Reviewer’s report

**Title:** Effectiveness of the Austrian Disease-Management-Programme for Type 2 Diabetes: Study Protocol of a Cluster-Randomized Controlled Trial

**Version:** 1 **Date:** 5 March 2008

**Reviewer:** Shawn Aaron

**Reviewer’s report:**

I would like to see some necessary major revisions:

Instructions for authors:

1) Please list the primary and secondary objectives of the study

2) When will the change in the primary outcome (HbA1C) be measured? Please specify.

3) I do not understand the sample size calculation- where did the numerator in the sample size calculation come from?

4) The authors assume a standard deviation of 2 in HgBA1C values- but shouldn’t the standard deviation be calculated for the expected change in HgBA1C values rather than for the baseline values?

5) There is no section specifying how they will statistically analyze their primary and secondary outcomes- this section must be added to the manuscript.

6) The study is cluster-randomizing at the level of the district, but the outcomes are being measured at the level of the patient. Discuss why you chose not to measure district-level outcomes (ex. Hospital admission for diabetes or diabetes-related complications across each district). Discuss the limitations of your intended approach.

7) One major weakness may be that there is no economic analysis attached to this trial. Please discuss this. How will a change in HgB A1C value convince policy makers that they should fund this intervention? Shouldn’t an economic analysis be added?

8) The study is using a surrogate endpoint HgBA1C- please discuss how this might correlate with important clinical outcomes and economic outcomes.

9) Please fix the first reference on page 3; please fix the sentence on page 5 beginning “With nationwide, meanwhile…. “.