Author’s response to reviews

Title: Self-monitoring of Blood Glucose in Non-insulin Treated Type 2 Diabetes (The SMBG Study): Study Protocol for a Randomised Controlled Trial

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Thank you for considering the above named paper for publication. We have revised the paper in line with the reviewer comments and would like to resubmit for publication. We feel we have addressed all the reviewer comments and detail the responses to individual comments below:

• Reviewer 1, Q1 – Did the authors consider the possibility of stepwise approach consisting first of SMBG only with telecare added later in the study?

Response – No, the study was designed and powered as a randomised controlled trial with 3 arms, as approved by the EFSD.

• Reviewer 2, Q1 – Paper needs to be shortened

Response – We have taken the opportunity to reduce the text throughout, which can be seen through the tracked changes. More substantive reductions have been made in the following sections (page and line numbers refer to the tracked changes paper):
Background section, page 4, lines 60 - 63

Study Design section, page 6, lines 111 - 113

Participants section, page 8, lines 164 - 174

Study Visits section, page 10, lines 240 - 243

Safety Evaluations and Data Monitoring section, page 13, lines 322 - 326

Health Economic Evaluation section, page 14, lines 334 - 339

Sample Analysis section, page 14, lines 343 – 353

Sample Size section, page 15, lines 379 - 380

• Reviewer 2, Q2 – It would be appropriate if you could include a percentage of patients who achieved optimal glycaemic control in each group as an additional primary outcome.

Response – The percentage of persons achieving target of HbA1c 53 mmol/mol (≤7%) is a secondary outcome measure and included on page 13, line 315 in the Efficacy Measures section.

Reviewer 2, Q3 – I suggest to include BP and change in number and type of OADs at 3, 6, 9 and 12 months as secondary outcome measures.

Response – Blood pressure was not deemed a clinically important outcome measure for SMBG when the protocol was originally developed and we are unable to collect this data at this point in the study. We are collecting data on medication use / changes and it is our intention to analyse the data at 3, 6, 9 and 12 months as a secondary outcome measures. However, we neglected to mention this in the original paper and have added this into the revised version on page 13, line 313.

We hope we have addressed all the issues raised by the reviewers and would be grateful if you could consider the revised paper.