Reviewer’s report

Title: Case management for patients with chronic systolic heart failure in primary care: The HICMan exploratory randomised controlled trial

Version: 2 Date: 4 April 2010

Reviewer: John Kjekshus

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MS:
The manuscript report on patients in general practice randomised to guideline directed treatment by doctors assistants compared to usual office care. The study is small and limited by funding restrictions. The endpoints are the results from 5 different versions of quality of life and behaviour assessments.

Major Compulsory Revisions
There are no effects on QoL outcomes in this study, but the conclusions are presented on an unduly positive note. Probably because the authors find that that the patients score better on behaviour and response to the services provided. The discussion is very limited on the interpretation of the relevance of the different tests in this context. It is well known that patients on placebo benefit to the special care delivered in clinical trials. To the average cardiology reader the clinical relevance of the different qualitative scoring systems are controversial.

Twice as many patients were hospitalized for heart failure during the study. Although the numbers are small, this is disturbing. The authors claim it may be due to better care, but the alternative that over focusing may create anxiety and undue admissions should be discussed. This is also supported by slightly more patients withdrew from the study in the assistant managed group.

The number of patients who reported on the different scores varied largely at baseline and even more at follow up. This must have influenced the results. It is also surprising that consistently fewer patients reported in the case management group at follow up. The study was part of a subproject of quality of Life within the German “Competence Network Heart Failure” but there is no information on the overlap or relationship to the overall project. An incomplete reference (22) is given. Two thirds of the population in this study is in functional class I and II and limitations in QoL are small and any improvement may accordingly be small. This raises questions about a possible selection bias in the authors “brainstorming” case finding strategies. I understand that most patients in functional class III and IV are cared for by specialists in Germany.

According to my understanding of the protocol, patients in both treatment arms were seen by the same doctor, thus there must be some carry over effects between the two cohorts.

The time spent on patient control and doctor reports by the assistants is difficult
to understand. Please add up the time and convert into total working hours per patients in order to understand the implications of this care.

Minor Essential Revisions

P 2, results: high guideline adherence must be due to selection bias with reference to how the patients were selected.

P 6, bottom. How many patients had previously been hospitalised for heart failure. Also how many patients had a previous myocardial infarction? Infarct before the age of 60 has limited information in this context.

NT-proBNP is listed in the list of abbreviations. The numbers are not given but would be helpful in understanding the degree of heart failure.

P 7, l 9 from bottom: The randomisation procedure should be explained. I do not understand what is meant by a weekly basis. Considering the low number of patients per practice randomisation on a weekly basis may suggest that the doctors could choose between several options.

P 9, Top: There is overlap between SF-36 and KCCQ. Was there any indication for this in the study and why was both methods used in the study. I get a feeling that the patients were over exposed to questionnaires with a possibility of trial fatigue.

P 10, bottom: Please explain why not all patients adhered to the questionnaires reporting.

P 11, l 6 from top: Why was a one sided t-test applied and not a two sided?

P 14, l 3 from bottom: What is meant by practice attendance of 27.6 and 23.9 Is it days, percent or times. Please be specific.

P 15, l 12 from bottom: The feasibility to conduct should be documented by how many hours or days totally were spent during the year on each patient.

P 20, l 5 from top: I disagree with that this trial demonstrated positive effects of clinical relevance for patients with mild heart failure. I suggest that the conclusion should be softened.

P 20, l 8 from bottom: The self-care aspect of this intervention is unclear and should be specified. Does it concern information on diet, weight watching etc beyond that provided to all CHF patients?

Table 1: Please explain patients per quarter. Is it per doctor or per practice or something else?

The manuscript could be shortened.

Level of interest: An article of limited interest

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, and I have assessed the statistics in my report.
Declaration of competing interests:

I declare that I have no competing interests.