Effects of physician’s diabetes self-management education using Japan Association of Diabetes Education and Care Diabetes Education Card System Program and a self-monitoring of blood glucose readings analyzer in individuals with type 2 diabetes: An exploratory, open-labeled, prospective randomized clinical trial

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ABSTRACT
Aims/Introduction: This 6-month, single-center, prospective, open-labeled, randomized trial was designed to investigate whether physicians’ diabetes self-management education using an education tool developed by the Japan Association of Diabetes Education and Care and a self-monitoring of blood glucose (SMBG) analyzer improves glycemic control in individuals with type 2 diabetes receiving insulin and SMBG.

Materials and Methods: Participants were randomized into intervention (I) and control (C) groups. Both groups received physicians’ diabetes self-management education at each hospital visit, whereas the Japan Association of Diabetes Education and Care education tool and the SMBG readings analyzer was used in group I, but not group C. All participants filled out a diabetes treatment-related quality of life form and an original questionnaire on SMBG use with five questions (Q1–Q5) before and after the study period.

Results: A total of 76 individuals were recruited and randomized. Glycated hemoglobin (HbA1c) was significantly improved during the study period in group I, whereas no significant change was observed in group C. The change in HbA1c was greater in group I, although it did not reach statistical significance. The diabetes treatment-related quality of life total score was not changed in either group. Interestingly, the score of Q1 (‘‘How important is SMBG to you?’’) in the SMBG questionnaire was unchanged in group I,
INTRODUCTION

Education for self-management and lifestyle modification are fundamentally important in the management of diabetes. Diabetes self-management education (DSME) has been found to improve patient diabetes knowledge and self-care behavior, as well as glycated hemoglobin (HbA1c) and quality of life (QOL). Better outcomes were reported for DSME that includes ongoing support, is tailored to the needs and preferences of each patient, and incorporates behavioral strategies. A multidisciplinary team approach involving physicians, nurses, dietitians, pharmacists, physical therapists and laboratory technicians as providers of DSME is also required to tailor the curriculum to the needs of each patient. To optimize DSME by the multidisciplinary team, information on the needs and preferences of each patient must be shared by team members. The Japan Association for Diabetes Care and Education (JADEC) recently developed the JADEC Diabetes Education Card System Program to improve DSME by facilitating interaction between patients and healthcare professionals, which includes 71 guidance points. The Japan Association for Diabetes Education and Care education tool incorporates behavioral strategies. The protocol was approved by the Ethical Committees of Kansai Electric Power Medical Research Institute. Eligible individuals included: (i) those with type 2 diabetes aged 20 years, but ≤ 5 years; (ii) those using SMBG for ≥3 months; (iii) those with HbA1c < 7.0%, but ≤ 11.0%; (iv) those capable of answering the questionnaires; and (v) those receiving insulin, which allows use of SMBG under the Japanese national health insurance coverage plan. Individuals were excluded if they were: (i) susceptible to psychiatric disorders, and/or psychological and/or dementia; (ii) receiving only glucagon-like peptide-1 receptor agonist as an injection therapy; or (iii) considered to be ineligible by physicians-in-charge. As the current study was exploratory, the sample size was not set for hypothesis testing; we planned to analyze 60 participants (30 participants in each group), and tried to recruit 76 participants, as we expected 20% of participants to drop out.

Study protocol

Study participants were randomized into two groups: an intervention (I) group and a conventional (C) group (Figure 1).
Stratified block randomization, taking age, HbA1c and frequency of insulin injection into consideration, was carried out in the research center independently of the study investigators to allocate participants into group I or group C. Physicians and participants are open to the randomization. At screening, all study participants were trained to use the SMBG device (Medi-Safe Fitsmile®; Terumo Corporation, Tokyo, Japan). Individuals in both groups received physicians’ DSME at baseline, and at 2, 4 and 6 months after randomization. A physician reviewed SMBG values with participants and delivered necessary information to achieve optimal glycemic control using the JADEC Diabetes Education Card System®, SMBG values were reviewed with participants using the SMBG reading analyzer (HR Joint Data Vision®, Terumo Corporation), which provides comprehensive summary statistics, listings and graphical plots of blood glucose profiles, together with the JADEC self-management notebook in which patients can record their SMBG values. In group C, physicians orally delivered necessary information without using the JADEC Diabetes Education Card System; SMBG values were reviewed with participants using only the JADEC self-management notebook.

Individuals in both groups received physicians’ DSME at baseline, and at 2, 4 and 6 months after randomization. A physician reviewed SMBG values with participants and
delivered necessary information to achieve optimal glycemic control (e.g., the target fasting and post-prandial glucose levels, as well as potential lifestyle modifications) to participants at every visit. In group I, a physician delivered necessary information to achieve optimal glycemic control using the JADEC Diabetes Education Card System\textsuperscript{18}; SMBG values were reviewed with participants using the SMBG reading analyzer (HR Joint Data Vision\textsuperscript{26}; Terumo Corporation), which provides comprehensive summary statistics, listings and graphical plots of blood glucose profiles\textsuperscript{24}, together with the JADEC self-management notebook in which patients can record their SMBG values\textsuperscript{25}. In group C, physicians orally delivered necessary information without using the JADEC Diabetes Education Card System; SMBG values were reviewed with participants using the JADEC self-management notebook only. Physicians were allowed to change insulin doses, regimens or diabetes medications, as well as the frequency of SMBG testing based on their clinical judgement. Anthropometric measures, HbA1c, duration of diabetes, duration of insulin use and frequency of SMBG measurements, as well as antidiabetes medications, were recorded at baseline and 6 months after randomization. Health-related QOL was evaluated using the Diabetes Therapy-Related QOL (DTR-QOL) questionnaire, which assesses the influence of diabetes treatment on patient QOL irrespective of treatment method. The DTR-QOL consists of the following four categories: D1, “Burden on social activities and daily activities”; D2, “Anxiety and dissatisfaction with treatment”; D3, “Hypoglycemia”; and D4, “Satisfaction with treatment.” The score of each domain and the total score were converted to a scale of 0–100, as described elsewhere\textsuperscript{26}. The attitude of individuals regarding SMBG and SMBG use was evaluated by a SMBG questionnaire developed for this study; five questions are answered using a 5-point Likert scale with responses ranging from “very unlikely” (1) to “very likely” (5): (Q1) “How important is SMBG to you?”; (Q2) “How much pain do you feel when you prick a finger with a lancing device?”; (Q3) “How frustrated are you with SMBG?”; (Q4) “How confident are you to enter SMBG results correctly in your SMBG diary?”; and (Q5) “Would you like to share your SMBG results with your physician?”. Participants were asked to complete DTR-QOL and SMBG questionnaires at baseline and 6 months after randomization. The primary end-point of the present study was change in HbA1c (ΔHbA1c) and DTR-QOL questionnaire scores (ΔDTR-QOL) from baseline (0 M) to 6 months after the randomization (6 M). Secondary end-points included changes in body mass index (ΔBMI), SMBG frequency (ΔSMBG frequency), daily insulin dose (Δinsulin dose) and SMBG questionnaire scores.

**Statistical analysis**

ΔHbA1c and ΔBMI were compared between groups I and C by unpaired \( t \)-test; ASMBG frequency, Δinsulin dose and Δinsulin frequency, as well as ΔDTR-QOL total score, ΔDTR-QOL D1-D4 scores and ΔSMBG Q1-Q5 scores, were compared between groups I and C by the Mann–Whitney \( U \)-test. HbA1c and BMI at 0 M and 6 M were compared within the two groups by paired \( t \)-test; SMBG frequency, insulin dose and insulin frequency, as well as DTR-QOL total score, DTR-QOL D1-D4 scores and SMBG Q1-Q5 scores at 0 M and 6 M, were also compared within the two groups by Wilcoxon’s signed rank test. Stepwise linear regression was used to assess the association between ΔHbA1c and other clinical parameters. All statistical analyses were carried out using SPSS version 24.0 (SPSS

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**Figure 2** | Flow diagram of the study.
Inc., Chicago, IL, USA). 

RESULTS

Of 87 individuals recruited, 77 who met the criteria were randomized to groups I and C (I, n = 39; C, n = 38; Figure 2). One patient in group I withdrew consent for participation in the study because of being over-burdened with the DMSE required. As shown in Table 1, clinical characteristics including age, HbA1c and frequency of insulin injection, as well as DTR-QOL scores and the results of SMBG questionnaire, were comparable between the two groups, indicating successful randomization.

HbA1c improved during the 6 months after randomization in group I (baseline, 8.0 ± 0.9% and 6 M 7.7 ± 0.9%; P < 0.05), whereas no statistically significant change in HbA1c was observed in group C (baseline, 8.0 ± 0.8% and 6 M 7.9 ± 0.9%; P = 0.630; Figure 3a). ΔHbA1c was greater in group I than that in group C, although the difference did not reach statistical significance (I, −0.28 ± 0.67% and C, −0.09 ± 1.13%; P = 0.412). ΔHbA1c was also compared between groups I and C in a sub-group of baseline HbA1c <8.0% (I, 0.09 ± 0.55% [n = 19] and C, 0.31 ± 0.77% [n = 18]; P = 0.118) and baseline HbA1c

Table 1 | Characteristics of study participants

| Characteristics of study participants | Total | I | C | P |
|--------------------------------------|-------|---|---|---|
| n (male/female)                      | 76 (60/16) | 38 (29/9) | 38 (31/7) | 0.574 |
| Age (years)                          | 61.0 ± 8.4 | 60.6 ± 8.3 | 61.4 ± 8.7 | 0.676 |
| BMI (kg/m²)                          | 25.2 ± 3.0 | 25.6 ± 3.0 | 24.8 ± 2.9 | 0.274 |
| Duration of diabetes (years)         | 15.7 ± 7.6 | 16.6 ± 7.6 | 14.8 ± 7.6 | 0.312 |
| Duration of insulin use (years)      | 6.6 ± 4.9  | 7.1 ± 4.8  | 6.1 ± 5.0  | 0.409 |
| HbA1c (%)                            | 7.9 ± 0.8  | 80.0 ± 0.9 | 79.0 ± 0.8 | 0.738 |
| Frequency of SMBG per day            | 1.39 ± 0.62| 1.38 ± 0.65| 1.40 ± 0.60| 0.884 |
| Frequency of insulin injection per day| 1 (1–2)   | 1 (1–2)   | 1 (1–2)   | 0.684 |
| Once per day (%)                     | 71.1      | 71.1      | 71.1      |       |
| Twice per day (%)                    | 10.5      | 79.1      | 13.2      |       |
| Three times per day (%)              | 26        | 26        | 2.6       |       |
| Four times per day (%)               | 15.8      | 18.4      | 13.2      |       |
| Daily total insulin dose (units/kg bodyweight) | 0.32 ± 0.19 | 0.32 ± 0.18 | 0.31 ± 0.20 | 0.873 |
| Co-administration of GLP-1RA (%)     | 43.4      | 47.4      | 39.5      | 0.488 |
| Frequency of GLP-1RA injection per day| 1.2 ± 1.0 | 1.1 ± 1.1 | 1.3 ± 0.9 | 0.365 |
| No. oral antidiabetes drugs          | 1.2 ± 1.0 | 1.1 ± 1.1 | 1.3 ± 0.9 | 0.365 |
| DTR-QOL questionnaire                 |          |           |           |       |
| Total                                | 698 ± 13.2 | 698 ± 14.5 | 699 ± 12.6 | 0.979 |
| D1                                   | 742 ± 15.4 | 758 ± 15.9 | 727 ± 15.0 | 0.405 |
| D2                                   | 632 ± 17.1 | 626 ± 18.6 | 638 ± 15.8 | 0.761 |
| D3                                   | 766 ± 22.5 | 743 ± 24.7 | 790 ± 20.1 | 0.382 |
| D4                                   | 619 ± 16.8 | 602 ± 17.3 | 636 ± 16.4 | 0.398 |
| SMBG questionnaire                    |          |           |           |       |
| Q1                                   | 5 (1)     | 5 (1)     | 4 (1)     | 0.251 |
| Q2                                   | 3 (2)     | 3 (2)     | 3 (2)     | 0.830 |
| Q3                                   | 3 (2)     | 3 (2)     | 2.5 (2)   | 0.826 |
| Q4                                   | 3 (1)     | 3 (1)     | 3 (1)     | 0.978 |
| Q5                                   | 4 (2)     | 4 (2)     | 4 (2)     | 0.965 |

Data are shown as the mean ± standard deviation or the median (interquartile range). BMI, body mass index; C, control group; D1, domain of diabetes treatment-related quality of life questionnaire “Burden on social activities and daily activities”; D2, domain of diabetes treatment-related quality of life questionnaire “Anxiety and dissatisfaction with treatment”; D3, domain of diabetes treatment-related quality of life questionnaire “Hypoglycemia”; D4, domain of diabetes treatment-related quality of life questionnaire “Satisfaction with treatment”; DTR-QOL, diabetes treatment-related quality of life questionnaire; GLP-1RA, glucagon-like peptide-1 receptor agonist; I, intervention group; Q1, the original self-monitoring of blood glucose questionnaire asking “How important is self-monitoring of blood glucose to you?”; Q2, the original self-monitoring of blood glucose questionnaire asking “How much pain do you feel when you prick a finger with a lancing device?”; Q3, the original self-monitoring of blood glucose questionnaire asking “How frustrated are you with self-monitoring of blood glucose?”; Q4, the original self-monitoring of blood glucose questionnaire asking “How confident are you to enter self-monitoring of blood glucose results correctly in your self-monitoring of blood glucose diary?”; Q5, the original self-monitoring of blood glucose questionnaire asking “Would you like to share your self-monitoring of blood glucose results with your physician?” each of which uses a 5-point Likert scale with responses ranging from “very unlikely” (1) to “very likely” (5); SMBG, self-monitoring of blood glucose.
≥8.0% (I, −0.51 ± 0.75% [n = 15] and C, −0.49 ± 1.30% [n = 18]; P = 0.789). No statistically significant changes in BMI, SMBG frequency, insulin dose and insulin injection frequency were observed in either group (Figure 3b–e). ΔBMI (I, 0.01 ± 0.60 kg/m² and C, 0.11 ± 0.72 kg/m²; P = 0.534), ΔSMBG frequency (I, 0.09 ± 0.47 times per day and C, −0.03 ± 0.52 times per day; P = 0.277), Δinsulin dose (I, 0.01 ± 0.06 units/bodyweight kg/day and C, 0.01 ± 0.07 units/bodyweight kg/day; P = 0.532) and Δinsulin injection frequency (I, −0.09 ± 0.51 times per day and C, 0.06 ± 0.41 times per day; P = 0.0314) were similar between the two groups. The proportion of individuals whose insulin doses changed ≥1 unit was greater in the group I than that in the group C (Figure 3f).

The DTR-QOL total score did not change during the study period in group I (0 M, 70.6 ± 13.9 points and 6 M, 70.4 ± 14.2 points; P = 0.304).
70.5 ± 14.4 points; P = 0.963) or group C (0 M, 68.9 ± 11.6 points and 6 M 68.1 ± 14.4 points; P = 0.687). 

\[ \text{ΔDTR-QOL} = \text{DTR-QOL baseline} - \text{DTR-QOL at 6 months} \]

\[ \text{ΔHbA1c} = \text{HbA1c baseline} - \text{HbA1c at 6 months} \]

\[ \text{ΔSMBG Q1-Q5} = \text{SMBG Q1-Q5 baseline} - \text{SMBG Q1-Q5 at 6 months} \]

Figure 4 | (a) The Diabetes Therapy-Related Quality of Life (DTR-QOL) and (b) the self-monitoring of blood glucose (SMBG) questionnaire scores at baseline (0 M) and 6 months after the randomization (6 M) are shown. The total score and domain scores in the DTR-QOL questionnaire were converted to a scale of 0–100. Each item in the SMBG questionnaire was answered by using a 5-point Likert scale from *1: very unlikely* to *5: very likely*. Values are the mean ± standard error of the mean. *P < 0.05 versus baseline (Wilcoxon’s signed rank test), C, control group; I, intensive group.

**DISCUSSION**

The present single-center, prospective interventional study shows that greater HbA1c-lowering by physicians’ DSME using the JADEC Diabetes Education Card System and the SMBG analyzer in individuals with type 2 diabetes receiving insulin was suggested, but not confirmed. The current study also suggests that patient attitude regarding their SMBG results and sharing them with a physician had an effect on glycemic control.

DSME has previously been shown to enhance self-care in individuals with diabetes, as well as reduce their HbA1c. In fact, enhancement DSME is recommended when patients do not reach treatment targets. To achieve better outcomes, education tools that can deliver content relevant to each patient’s needs and preferences are required. Although the American Association of Diabetes Care & Education Specialists provides AADE7 Self-Care Behaviors, a robust online software package for diabetes care and education specialists, education tools must be customized to culture, language and customs to be effective in improving self-care and subsequent glycemic control.

According to the present findings, diabetes education using the JADEC Diabetes Education Card System Program and the SMBG analyzer reduced the HbA1c level by 0.3% in 6 months.
in group I, most likely due to improved self-care. Relevantly, recent research showed that significant HbA1c reduction by SMBG use occurs primarily in individuals who raise their self-care stage to action, indicating that enhanced self-care can improve glycemic control. In the current study, the frequency of SMBG testing tended to be increased in group I, whereas it remained unchanged in group C. In addition, insulin dose and BMI tended to increase in group C, whereas they remained unchanged in group I. Although these changes did not reach statistical significance, they suggest that physicians' DMSE using the JADEC Diabetes Education Card System Program and an SMBG readings analyzer can facilitate optimal treatment planning, including insulin dosage adjustments.

Changes in QOL were not observed in either group. This finding is in accord with other short-term studies that found no significant difference between patients with and without SMBG intervention regarding health-related QOL, even though a clinically relevant reduction of HbA1c through improved patient-physician interaction might be expected to improve patient QOL with regard to diabetes treatment. Interestingly, however, the current study found that patient attitude regarding the importance of SMBG was significantly poorer in group C. Thus, a longer intervention period might be required to establish a difference in DTR-QOL with or without diabetes self-care education using the JADEC Diabetes Education Card System Program and an SMBG readings analyzer.

The present study shows the importance of patient-physician interaction, which is encouraged by a diabetes educational tool, such as the JADEC Diabetes Education Card System Program.

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**Table 2** | Association of change in glycated hemoglobin during the study period with various clinical parameters and questionnaire scores at baseline

|                      | Simple regression analysis | Multiple regression analysis |
|----------------------|----------------------------|------------------------------|
|                      | r  | P      | B   | β   | P  |
| Age (years)          | −0.071 | 0.296 |     |     |     |
| BMI (kg/m²)          | −0.018 | 0.446 |     |     |     |
| Duration of diabetes (years) | 0.040 | 0.380 |     |     |     |
| Duration of insulin use (years) | 0.135 | 0.152 |     |     |     |
| HbA1c (%)            | −0.518 | <0.001 | −0.550 | −0.518 | <0.001 |
| Frequency of SMBG (times/day) | 0.029 | 0.413 |     |     |     |
| Frequency of insulin injection (times/day) | −0.091 | 0.245 |     |     |     |
| Daily total insulin dose (units/kg) | 0.020 | 0.441 |     |     |     |
| DTR-QOL questionnaire Total | −0.140 | 0.413 |     |     |     |
| DTR-QOL questionnaire D1 | −0.136 | 0.150 |     |     |     |
| DTR-QOL questionnaire D2 | −0.020 | 0.439 |     |     |     |
| DTR-QOL questionnaire D3 | −0.161 | 0.110 |     |     |     |
| DTR-QOL questionnaire D4 | −0.133 | 0.156 |     |     |     |
| SMBG questionnaire Q1 | 0.058 | 0.331 |     |     |     |
| SMBG questionnaire Q2 | 0.030 | 0.409 |     |     |     |
| SMBG questionnaire Q3 | 0.044 | 0.369 |     |     |     |
| SMBG questionnaire Q4 | 0.083 | 0.265 |     |     |     |
| SMBG questionnaire Q5 | 0.136 | 0.150 |     |     |     |

A stepwise linear regression analysis regarding change in glycated hemoglobin (HbA1c) by taking into account age, body mass index (BMI), duration of diabetes, duration of insulin use, HbA1c, self-monitoring of blood glucose (SMBG) frequency, insulin injection frequency and daily total insulin dose, SMBG questionnaire scores (Q1–Q5) and diabetes treatment-related quality of life questionnaire (DTR-QOL) scores (total and D1–D4) in 75 individuals with type 2 diabetes. B and β denote non-standardized and standardized regression coefficients, respectively. For analysis of ΔHbA1c, the correlation coefficient squared (r²) was 0.443 and the F-value with 21.313 degrees of freedom was 1 for a P-value of <0.001. D1, domain diabetes treatment-related quality of life questionnaire “Burden on social activities and daily activities”; D2, domain of diabetes treatment-related quality of life questionnaire “Anxiety and dissatisfaction with treatment”; D3, domain of diabetes treatment-related quality of life questionnaire “Hypoglycemia”; D4, domain of diabetes treatment-related quality of life questionnaire “Satisfaction with treatment”; Q1, the self-monitoring of blood glucose questionnaire asking “How important is self-monitoring of blood glucose to you?”; Q2, the self-monitoring of blood glucose questionnaire asking “How much pain do you feel when you prick a finger with a lancet device?”; Q3, the self-monitoring of blood glucose questionnaire asking “How frustrated are you with self-monitoring of blood glucose?”; Q4, the self-monitoring of blood glucose questionnaire asking “How confident are you to enter self-monitoring of blood glucose results correctly in your self-monitoring of blood glucose diary?”; Q5, the self-monitoring of blood glucose questionnaire asking “Would you like to share your self-monitoring of blood glucose results with your physician”, each of which is using a 5-point Likert scale with responses ranging from “very unlikely” (1) to “very likely” (5).
when used to maximize the benefits of SMBG use. Although earlier reports showed the utility of SMBG for glycemic control by enrolling mostly SMBG-naive individuals, participants in the current study had been using SMBG well before initiation of educational intervention, permitting us to evaluate the JADEC Diabetes Education Card System Program with an SMBG readings analyzer.

There were several limitations to the present study. First, this is a single-center study on individuals with type 2 diabetes receiving insulin, so it might be difficult to generalize our findings. Second, both physicians and patients were open to the randomization in this study due to the nature of the interventions (i.e., use of the JADEC Diabetes Education Card System and the SMBG reading analyzer). Thus, the results presented here should be interpreted carefully in this context. Third, antidiabetes drugs could be freely changed by physicians-in-charge. Fourth, HbA1c targets were individually decided by physicians-in-charge. Fourth, HbA1c targets were individually decided by physicians-in-charge. Fourth, HbA1c targets were individually decided by physicians-in-charge. Fourth, HbA1c targets were individually decided by physicians-in-charge. Fifth, although the current study had been using SMBG well before initiation of educational intervention, permitting us to evaluate the JADEC Diabetes Education Card System Program with an SMBG readings analyzer.

In conclusion, greater HbA1c-lowering by physicians’ DSME using the JADEC Diabetes Education Card System and the SMBG analyzer in individuals with type 2 diabetes receiving insulin and SMBG was suggested, but not confirmed.

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DISCLOSURE
D Yabe received consulting or speaker fees from Astellas Pharma Inc., Eli Lilly Japan, MSD, Novo Nordisk Pharma, Nippon Boehringer Ingelheim, Ono Pharmaceutical, Sumitomo Dainippon Pharma and Takeda Pharmaceutical. D Yabe also received clinically commissioned/joint research grants from Ono Pharmaceutical, Novo Nordisk Pharma, Taisho Pharmaceutical, Arklay and Terumo. T Kurose received consulting or speaker fees from Arklay, Astra Zeneca, Kissei Pharmaceutical, LifeScan Japan, Medtronic Japan, Nippon Boehringer Ingelheim, Novo Nordisk Pharma, Sanofi and Terumo. Y Hama moto received consulting or speaker fees from Novo Nordisk Pharma. T Kurose received consulting or speaker fees from Sanofi. Y Yamada received consulting or speaker fees from MSD, Novo Nordisk Pharma, Ono Pharmaceutical, Sumitomo Dainippon Pharma, Takeda Pharmaceutical, Sanofi, Daiichi Sankyo and Mitsubishi Tanabe Pharma. Y Yamada also received clinically commissioned/joint research grants from Novo Nordisk Pharma, Ono Pharmaceutical, Sumitomo Dainippon Pharma, Takeda Pharmaceutical, Daiichi Sankyo and Mitsubishi Tanabe Pharma. Y Seino received consulting or speaker fees from Eli Lilly Japan, Sanofi, Novo Nordisk Pharma, Glaxo-Smith-Kline, Taisho Pharmaceutical, Taisho

Table 3 | Association of change in glycated hemoglobin during the study period with changes in self-monitoring of blood glucose frequency, insulin doses and self-monitoring of blood glucose questionnaire scores

|                      | Simple regression analysis | Multiple regression analysis |
|----------------------|---------------------------|-----------------------------|
|                      | $r$                       | $P$                         | $B$                        | $\beta$ | $P$      |
| $\Delta$SMBG frequency (times/day) | -0.184 | 0.083 | | | |
| $\Delta$Insulin injection frequency | 0.073 | 0.294 | | | |
| $\Delta$Insulin dose (units/kg) | 0.295 | 0.012 | | | |
| SMBG questionnaire |                  |                             | 4.394 | 0.293 | 0.022 |
| $\Delta$Q1 | -0.082 | 0.270 | | | |
| $\Delta$Q2 | -0.106 | 0.215 | | | |
| $\Delta$Q3 | -0.020 | 0.442 | | | |
| $\Delta$Q4 | -0.087 | 0.258 | | | |
| $\Delta$Q5 | -0.254 | 0.027 | | | |

A stepwise linear regression analysis regarding change in glycated hemoglobin by taking into account change in self-monitoring of blood glucose ($\Delta$SMBG) frequency, $\Delta$Insulin injection frequency, $\Delta$Insulin dose and changes in SMBG questionnaire scores in 75 individuals with type 2 diabetes. $B$ and $\beta$ denote non-standardized and standardized regression coefficients, respectively. For analysis of $\Delta$HbA1c, the correlation coefficient squared ($r^2$) was 0.151 and the $F$-value with 4883 degrees of freedom was 2 for a $P$-value of 0.011. Q1, the self-monitoring of blood glucose questionnaire asking “How important is self-monitoring of blood glucose to you?”, Q2, the self-monitoring of blood glucose questionnaire asking “How much pain do you feel when you prick a finger with a lancing device?”, Q3, the self-monitoring of blood glucose questionnaire asking “How often do you feel when you prick a finger with a lancing device?”, Q4, the self-monitoring of blood glucose questionnaire asking “How confident are you to enter self-monitoring of blood glucose results correctly in your self-monitoring of blood glucose diary?” Q5, the self-monitoring of blood glucose questionnaire asking “Would you like to share your SMBG results with your physician,” each of which uses a 5-point Likert scale with responses ranging from “very unlikely” (1) to “very likely” (5).
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