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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

Nagaaki Tanaka[1,2], Daisuke Yabe[1,3,4], Kenta Murotani[5], Yuko Yamaguchi[1,2], Yuki Fujita[2], Sodai Kubota[1,2,†], Rena Nakashima-Yasuda[2,‡], Saki Kubota-Okamoto[1,2,¶], Shinji Ueno[2], Yuji Yamazaki[1,2], Hitoshi Kuwata[1,2], Koin Watanabe[2,§], Takanori Hyo[2], Yoshiyuki Hamamoto[1,2], Takeshi Kurose[1,6], Hiroko Higashiyama[7], Yusuke Seino[8], Yuichiro Yamada[1,2], Yutaka Seino[1,2,*]

[1]Yutaka Seino Distinguished Center for Diabetes Research, Kansai Electric Power Medical Research Institute, Kobe, Japan, [2]Center for Diabetes, Endocrinology and Metabolism, Kansai Electric Power Hospital, Osaka, Japan, [3]Department of Diabetes, Endocrinology and Metabolism/Department of Rheumatology and Clinical Immunology, Gifu University Graduate School of Medicine, Gifu, Japan, [4]Division of Molecular and Metabolic Medicine, Kobe University Graduate School of Medicine, Kobe, Japan, [5]Biostatistics Center, Graduate School of Medicine, Kurume University, Kurume, Japan, [6]Nakanoshima Clinic, Osaka, Japan, [7]Division of Medical Education Research, Kansai Electric Power Medical Research Institute, Kobe, Japan, and [8]Department of Endocrinology and Metabolism, Fujita Health University, Toyoake, Japan

Keywords
Diabetes Card System Program, Diabetes self-management education, Japan Association of Diabetes Education and Care

***Correspondence**
Yutaka Seino
Tel.: +81-78-303-6090
Fax: +81-78-303-6090
E-mail address:
yutaka.seino@kepmri.org

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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,

[†]Department of Diabetes and Endocrinology, Gifu University Graduate School of Medicine, Gifu, Japan.
[‡]Division of Diabetes, Japan Community Health Care Organization Osaka Hospital, Osaka, Japan.
[¶]Division of Diabetes and Endocrinology, Gifu Municipal Hospital, and Department of Diabetes and Endocrinology, Gifu University Graduate School of Medicine, Gifu, Japan.
[§]Department of Endocrinology and Metabolism, Fujita Health University, Toyoake, Japan;. Sasaki Naika Clinic, Osaka, Japan.

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whereas it was significantly decreased in group C. HbA1c change was independently associated with changes in insulin dose and SMBG Q1 score.

Conclusion: Greater HbA1c-lowering by physicians' diabetes self-management education using the Japan Association of Diabetes Education and Care education tool and SMBG analyzer in individuals with type 2 diabetes receiving insulin and SMBG was suggested, but not confirmed.

INTRODUCTION

Education for self-management and lifestyle modification are fundamentally important in the management of diabetes [1,2]. Diabetes self-management education (DSME) has been found to improve patient diabetes knowledge and self-care behaviors[3,4], as well as glycated hemoglobin (HbA1c)[3-7] and quality of life (QOL)[5,8]. Better outcomes were reported for DSME that includes ongoing support[9,10], is tailored to the needs and preferences of each patient, addresses psychosocial issues, and incorporates behavioral strategies[11-14]. 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[15-17]. 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 of essential knowledge to self-manage diabetes (e.g., the importance of self-monitoring blood glucose)[18]. The multidisciplinary team members choose a set of appropriate guidance points according to the patient's needs to facilitate coherent DMSE at each hospital visit. JADEC proposes nationwide implementation of the JADEC Diabetes Education Card System Program, but its efficacy remains to be investigated in a randomized, controlled trial.

Self-monitoring of blood glucose (SMBG) is widely used for monitoring daily blood glucose profiles, and improving treatment by adjusting insulin timing and dosage [19]. Although many clinical trials clearly show that SMBG is beneficial for glycemic control in individuals with type 1 and type 2 diabetes, SMBG can nevertheless represent a critical psychological burden for individuals, owing to fear of the pain of finger-pricking and reporting untoward results[19-22]. We previously showed that individuals with type 1 and type 2 diabetes experiencing SMBG-associated pain have more mental distress, lower health-related QOL and higher HbA1c[23]. In the same study, we also showed that individuals who appreciate the importance of SMBG testing are more willing to share their SMBG results with their physician. Furthermore, this is more likely when the physician regularly checks the individual's SMBG results and provides meaningful feedback. As the previous study was a cross-sectional survey, it is still unclear to what degree intensive interaction between a patient and healthcare professionals in SMBG use benefits the patient.

In the current study, we carried out a prospective interventional study to clarify whether physicians' DMSE using the JADEC Diabetes Education Card System together with a SMBG analyzer that shows daily glucose fluctuations facilitates feedback that improves glycemic control and QOL in individuals with type 2 diabetes receiving insulin.

MATERIALS AND METHODS

Study design and participants

This was a 6-month, prospective, open-labeled, single-center, randomized study carried out in Kansai Electric Power Hospital, Osaka, Japan, between November 2017 and December 2018 (Clinical trial registration number: UMIN000035349). The study was designed to determine the value of physicians delivering necessary information for better glycemic control using the JADEC Diabetes Card System Program and providing feedback on SMBG values using a SMBG readings analyzer. The study was carried out in accordance with the Declaration of Helsinki and the Ethical Guidelines for Medical and Health Research Involving Human Subjects established by the Ministry of Health, Labor and Welfare of Japan and the Ministry of Education, Culture, Sports, Science and Technology. 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).

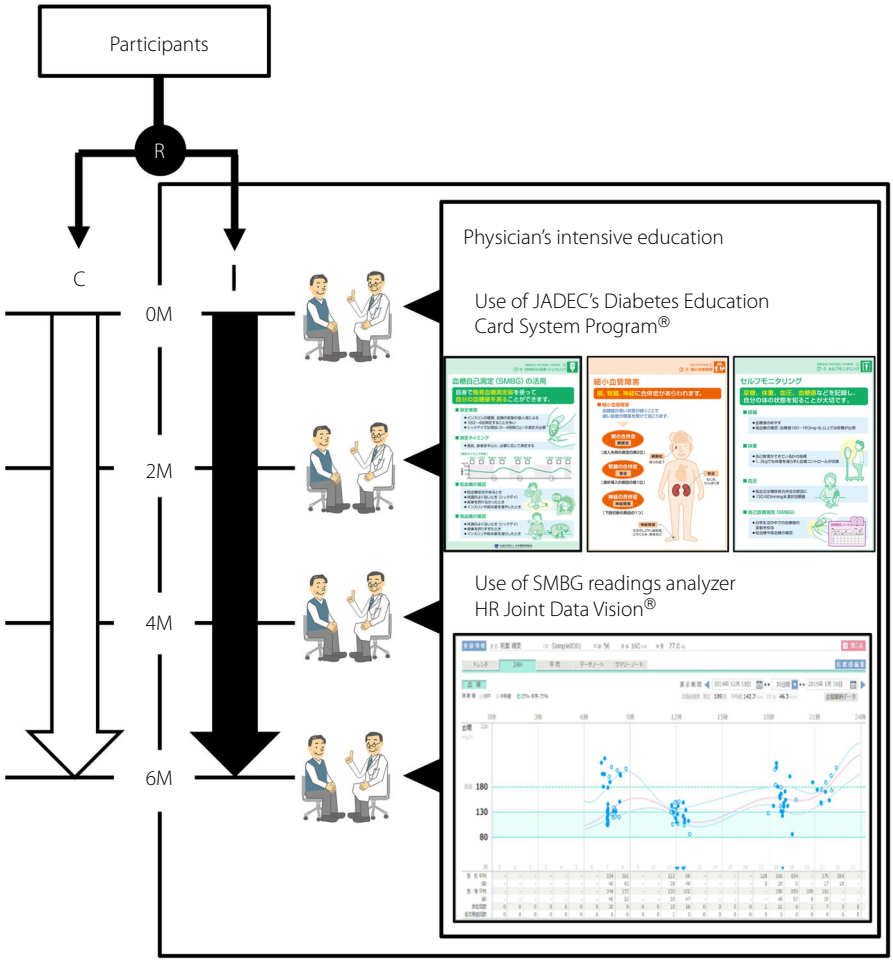

Figure 1 | Study protocol. Participants were randomized (R) into two groups: an intervention (I) group and a control (C) group. At 0, 2, 4 and 6 months (M) after the randomization, individuals in group I received physicians' diabetes self-management education (DMSE) at each hospital visit by using the Japan Association of Diabetes Education and Care (JADEC) Diabetes Education Card Program on each patient's blood glucose profiles analyzed by the self-monitoring of blood glucose (SMBG) readings analyzer, HR Joint Data Vision®, which provides comprehensive summary statistics, listings and graphical plots of blood glucose profiles. Individuals in group C received physicians' DMSE at each hospital visit without using the JADEC Diabetes Education Card Program and the SMBG reading analyzer. A diabetes treatment-related quality of life questionnaire and an original SMBG questionnaire were carried out at 0 M and at 6 M.

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 (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[18]; 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[24], together with the JADEC self-management notebook in which patients can record their SMBG values[25]. 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[18]; 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[24], together with the JADEC self-management notebook in which patients can record their SMBG values[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[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; ΔSMBG 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

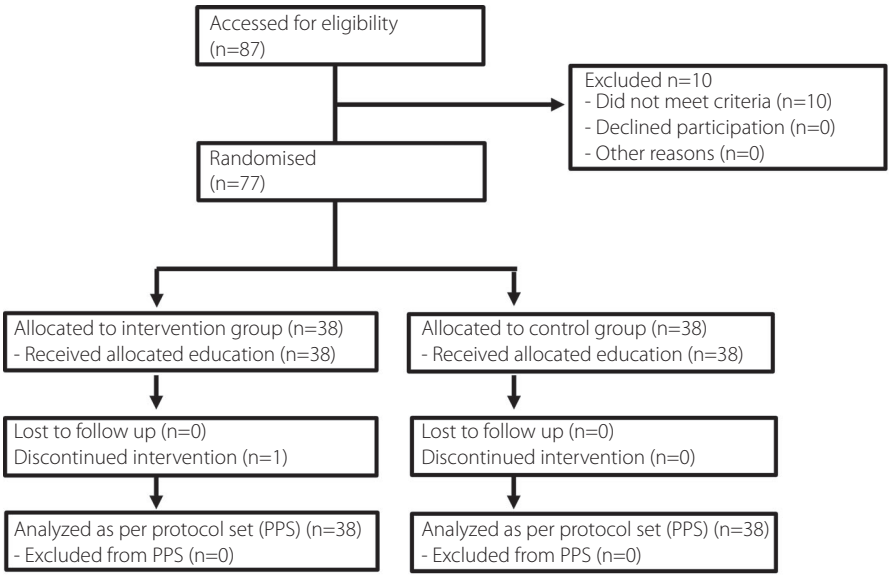

Figure 2 | Flow diagram of the study.

Inc., Chicago, IL, USA). $P < 0.05$ was considered statistically significant. Values are expressed as the mean ± standard deviation, unless otherwise stated.

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 subgroup 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

	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/m^2)	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	8.0 ± 0.9	7.9 ± 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	7.9	13.2	
Three times per day (%)	2.6	2.6	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	69.8 ± 13.2	69.8 ± 14.5	69.9 ± 12.6	0.979
D1	74.2 ± 15.4	75.8 ± 15.9	72.7 ± 15.0	0.405
D2	63.2 ± 17.1	62.6 ± 18.6	63.8 ± 15.8	0.761
D3	76.6 ± 22.5	74.3 ± 24.7	79.0 ± 20.1	0.382
D4	61.9 ± 16.8	60.2 ± 17.3	63.6 ± 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.

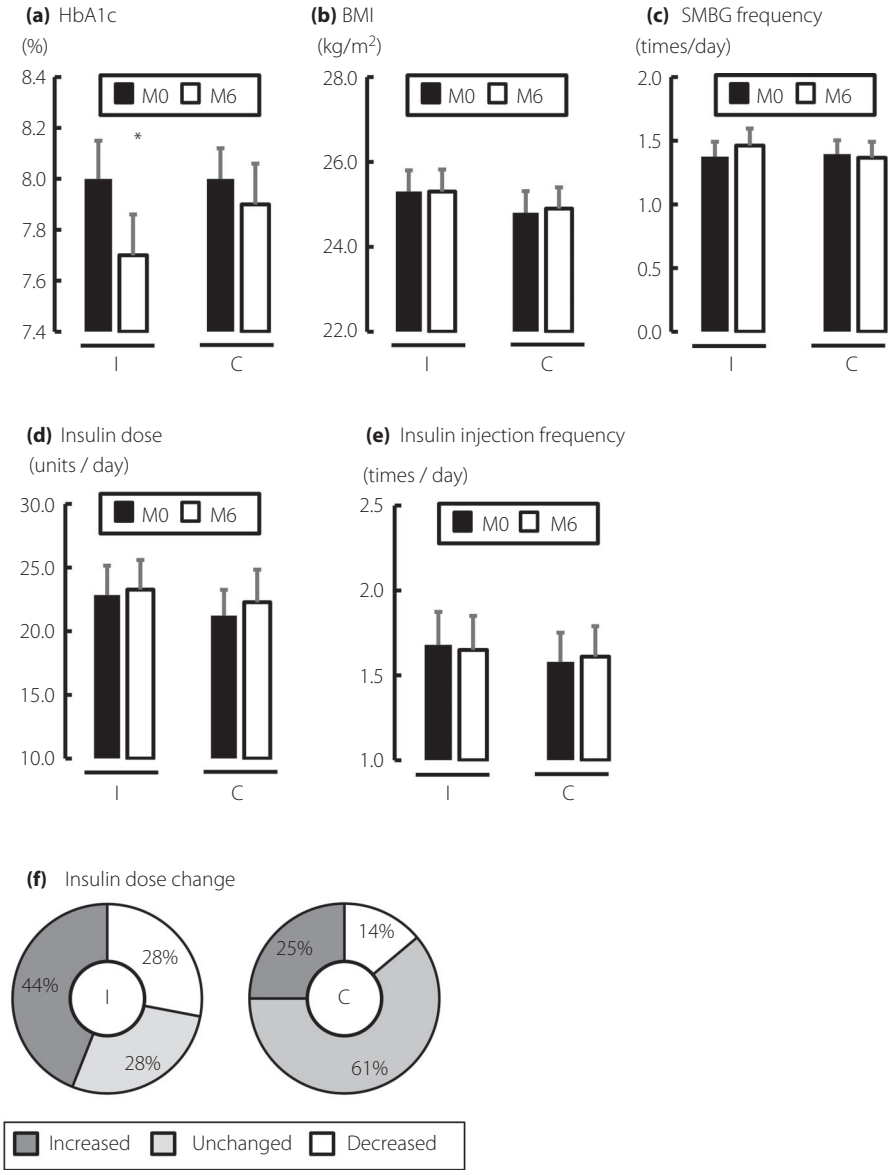

Figure 3 | (a) Glycated hemoglobin (HbA1c), (b) body mass index (BMI), (c) frequency of self-monitoring of blood glucose (SMBG) per day and (d) insulin doses at baseline (0 M) and 6 months after randomization (6 M) are shown. Values are the mean ± standard error of the mean. *$P < 0.05$ versus baseline (paired *t*-test for HbA1c and BMI; and Wilcoxon's signed rank test for SMBG frequency, insulin dose, and insulin injection frequency). (e) Distribution of changes in insulin doses during the 6 months is also shown. Categories of "increased" and "decreased" refer to individuals whose insulin doses were increased or decreased by ≥1 unit during the 6 months, respectively. The category of "unchanged" refers to individuals whose insulin doses were unchanged during the study. C, control group; I, intervention group.

≥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/m^2 and C, 0.11 ± 0.72 kg/m^2; $P = 0.534$), 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; $P = 0314$) 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

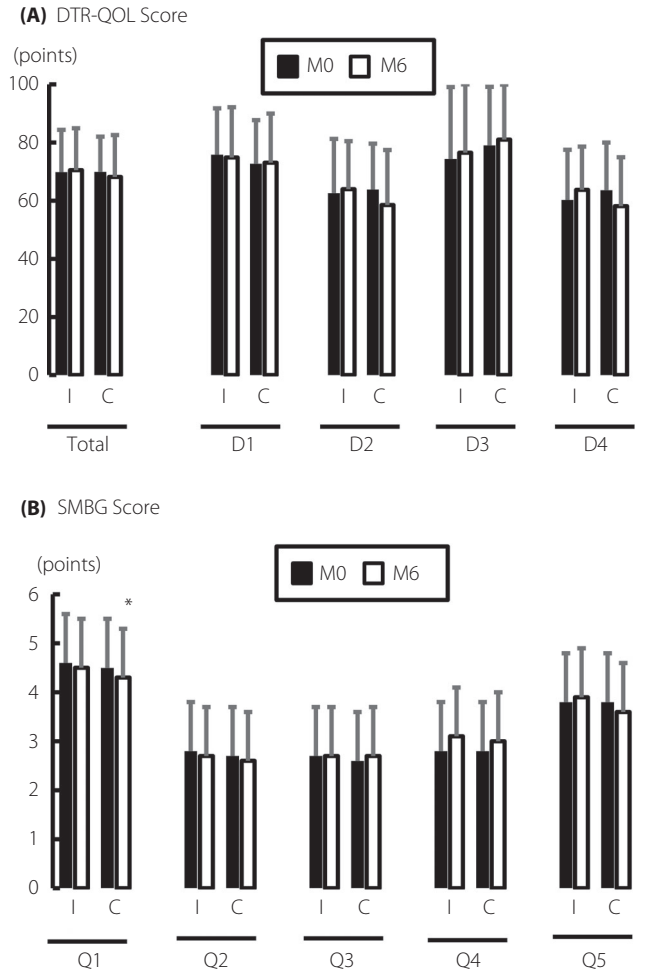

Figure 4 | (a) The Diabetes Therapy-Related Quality of Life (DTR-QOL) and (b) the self-monitoring of blood glucose (SMBG) questionnaire scores at baseline (0 M) and 6 months after the randomization (6 M) are shown. The total score and domain scores in the DTR-QOL questionnaire were converted to a scale 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.

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; $P = 0.687$). ΔDTR-QOL was similar between groups I and C (I, −0.10 ± 12.73 points and C, −0.84 ± 11.82 points; $P = 0.551$). ΔDTR-QOL was also compared between groups I and C in a subgroup of baseline HbA1c <8.0% (I, −1.19 ± 13.86 points [$n = 19$] and C, 0.79 ± 10.87 points [$n = 18$]; $P = 0.988$) and baseline HbA1c ≥8.0% (I, 1.37 ± 11.35 points [$n = 15$] and C, −2.79 ± 10.87 points [$n = 18$]; $P = 0.425$). Scores of DTR-QOL D1, D2, D3 and D4 did not change during the study period in either group (Figure 4a). ΔDTR-QOL total (I, −0.10 ± 12.37 points and C, −0.84 ± 11.82 points; $P = 0.810$), ΔDTR-QOL D1 (I, −1.21 ± 13.73 points and C, 1.52 ± 11.37 points; $P = 0.383$), ΔDTR-QOL D2 (I, 0.12 ± 8.25 points and C, −2.36 ± 10.46 points; $P = 0.288$), ΔDTR-QOL D3 (I, 0.39 ± 5.33 points and C, 0.55 ± 5.33 points; $P = 0.908$) and ΔDTR-QOL D4 (I, 0.48 ± 4.98 points and C, −1.39 ± 4.95 points; $P = 0.129$) did not differ between the two groups. Scores of Q1, "How important is SMBG to you?", in the SMBG questionnaire did not change during the study period in group I (0 M, 4.6 ± 0.6 and 6 M 4.6 ± 0.7; $P = 1.000$), while they were significantly reduced in Group C (0 M, 4.5 ± 0.5 and 6 M 4.3 ± 0.7; $P < 0.05$) (Figure 4b). ΔSMBG Q1 (I, 0.00 ± 0.51 points and C, −0.84 ± 11.82 points; $P = 0.810$), ΔSMBG Q2 (I, 0.00 ± 0.95 points and C, −0.06 ± 1.14 points; $P = 0.822$), ΔSMBG Q3 (I, 0.21 ± 0.95 points and C, 0.06 ± 1.16 points; $P = 0.562$), ΔSMBG Q4 (I, 0.44 ± 1.37 points and C, 0.09 ± 0.66 points; $P = 0.173$) and ΔSMBG Q5 (I, −0.03 ± 0.97 points and C, −0.26 ± 0.85 points; $P = 0.303$) did not differ between the two groups (Figure 4b).

Associations of ΔHbA1c during the study period with various clinical parameters, DTR-QOL scores and SMBG scores at baseline were investigated by simple and multiple regression analyses (Table 2). ΔHbA1c was independently associated with baseline HbA1c (β = −0.518 and $P < 0.001$). Associations of ΔHbA1c with ΔSMBG frequency, Δinsulin injection frequency, Δinsulin dose and ΔSMBG Q1-Q5 scores were also investigated (Table 3). ΔHbA1c was independently associated with ΔQ5 (β = −0.252 and $P = 0.047$) and Δinsulin dose (units/kg) (β = 0.293 and $P = 0.022$). These findings indicate that participants who more readily shared their SMBG results with their physician had better HbA1c and optimized insulin dosage.

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[2,27], as well as reduce their HbA1c[28,29]. In fact, enhancement DSME is recommended when patients do not reach treatment targets[2]. 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[11], education tools must be customized to culture, language and customs to be effective in improving self-care and subsequent glycemic control [2,30].

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

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/m^2)	−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			
D1	−0.136	0.150			
D2	−0.020	0.439			
D3	−0.161	0.110			
D4	−0.133	0.156			
SMBG questionnaire					
Q1	0.058	0.331			
Q2	0.030	0.409			
Q3	0.044	0.369			
Q4	0.083	0.265			
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 (r^2) 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 lancing 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).

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 [31], 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[32,33], 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[31]. 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,

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	β	*P*
ΔSMBG frequency (times/day)	−0.184	0.083			
ΔInsulin injection frequency	0.073	0.294			
ΔInsulin dose (units/kg)	0.295	0.012	4.394	0.293	0.022
SMBG questionnaire					
ΔQ1	−0.082	0.270			
ΔQ2	−0.106	0.215			
ΔQ3	−0.020	0.442			
ΔQ4	−0.087	0.258			
ΔQ5	−0.254	0.027	−0.255	−0.252	0.047

A stepwise linear regression analysis regarding change in glycated hemoglobin by taking into account change in self-monitoring of blood glucose (ΔSMBG) frequency, Δinsulin injection frequency, Δinsulin dose and changes in SMBG questionnaire scores 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 (r^2) was 0.151 and the *F*-value with 4.883 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 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 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).

when used to maximize the benefits of SMBG use. Although earlier reports showed the utility of SMBG for glycemic control by enrolling mostly SMBG-naïve individuals[33-36], 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 based on the physical and cognitive abilities of elderly adults with diabetes[37]. Nevertheless, the current findings clearly show that the JADEC Diabetes Education Card System Program, together with an SMBG readings analyzer, might contribute to improvement of patient–physician interaction and HbA1c in individuals with type 2 diabetes receiving insulin.

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

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