Reviewer's report

Title: Improvement of primary care for patients with chronic heart failure: a study protocol for comparing two strategies.

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Reviewer: Petra Denig

Reviewer's report:

This protocol addresses an interesting hypothesis. The study design may be adequate but I have some questions regarding the chosen primary outcome measures, about not including a baseline measurement, and the sample size calculation. Also, some clarification is needed regarding the tailoring of the intervention, and timing of data collection. The statistical analysis seems appropriate, and the writing is acceptable. See for my detailed comments below.

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

Background

1. In the first paragraph, the authors focus on problems seen especially with drug treatment in CHF management. Given the adaptations of their implementation programme after their pilot study, and their choice of primary outcomes, it seems that they will now actually address/evaluate a different issue; i.e. not focusing primarily on (drug) treatment but more on quality of care following the chronic care model (CCM). This should be better covered at the start of the manuscript. See also point 2.

Intervention and Outcomes

2. The objective of the study is to examine the effectiveness of tailoring an implementation programme but from this it is unclear how ‘effectiveness’ should be defined. The primary outcomes focus on patient-oriented assessment of receiving care and general health status. The implementation programme appears to aim at better chronic hearth failure care from a clinical point of view. The implementation programme was originally developed to improve especially the treatment of CHF in primary care (the pilot study). It seems that some aspects were added or strengthened (a proposal for task delegation and cooperation within the primary care practice, support by a visiting practice consultant, the possibility to contact a GP with extra knowledge of heart failure treatment) but these are not clearly linked to these patient-oriented aspects of chronic care nor to the used to CCM-based evaluation of effectiveness. Thus, there appears to be a bit of a mismatch between what the implementation programme aims to achieve and the primary outcome measures chosen. Can the authors more clearly explain the link between the intervention programme and the chosen outcomes.
3. The main question relates to the effect of tailoring. However, this process of tailoring remains a bit vague, referring to barriers grouped in relation to the innovation, the health care professional, the patient, and the context. The reference provided shows that 39% of self-reported behaviour could be explained by 4 specific items (time-investment, attractiveness of guideline, applicability of guideline, and availability of supporting staff). Others have also tried to identify and classify barriers (see e.g. Légaré 2009 or Espeland e.a. 2003). Could the authors make clear how their choice of barriers to be included in the list for the tailoring is related to this previous work. Moreover, it is important to make clear that the intervention can be tailored to address the barriers. Some barriers might be difficult (or even impossible) to change. For example, I learned from the authors’ pilot study that starting treatment with beta-blockers was impossible in almost half of the patients because of contra-indications. This makes you wonder whether the implementation programme can really be tailored to the (most) relevant barriers perceived.

Measures
4. The timing of data-collection is unclear. As I understand it, patient questionnaires are send out only once, but it is not clear when. And can the authors explain why they do not plan to conduct a baseline measurement of these primary outcomes (and what the limitations of this decision could be).

Data analysis and sample size calculation
5. The primary analysis is a comparison of primary outcomes at follow-up between the study groups (apparently not taking baseline-measurements). It is not clear whether the effect sizes of 0.3 for the PACIC and 0.3 for the EQ-5D are anywhere in the range of what can be expected when comparing two interventions. This type of effect size using either the EQ5D-UK or US scoring was previously found to be related to an improvement of 2 NYHA classes. Could the authors provide more details on the measures (which scoring will be used) and whether the effect sizes used for the sample size calculation are likely to be found as a result of successful educational/organisational interventions.

6. Multilevel regression analyses will be used to explore the interaction effect of practice size and type of intervention programme. It is not clear why this specific interaction effect will be studied. Moreover, as I understand it, practice size is divided by ‘single handed’, ‘duo practice’, or ‘group practice’. Is this not also associated with differences in practice organisation? Why not just use the actual practice size, if size is relevant?

7. Some of the issues raised above could be dealt with by adding a discussion section.

- 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
8. I find the abstract not very clear. The main objective is to examine the effectiveness of tailoring a CHF implementation program to general practices compared to a standardised way of delivering a programme, but the description of the analysis focuses on an interaction effect. It would be better first to describe the main analysis. Also, it would be helpful to have a better description of the intervention in the abstract. Now, it is described as ‘implementation programme, comprising educational and organisational components’ but in the method part of the abstract ‘practice visits’ are mentioned and in the last sentence ‘goal attainment’ and ‘formalised cooperation with other disciplines’ are mentioned. After reading the abstract twice, it was still not clear what kind of intervention will be evaluated. Also, ‘medication and non pharmaceutical issues’ is very vague.

Background:

9. The hypothesis to be tested is relevant since there seems to be insufficient evidence of the additional value of tailoring. The authors, however, claim that ‘Tailoring has shown to improve the success of the implementation programme [12]’ whereas the conclusion in the referenced Cochrane review is that ‘Interventions tailored to prospectively identified barriers are more likely to improve professional practice than no intervention or dissemination of guidelines’. Please rephrase this to make clear that the review did not show that tailoring improves the success of an implementation programme (which would need a head-to-head comparison as is proposed in this new study).

10. The authors mention that ‘In The Netherlands, no such programme exists for CHF’. For those readers not familiar with the Dutch health care system, it would be good to explain that there are several of disease management programmes related to outpatient clinics, but that a substantial proportion of CHF patients do not attend such clinics but go to their GP instead.

Measures:

11. Patient registration forms are completed for all patient contacts throughout the study period. Which forms will be used for the effect evaluation; in other words, are there any limits set on the period still considered baseline and the period considered for outcome?

12. Questions about ‘continuity of care’, and Morisky’s questionnaire on medication adherence will be asked, but it is not clear how these will be used.

13. What is meant by goal attainment?

- Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)

14. All materials are offered paper based in a binder, and presented on a website. There are also plans to present the guiding patient registration forms on this website. It seems to me that these patient registration forms might be an important part of the intervention. Linking these forms directly to the electronic medical record system would be a much better option than on some website.
**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

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

**Declaration of competing interests:**

I declare that I have no competing interests.