a negative result based on the sample recruited. A comment to this effect should be made. (minor essential revision)

4. Some follow up data on the use of medication including the ACE inhibitors, and beta-blockers would be valuable to understand both the results as well as how this form of education impacted on
patient adherence to medical therapy. (minor essential revision)
5. Page 13, para 3, there were fewer men in the control group, not fewer women. While there were slight differences between the groups at baseline with regard to hypertension, diabetes (2 patients only difference), ACEi/ARB use, % with systolic dysfunction, these differences were small and did not reach statistical significance; this should be reflected in the text and clarified in the results section as it is misleading as written. (minor essential revision)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No

Declaration of competing interests:
'I declare that I have no competing interests'