Author's response to reviews

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

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Author's response to reviews: see over
23 June 2012

Dear Sir or Madam

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

We appreciate that the delay in contacting us with an initial editorial decision was caused by difficulty in securing a referee to assess our paper submitted in September 2011. Moreover, we are most grateful to you for extending the time for us to get back to you with our amendments because of difficulties in getting responses from all our authors during this busy season. We have also included one additional author from the ICCD Study Group (Natalie Armstrong) who has responsibility for the qualitative study.

Below we explain how we have addressed the reviewer’s specific comments and requests; any altered text in the revised manuscript is in red. Minor stylistic changes are not highlighted.

Reviewer 1: Harald Sourij
Date: 23 April 2012

This reviewer reported that this is ‘a well-designed and important study’ and ‘an article of importance in its field’.

He suggests the following points which required clarification as major revisions: All these revisions have been addressed as follows:

1a. 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?

This information is now provided – see red text on p8. Final number patients approached & consenting is 1,997. The number expected at final assessment ~ 66%.
2a. 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.

Layout has been simplified. Numbers have been changed to revised sample size (not original). Split of intervention group to 30% ICC and 70% usual care has been removed.
Figure 1 now just shows randomisation of practices to intervention & usual care group only.

The reviewer has also suggests the following as minor comments. All these comments have been addressed as follows:

1b. 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.

Both have been changed & updated.

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

This section has been shortened to 3 pages.

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

We assume that the reviewer meant we should remove ‘phase 1’, which we have done.

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

This is now mentioned.

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

This was omitted in error – now added.
6b. Page 9, outcome measures – “In each site practice and recruitment...” – I guess it should read “practice recruitment”.

This section has been simplified and shortened.

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

This has been changed – see top of p11.

We look forward to your response.

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On behalf of the ICCD Study Group.