Reviewer's report

Title: Patient education for chronic heart failure in primary care (ETIC): design of a cluster randomised trial

Version: 2  Date: 17 October 2014

Reviewer: Arno Hoes

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Major compulsory revisions

1. The inclusion criteria should be presented in more detail. I understand that if according to the cardiologist it is heart failure you consider it heart failure? How is this confirmed? From a hospital discharge letter? It would be good to ensure that patients really have heart failure and maybe include some of the criteria (notably echocardiographic criteria, also for diastolic dysfunction) included in the ESC guidelines. In addition, please included the terms universally applied in heart failure now: heart failure with reduced ejection fraction and with preserved ejection fraction (respectively HFrEF and HFpEF).

Perhaps patients not receiving betablockers or ACE inhibitors should be excluded because they are unlikely to really have heart failure. I know the trial is ongoing, but some additional information on how the inclusion criteria are "operationalized" should be included.

2. There are a lot of secondary endpoints. Why so many? Especially the power for the mortality outcome is too low and this may also hold for hospitalizations. In my view it makes more sense to instead include the number of days in hospital as an outcome.

3. The sample size calculation is not detailed enough. I cannot reproduce it now (or fail to understand how it is done). A difference of 12 points is chosen: why? Any rationale for this? Is this the absolute difference at 19 months (and thus is the baseline value ignored because of the randomization procedure?) or is it the difference in the delta (change)? Interestingly, the MLWHF outcome is dichotomized (see above), but in the sample size calculation this seems not to be taken into account. Please, improve the text of the sample size calculation so that it can be reproduced by others.

4. Statistical analysis: see above: where is the dichotomized MLWHF outcome?
What if there are baseline differences between the patients in the two groups. Will these differences be adjusted for and how? This should be dealt with.

Minor essential revisions

Abstract:

1. “The primary objective of this study is to improve chronic heart failure management in general practices by applying major elements of case management, including patient education to test the effectiveness on patient’s quality of life”. Please rephrase: the main aim seems to be to improve quality of life in heart failure patients though a complex intervention involving patient and GP education in primary care. The current wording is too complicated and unclear.

2. The methods section of the abstract has a somewhat unusual contents in that some essential information is missing, while there is too much information on the sample size calculation. The latter need not be included in the abstract in my view (the number of patients or practices included should be given), but other items, notably the inclusion and exclusion criteria should be mentioned here. In addition, some more information on the intervention would be helpful in the abstract.

Introduction

3. In the introduction, please spend some more words on the fact that there are only few studies assessing the effect of HF management programs in primary care and that more evidence is needed here, because the generalizability of hospital- or outpatient-based programs to primary care is limited. Also, refer to some studies that have been performed in primary care, such as a Belgian study (Dendale et al. TEMA-HF study, Eur J Heart Fail 2011) a few years ago and COACH-2 in the Netherlands (Luttik et al, Eur J Heart Fail 2014). Now, only an Italian study is mentioned in

4. As in the abstract, the wording of the primary objective is not clear enough. Please rephrase.

Methods

5. What is meant by “stratification on each of 4 areas”: randomization blocks?

6. “All GPs who volunteered were randomized”; does this mean that while group
practices were randomized, individual GPs with those practices could refuse to participate. If that is the case, this is unfortunate and this could induce bias (confounding) because of incomparability of the two groups.

7. Why include NYHA I patients, as they do not have complaints?

8. Why assess the outcome (quality if life, QoL)) at 7, 13 and 19 months and not at 6, 12 and 18 months?

9. The disease-specific QoL outcome MLWHF is dichotomized; I understand this is useful, but this also means that some information is lost. In the statistical analyses, however, the MLWHF outcome is analyzed in a continuous fashion. Where is the dichotomization then?

10. Explain in more detail how “evaluation of their treatment” and “adherence to therapy” (how is the latter measured in the questionnaire?) is quantified.

11. Is there any evidence that the GP training program tested in this study is feasible? And has this approach been tested for any outcome before in France (or elsewhere)? It would be good to know that this is indeed a potentially useful program.

12. I have the same question for the patient education intervention. Is there any evidence that this patient education program is feasible? It seems like a lot of work for the GP. It would be good to know that this is indeed a potentially useful program. In some countries this program would be best delivered by dedicated nurses.

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

Quality of written English: Not suitable for publication unless extensively edited

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

No conflict of interest