Author's response to reviews

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

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To the
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Manuscript: Effectiveness of the Austrian Disease-Management-Programme for NIDDM: Study Proto-col of a Cluster-Randomized Controlled Trial, MS: 1454113065182510

Dear Editors,

We would like to thank the reviewer for his helpful comments to improve our paper. We revised our manuscript accordingly. All changes are visible in correction mode.

1) At the end of the background-section we inserted the subtitle “Objectives”, and we listed the primary and secondary objectives after the research questions.

2) HbA1c will be measured at the beginning and at the end of the study as already stated in the section on the baseline- and final examinations. To emphasise this we included the times of measurement again in the endpoint-section.

3) The sample size calculation is based on the commonly used formula based on two-sided testing for continuous variables. Using an # of 0,05 and a # of 0,2, the numerator of the formula yields 15.698. We rewrote the paragraph and omitted the formula to avoid the confusion caused by the numerator as we feel it inappropriate in this paper to go into the details of where the formula comes from.

4) The assumed standard deviation of course applies to the expected change in HbA1c. The sentence was corrected accordingly.
5) We added a section on statistical analysis.

6) We feel that outcome should be measured at the patient level because clinical outcome is most important to the individual patient. Randomization on the other hand had to be done at the district level to avoid contamination. We added a paragraph in the discussion discussing the drawbacks of this approach.

7) An economic analysis will certainly be performed using the outcome measures of the RCT. We will base the economic evaluation on data derived from the UKPDS and other studies. This issue is discussed in the discussion-section. We didn’t go into the details of the economic evaluation because we feel that this reaches beyond the scope of the current paper.

8) We added a section to the discussion on the translation of HbA1c-changes into clinical outcomes. The discussion already addressed the weaknesses of using surrogate parameters instead of clinical endpoints.

9) The reference has been added, and the sentence on page 5 has been reworded.

We hope that we could improve our paper according to the suggestions of the reviewer. Please feel free to contact us in case of any further questions.

Sincerely yours,

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