Author's response to reviews

Title: The Value of Episodic, Intensive Blood Glucose Monitoring in Persons with Non-Insulin Treated Type 2 Diabetes: Critical Analysis of Recent Studies and Design of a Cluster-Randomized, Clinical Trial[NCT00674986]

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Dr Rikki Graham, PhD
BioMed Central Editorial Team

Dear Dr. Graham,

Thank you for your consideration of our manuscript and for the opportunity to respond to Dr. Farmer’s comments. We provide a response to each of his comments below. In response to Dr. Farmer’s comments, please note changes to the title of the paper and to the name of the study.

1. **Clarification of Control vs. Intervention Groups.** We agree that further clarification is needed and we have made several changes in the text to clearly define and differentiate each of the two active study groups.

2. **Justification of Comparison Group.** We fully agree with Dr. Farmer’s view that SMBG should typically not be used unless the purpose is clear and individuals are given support and guidance. It must be noted, however, that our study was finalized prior to the release of the new IDF guidelines and that we were interested in establishing a control arm that was generally representative of the standard of care for SMBG use in USA-based primary care practices. Toward this end, patients in the Active Control Group (ACG) receive a new blood glucose meter and unlimited free strips, are provided with detailed instruction in their use, and are encouraged to follow their health care provider’s (HCP) instructions for use. Patients in the ACG group are fully informed about the purpose and design of the research as part of the informed consent process, and they are expected to bring their meter to each clinic visit for download (for study monitoring). Therefore, we are confident that ACG patients are provided with SMBG encouragement and support that meets or exceeds the common standard of care for SMBG use in the USA.

3. **Length of Background Section.** In response to Dr. Farmer’s comments, we have sharply reduced the length of the background section and tightened the presentation. Since this new study builds upon lessons learned from previous reports, we now raise a series of questions derived from this literature and use them as a justification for the design of the new research. We believe that the presentation is clearer and more focused than in our initial submission, with more logical linkages to subsequent sections of the manuscript.

4. **Cluster Randomization issues.** The concern here is, we believe, that the cluster-randomization method we use permits HCPs to select patients for recruitment after being informed about which study arm they were randomized to. We agree with Dr. Farmer that this could lead to a potential patient selection bias. We now clarify in the text that all patients in a practice who meet inclusion criteria are identified, that the HCP reviews the list only to exclude patients for purposes of good medical care, and that the remaining patients are then randomly selected for recruitment using a defined protocol. We expect very few patients to be excluded by HCPs.
Thus, it should make little difference whether practices are informed of their study arm before or after the patient list is generated, since patient selection is accomplished through an external, study-standardized random selection protocol. In other words, HCPs have little influence on who is selected for recruitment. This process is now more fully outlined in the text.

5. Rationale for ITT and Per Protocol definitions. We have now clarified the presentation of the ITT and PP data sets and corrected several potential sources of confusion in the previous submission. We agree that a more robust ITT data set should include all patients who complete the training session (which we have now redefined as the baseline visit), rather than those who attend both the training session and the month 1 visit. Further attrition analyses at each step from screening to 12 months will be undertaken. This will permit a careful analysis of patient attrition and an analysis of how those patients who drop out at each step of the protocol might influence the findings. We have defined our per protocol analysis even more stringently than the suggestion offered by Dr. Farmer. The criteria for inclusion in this analysis are also outlined in the text to make a clear distinction between the ITT and per protocol approaches to data analysis.

We sincerely appreciate the reviewer’s comments and suggestions, and we believe that they have led to a stronger and more clearly presented manuscript. I am pleased to provide additional comments upon request, and I await the results of your editorial review.

Sincerely,

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