Reviewer's report

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]

Version: 1 Date: 8 March 2010

Reviewer: Andrew Farmer

Reviewer's report:

Thank you for asking me to review this protocol for a proposed clinical trial. Establishing the role of SMBG in patient care is of great importance for efforts to improve glycaemic control. This protocol reports a trial design that has potential to make a contribution, but requires clarification of a number of points. These are outlined below.

The basic design should be more clearly described. The protocol proposes a comparison of an intervention (use of a blood glucose meter plus structured training) with a control group (use of a blood glucose meter plus usual care). This should be made completely clear and consistent through all sections of the protocol (including the title, abstract, objectives and analysis plans). At present the intervention is frequently mentioned in context of the trial design without making clear the intended comparison group.

The comparison group proposed (use of a blood glucose meter plus usual care) should be fully justified. In particular, recent guidance on use of SMBG stresses that SMBG should not be used unless the purpose is clear and individuals are given support and guidance about how to make use of the information gained (e.g. the recent guidelines on use of SMBG in type 2 diabetes from the International Diabetes Federation). The protocol should make clear that patients in control practices would receive the minimum standard of care required under these guidelines and describe how this will be assured.

The Background section should be shortened. In particular it includes detailed critiques of trials and other work addressing different research questions (e.g. comparisons of SMBG with usual care alone), which do not support or justify the current research design. This peripheral material could be omitted.

The cluster design is not clearly described. The protocol currently reads as if sites are first allocated to usual care and structured testing and then patients recruited to the trial in each practice. If so, then this might lead to bias. Sites should remain unaware of their allocation until patients are recruited to the trial. This would avoid an unintended difference in recruitment of patients in the differently allocated sites. The protocol needs to be clarified and the procedures, to ensure that the process of patient recruitment prior to practice allocation, rigorously adhered to.
The definition of the ITT data set requires further justification. It currently excludes all recruited patients not returning to a one-month visit. An ITT data set might be better defined as those recruited to the trial to avoid confounding from variables that might influence both response to SMBG and motivation to remain adherent to the trial protocol. A per protocol analysis is also appropriate as a secondary analysis and this would include only those returning for a one-month visit.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I am leading an individual patient data meta-analysis of previous SMBG trials and am the lead investigator on a trial evaluating the role of SMBG in titration of oral glucose lowering medication.