Reviewer’s report

Title: Action Plan to enhance self-management and early detection of exacerbations in COPD patients; a multicenter RCT.

Version: 1 Date: 2 October 2009

Reviewer: Rodolfo Dennis

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I think that the protocol has merit, and if carried out satisfactorily will no doubt provide an important addition to the current level of knowledge in this field. I also think that the current manuscript (only on the methodology) may be innovative enough to be of sufficient interest to journal readers. The “postponed informed consent procedure” is interesting to assure patient blinding on their group allocation in the context of this study, and other aspects such as the description of the action plan, choice of outcome, and sample size, is different from previous studies (as the authors correctly point out), and may also be of sufficient interest to readers. I think the architecture of the RCT conforms to CONSORT statement standards, and authors provide sufficient information in general so that readers may be able to replicate results if the effect size is of clinical importance.

- Major Compulsory Revisions

1. Authors should discuss the assumption that a 70% symptom-based exacerbation rate will be seen over 6 months in the study population is a valid assumption, within the inclusion criteria postulated. Perhaps another inclusion criteria based on a minimum number of exacerbation events within the past 12 months may add validity to the assumption.

2. It seems that following an action plan, as is the hypothesis, may impact on exacerbation rates and other secondary outcomes, but it seems that it may be somewhat labor-intensive on the health care provider(s). That is, it is likely that it will increase both the efficacy and the health care costs (of providing the service). On the other hand, a decrease in the number of exacerbations may actually reduce health care costs. Authors should discuss why not including a health economic component in the study, given that health care utilization will be measured.

3. Data analysis aspects seem somewhat brief. The software package to be used would also be important to include. The analysis of QOL data with the SGRQ has a minimal clinical significant difference that should be mentioned in the analysis. Analysis of event rates over time with patient-time as the denominator could be discussed further.

- Minor Essential Revisions

1. The case for the action plan could be magnified if the intervention reduces exacerbations that require hospitalization, aside from health status/ symptom
recovery time. While I understand that such an event over time is infrequent enough that the sample size would need to be larger, authors should discuss why such an outcome is not one of the main outcomes selected.

2. 15% expected loses to follow-up seem somewhat high for a 6 month trial, aside from drop-outs. Authors could discuss more why this proportion has been selected, and if differential loses to follow-up are to be expected.

3. There are minor spelling mistakes that can be corrected with a final review of the manuscript.

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

**Quality of written English:** Acceptable

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

**Declaration of competing interests:**

no competing interests