Reviewer's report

Title: A cluster randomised controlled trial of the effectiveness and cost-effectiveness of Intermediate Care Clinics for Diabetes (ICCD): Study protocol.

Version: 1 Date: 23 April 2012

Reviewer: Harald Sourij

Reviewer's report:

Reviewer comments:

Intermediate care clinics for diabetes have been suggested as a model to improve diabetes care. Baines et al. designed a cluster randomized trial where GP practices are randomized to either an intervention group with access to intermediate care clinics or to a usual care group. Their primary endpoint chosen, is the percentage of patients reaching treatment targets for HbA1c, total cholesterol and blood pressure.

This is a well-designed and important study.

The study methods are described in detail including the randomisation procedure. However, sample size estimation lacks details and justification of the latest revision.

Further comments:

Major issues:

1.) The authors provide details about the initial sample size estimation (3700 participants), but actually I am more interested in the details and reasons for the revised sample size estimation (2000 participants) and the justification for the substantial reduction in participants. What is the final number of patients recruited and the number of patients expected at final assessment?

2.) Figure 1
   - layout needs some improvement.
   - numbers do not match with final sample size calculation (1785 participants in each group versus 1000 according to the revised sample size)
   - I would recommend not to use the split of the intervention group into 30% ICC and 70% usual care in the figure – this is misleading for the readers, since it is an estimated percentage and it is not a randomised process. The figure should show the randomisation of the practices to the intervention and usual care group only.

Minor comments:

1. Abstract and page 18: please change “Follow up will finish in October 2011” to
“finished in October 2011”. Likewise the definitive number of participants recruited should be known by now and needs to be updated.

2. The Background section would benefit of some shortening – I would suggest to reduce in particular page 4.

3. Please correct page 4, second paragraph line 7: “A phase 1 report has been has published…“

4. Background page 5 list of aims: for completeness CV risk assessed by UKPDS risk engine should be mentioned.

5. Clinicaltrials.gov lists pregnancy as exclusion criterion for the trial, which is not mentioned in the manuscript – please clarify.

6. Page 9, outcome measures – “In each site practice and recruitment...” – I guess it should read “practice recruitment”.

7. Page 10, section 2.5.1: authors should use „total cholesterol“ instead of cholesterol only.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare that I have no competing interests.