Reviewer's report

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

Version: 2 Date: 4 November 2005

Reviewer: Finlay A McAlister

Reviewer's report:

General

Nicely written and easy to follow- the investigators followed the CONSORT suggestions for reporting their RCT. The investigators are to be congratulated on mounting an RCT of self-management programs in CHF as too frequently disease management programs are developed and disseminated into particular locales without rigorously proving that the particular interventions in that program work in that setting and with that patient population. Attempting to target the intervention to vulnerable patient populations, and particularly adults with low literacy, is a unique feature of this RCT. This study complements their earlier work on disease management for diabetes published in JAMA last year.

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

1. This paper would be substantially strengthened if the authors had data on causes for hospital readmissions and could provide the data for "CHF readmissions" or even "cardiac readmissions" and "CHF deaths", as well as the all-cause readmissions/death data they do report. Also, I'd suggest they report the hospitalization data as #of pts hospitalized at least once/#of pts in that arm of the trial as well as the way they chose to report it (total # of hospitalizations/#of pts in that arm of the trial).

2. The glaring imbalance in Table 1 is the substantially poorer MLWHF scores in the control group at baseline (12 points higher and p=0.0028). The remaining imbalances described in para 3 on page 13 are minor (and many were not statistically significant) and I'd suggest shortening that paragraph substantially. I am surprised that adjustment for baseline imbalances increased the size of the treatment effect in favour of the intervention given that the intervention group had better QOL and a trend towards less severe NYHA class distribution, as well as being more likely to be taking ACEi/ARB and digoxin (granted controls were more likely to be on B-blockers) as such, I would have expected adjustment for these positive prognostic factors to reduce the apparent impact of the intervention. What variables were included in the adjustment? I would suggest these be explicitly defined in para 4 on page 13 (I know the investigators described which variables they would consider for adjusting in the methods section, but I'd like to know which ones were actually included in the adjustments).

3. Given that they modified the MLWHF questionnaire from the usual version, do they have any data they can provide confirming the reliability/validity of their modified MLWHF questionnaire? Did they develop the self-efficacy and knowledge questionnaires de novo for this project? Any reliability/validity data for these scales? Can the authors provide some guidance in the text for readers such as myself un-familiar with these scales what a clinically important difference would be (ie. what does the 12% improvement in knowledge scores and 2 point improvement in self-efficacy scores described on page 14 mean?). Given the questions over the modified scales performance characteristics in this patient population and since neither the patients nor the research assistants performing the questionnaires with the patients and collecting the data were blinded (as per para 2...
on page 18), my enthusiasm for these subjective endpoints is muted.

4. Given how small the "inadequate literacy" subgroup is and the imbalances at baseline between controls and interventions within that subgroup, I'd suggest deleting the first 2 paras on page 15 and merely saying that "there was no statistically significant effect modification between literacy and the intervention". As this subgroup is even more under-powered than the main trial comparison, I think it is a stretch to say that this disease management intervention in CHF has a greater effect in patients with low literacy (as implied currently on page 17 of the manuscript).

5. It would be helpful to provide demographic details on the total patient population with heart failure cared for in their GIM Practice (to ensure that the 118 patients deemed eligible for this trial were somewhat representative of the 500 patients with CHF in their practice). Alternately, I would suggest that the authors provide details on what the reasons were for exclusion in the 367 patients with CHF who were deemed ineligible for this study.

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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)

1. It is difficult to isolate the impact of particular elements of their intervention (the 1 hour educational session + educational booklet + 10 telephone calls over 6 months + scheduling of appointments with their attending physician for patients experiencing worsening symptoms) and, given the apparent intensity of the resources needed, did the authors collect cost data and can the authors make some comment in their discussion on this point?

2. I suggest that the authors clarify how diagnoses of heart failure were made. I'm not clear from the description at the bottom of page 5 whether a patient taking lasix for peripheral edema could be included in this study without objective assessment of their LVEF or confirmation of CHF diagnosis by at least 2 observers or 1 observer using standardized criteria?

3. How was "moderate to severe dementia" defined and did they adjust standard dementia rating scales (such as the Folstein MMSE) for literacy level?

4. Who collected the outcome data and who ascertained clinical endpoints? I take it that neither the study staff nor the patients were blinded to treatment allocation, but were the individuals reviewing the admissions and deaths blinded to treatment allocation?

5. From my reading of page 10, it appears as if the investigators relied solely on patient self-report for collecting baseline data- is this just a typo? (I imagine they must have used the clinical charts and medical records as well).

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Discretionary Revisions (which the author can choose to ignore)

1. Why the upper age limit on the eligibility criteria? I was surprised how young their CHF patients appeared to be (the patients in our Heart Function Clinic have an average age of over 70 years).

2. I'm surprised they designed this study and calculated sample size to detect a 9 point difference in MLWHF scores- this is nearly twice as large as the effect seen in the ACEi vs. placebo trials in CHF patients. (not relevant to this manuscript, but for future studies they may be planning)

3. While the authors statement at the bottom of page 16 that self-management training programs reduce hospitalization rates to a similar extent as comprehensive programs employing multidisciplinary teams and clinics is technically correct, it should also be acknowledged that multidisciplinary clinics/teams have been shown to reduce mortality (RR 0.75, 95% CI 0.59-0.96 in the meta-analysis in ref #6) while self-management programs have not (RR 1.14, 95% CI 0.67-1.94)

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