

## ORIGINAL ARTICLE

### Effects of a shared decision-making guide tool on confidence in diabetes management using continuous glucose monitoring among diabetes nurses: a randomized controlled trial

Yaeko Kawaguchi, Seiko Sakane, Akiko Suganuma, Masayuki Domichi and Naoki Sakane\*

Division of Preventive Medicine, Clinical Research Institute, National Hospital Organization Kyoto Medical Center, Kyoto Japan

#### Abstract

**Background:** Shared decision-making (SDM) between patients and their healthcare professionals in developing treatment plans is increasingly recognized as central to improving treatment adherence and, ultimately, patient outcomes. This study investigated the effects of a SDM guide tool on confidence in diabetes management using continuous glucose monitoring (CGM) among diabetes nurses.

**Methods:** Twenty-seven diabetes nurses were randomly assigned to either an intervention group or a control group. Participants in both groups received a 60-min basic course on CGM. Participants in the intervention group underwent a 90-min advanced course using a SDM guide tool. Confidence (13 items), attitude (11 items), knowledge (16 items), and consultation style (5 items) were assessed at baseline and 1 month after the intervention. Evaluation of the tool (13 items) was assessed in the intervention group.

**Results:** Compared to the control group, the intervention group had greater changes in confidence score after the intervention ( $1.4 \pm 1.5$  vs.  $2.6 \pm 1.5$  points;  $P < 0.001$ ). There were no significant changes in the attitude, knowledge, and consultation style scores between the groups. The evaluation score with the tool was relatively high.

**Conclusion:** This program using a SDM guide tool may be effective in increasing confidence in diabetes management using CGM among diabetes nurses.

**Trial registration:** University hospital Medical Information Network (UMIN) Center: UMIN000052495. (25 September 2023) ([https://center6.umin.ac.jp/cgi-open-bin/ctr/ctr\\_view.cgi?recptno=R000059789](https://center6.umin.ac.jp/cgi-open-bin/ctr/ctr_view.cgi?recptno=R000059789)).

**Keywords:** *continuous glucose monitoring; shared decision-making; real-time continuous glucose monitoring; intermittently scanned continuous glucose monitoring*

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Continuous glucose monitoring (CGM) has revolutionized diabetes management by providing real-time glucose data and alerts for hypo/hyperglycemia. These devices, worn continuously, improve safety, reduce glycemic variability, and are especially beneficial for individuals using insulin.<sup>1–3</sup> CGM use improves key outcomes such as HbA1c, time in range (TIR), and time below range (TBR) in people with type 1 and type 2 diabetes.<sup>4,5</sup> Effective CGM use requires collaboration between patients and healthcare professionals.<sup>6,7</sup>

Two main CGM types are used in Japan: real-time CGM (rtCGM; Dexcom G6) and intermittently scanned CGM (isCGM; FreeStyle Libre), with options to use a dedicated reader or a smartphone app. These systems differ in accuracy, alerts, wearability, cost, and other factors.<sup>8</sup> However, the choice of CGM is often made

solely by physicians, potentially reducing patient engagement and adherence.

Shared decision-making (SDM) is increasingly recommended for preference-sensitive decisions. It involves four key steps: informing the patient of a choice, presenting options, discussing patient preferences, and jointly making a decision. While SDM is linked to improved satisfaction, adherence, and empowerment,<sup>9,10</sup> its full implementation remains limited in clinical practice. Factors affecting SDM include patient characteristics, healthcare provider experience, and communication style.<sup>11–13</sup>

Despite the growing use of CGM in Japan, tools for comparing devices are lacking, as each company promotes only its own products. To address this gap, we developed an SDM guide tool and evaluated its impact on nurses' confidence in diabetes care using CGM.

## Methods

### Study design and participant information

All participants provided written informed consent after receiving a thorough explanation of the study. The target participants for this study met all of the following criteria: (1) healthcare professionals and (2) engaged in providing therapeutic guidance for individuals with diabetes at medical institution. The exclusion criteria consisted of individuals with the following conditions: (1) inability to complete a self-administered questionnaire and (2) inability to participate in online training sessions.

### Intervention: basic and advanced course

The intervention was conducted through a collaborative workshop involving nurses, dietitians, medical doctors, researchers, and patients (Table 1). The program was led by two professionals, a registered dietitian with a certified diabetes educator of Japan/certified psychologist, and a certified diabetes care and education specialist nurse. Participants in both groups attended a 60-min basic course on CGM using brochures from each company. The intervention group received a 90-min advanced course using a SDM guide tool. These scenarios included: (1) explaining the benefits and limitations of CGM to self-monitoring of blood glucose (SMBG) users, (2) comparing FreeStyle Libre and Dexcom G6 for those interested in trying CGM, (3) explaining the comparison between the app and reader for those wanting to try FreeStyle Libre, (4) providing information on the app and monitoring comparison for those interested in trying Dexcom G6, and (5) explaining the pros and cons of Dexcom G6 to FreeStyle Libre users (Figure 1). The four steps involved were: (1) identifying concerns (e.g. pain or inconvenience for SMBG users), (2) sharing information on CGM using a comparison table, (3) addressing questions about CGM, and (4) confirming patient preferences (e.g. choosing Libre, opting for Dexcom G6, or taking more time to decide). The method for choosing CGM using SDM, along with the five scenarios and four steps, was compiled into a seven-page booklet and used. Participants in both groups answered the questionnaire regarding diabetes management using CGM and SDM before and after attending the course.

### Measurement

Participant information included age groups (20s, 30s, 40s, 50s, and 60+ years), sex (female, male), medical institutions (hospitals, clinics), teaching experience (none, 1–2 years, 3–5 years, and ≥5 years), CGM teaching experience (none, <6 months, 1–2 years, 3–5 years, and ≥5 years), and diabetes specialty.

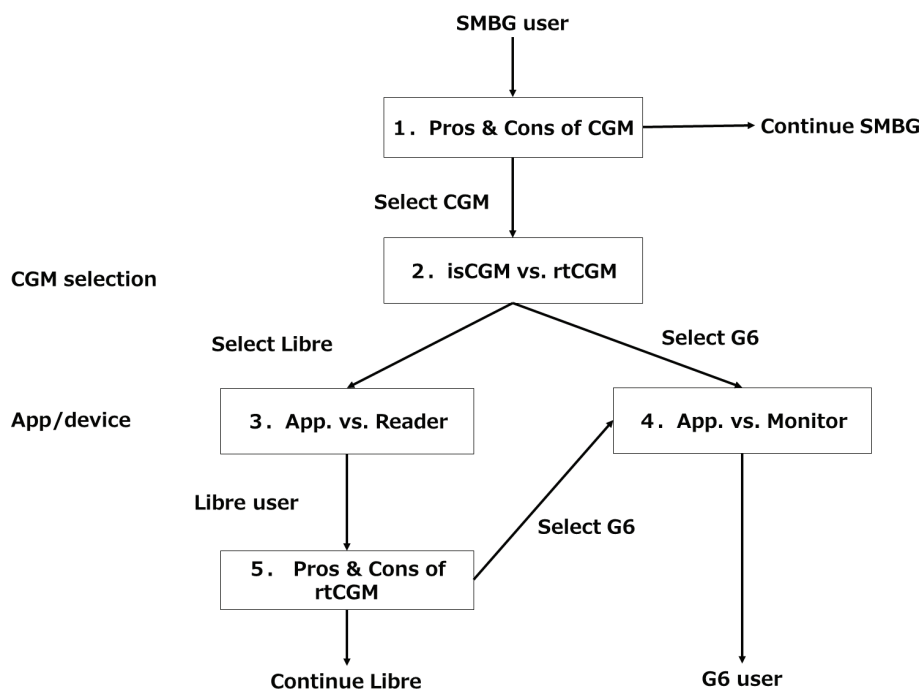
### Confidence scale for diabetes management using CGM

The confidence scale comprised 13 items rated on an 11-point scale ranging from ‘no confidence at all’ (0 points) to ‘extremely confident’ (10 points). These items are the following questions: (c1) Explain the advantage of CGM to SMBG users. (c2) Explain the disadvantage of CGM to SMBG users. (c3) Explain isCGM (FreeStyle Libre) to those interested in trying isCGM. (c4) Explain rtCGM (Dexcom G6) to individuals interested in trying rtCGM. (c5) Explain the differences between isCGM (FreeStyle Libre) and rtCGM (Dexcom G6) to those considering CGM. (c6) Explain the advantage of rtCGM (Dexcom G6) to individuals using isCGM (FreeStyle Libre). (c7) Explain the disadvantage of rtCGM (Dexcom G6) to individuals using isCGM

Table 1. Contents of basic and advanced course

Course	Contents
Basic course (60 minutes)	What is CGM?
	Features of Libre
	Features of G6
	Reading of AGP report
Advanced course (90 minutes)	Question and Answer Session
	What is SDM?
	Five scenarios based on SDM
	1) Explain the benefits and limitations of CGM to SMBG users
	2) Compare Libre and G6 for those interested in trying CGM
	3) Explain the comparison between the app and reader for those wanting to try Libre
	4) Provide information on the app and monitor comparison for those interested in trying G6
	5) Explain the pros and cons of G6 to Libre users
	Four steps of choice for selecting CGM using the principles of SDM
	1) Identify concerns
	2) Share information on CGM using a comparison table
	3) Address questions about CGM
	4) Confirm the patient preferences
	Question and answer session

CGM, continuous glucose monitoring; SDM, shared decision-making; Libre, FreeStyle Libre; G6, Dexcom G6; AGP, ambulatory glucose profile; SMBG, self-monitoring of blood glucose.



**Fig. 1.** Algorithm of the CGM-SDM study. CGM, continuous glucose monitoring; SDM, shared decision-making; SMBG, self-monitoring of blood glucose; rtCGM, real-time CGM; is CGM, intermittently scanned CGM.

(FreeStyle Libre). (c8) Explain the differences between the app and reader for those wanting to try isCGM (FreeStyle Libre). (c9) Explain the differences between the app and monitor for individuals interested in trying rtCGM (Dexcom G6). (c10) Educate preventing hypoglycemia using CGM. (c11) Educate preventing hyperglycemia using CGM. (c12) Explain troubleshooting measures for CGM issues. (c13) Perform overall diabetes management using CGM. The 13 items had excellent internal consistency with a Cronbach's alpha of 0.988. Low confidence was characterized as a confidence score below 5 points, while high confidence was designated as a score equal to or exceeding 5 points.

#### *Attitude scale for diabetes management using CGM*

The attitude scale comprised 11 items rated on an 11-point scale, ranging from 'not at all' (0 points) to 'very much' (10 points). These items are the following questions: (a1) The use of CGM makes blood glucose management easier. (a2) CGM is helpful in preventing hyperglycemia. (a3) CGM is beneficial for preventing hypoglycemia. (a4) Compared with SMBG, CGM has a higher insurance point, but the effectiveness is not proportional. (a5) Diabetes education using CGM requires time and effort, and the effectiveness may be modest. (a6) It is important to communicate the advantages of CGM to patients. (a7) It is important to communicate the disadvantages of CGM to patients. (a8) Inquiring about patient concerns regarding CGM is crucial. (a9) The decision to use CGM is made by the physician. (a10) Choosing CGM is

important, and it should be decided through consultation between the patient and healthcare professionals. (a11) It is crucial for healthcare professionals to learn about CGM. The 11 items had acceptable internal consistency, with a Cronbach's alpha value of 0.645.

#### *Knowledge for diabetes management using CGM*

The knowledge scale consist of 16 items, where respondents select from three options – 'correct', 'incorrect', or 'unknown' – in response to the following questions: (k1) CGM measures glucose levels in the skin, not capillary blood. (k2) An 80% TIR corresponds to an HbA1c of 7%. (k3) If SMBG reads 115 and CGM reads 100, the CGM is functioning properly. (k4) CGM must be removed during MRI examinations. (k5) With CGM, performing SMBG is not required. (k6) CGM insurance coverage may vary with points sometimes higher or lower than SMBG. (k7) Libre can be worn not only on the upper arm but also on the abdomen. (k8) Libre can display glucose values every 5 min. (k9) Libre can be calibrated by entering blood glucose values. (k10) To ensure data continuity, Libre must be scanned every 8 h. (k11) Libre has an alarm feature to notify of low blood glucose. (k12) G6 can be worn on both the abdomen and upper arm. (k13) G6 (monitor version) allows blood glucose measurements. (k14) G6 is eligible for insurance coverage for ages two and above. (k15) G6 has a longer wear duration compared with Libre. (k16) G6 includes an alarm feature to alert for high blood glucose. The Spearman–Brown split-half reliability coefficient was 0.644 for the knowledge score.

**Consultation style regarding CGM selection**

The selection style of the CGM device was based on the theory of SDM.<sup>14</sup> The selection of a CGM device involved a scale of six items, where respondents use a five-point scale – always (5), usually (4), sometimes (3), rarely (2), or never (1). These items pertain to the following questions: (s1) The healthcare professional (you) unilaterally determines all treatment methods (paternalism). (s2) The healthcare professional (you) explains the treatment method they deem best and obtains the consent of the patient (near paternalism). (s3) After explaining multiple treatment methods, the healthcare professional (you) outlines the method they believe is optimal and secures the consent of the patient (informed consent). (s4) After explaining multiple treatment methods, the healthcare professional (you) engages in discussion and decision-making with the patient (SDM). (s5) After explaining multiple treatment methods, the decision is entrusted to the patient (informed decision-making).

**Evaluation of the SDM guide tool**

Concerning the SDM guide tool for participants in the intervention group, respondents used a five-point scale, ranging from ‘not at all’ (1) to ‘very much’ (5), to answer the following questions in whether they were: (e1) Assisting patients in thoroughly understanding the advantage and disadvantage of CGM. (e2) Facilitating the identification of patients’ concerns among the pros and cons of CGM. (e3) Acting as a preparation base for patient education. (e4) Aiding in reflecting the patient’s opinions when choosing CGM. (e5) Supporting patients in decision-making based on a wealth of information. (e6)

Helping to gain a deeper understanding of the most important issues for the patient. (e7) Enabling patient participation in decision-making, thus contributing to personalized healthcare guidance. (e8) Facilitating the smooth progression of healthcare guidance. (e9) Influencing the relationship between patients and healthcare providers. (e10) Efficiently utilizing the time spent on healthcare guidance. (e11) Enhancing the quality of healthcare guidance. (e12) Expressing satisfaction with this tool. (e13) Recommending this tool to others.

**Statistical analysis**

Descriptive statistics, *t*-tests, stratified *t*-tests, chi-square tests, Mann–Whitney U tests, and Fisher’s exact tests were used where appropriate. Pearson’s correlation coefficients assessed associations. Reliability was evaluated using Cronbach’s  $\alpha$  and split-half coefficients. Missing data were excluded from relevant analyses, and sensitivity analyses were conducted. All analyses were performed using R software, with significance set at  $P < 0.05$ .

**Results**

Out of the 28 healthcare professionals, 27 nurses (excluding one medical doctor) were included in the study and randomly assigned to either the intervention or control group (Figure 2). The overall dropout rate was 18.5%, with no significant difference between the intervention (15.4%) and control groups (21.4%;  $P > 0.999$ ). No significant differences were observed in age group, sex, medical institution, teaching experience, CGM teaching experience, or diabetes specialty (Table 2). Compared to the control group, the intervention group had greater changes

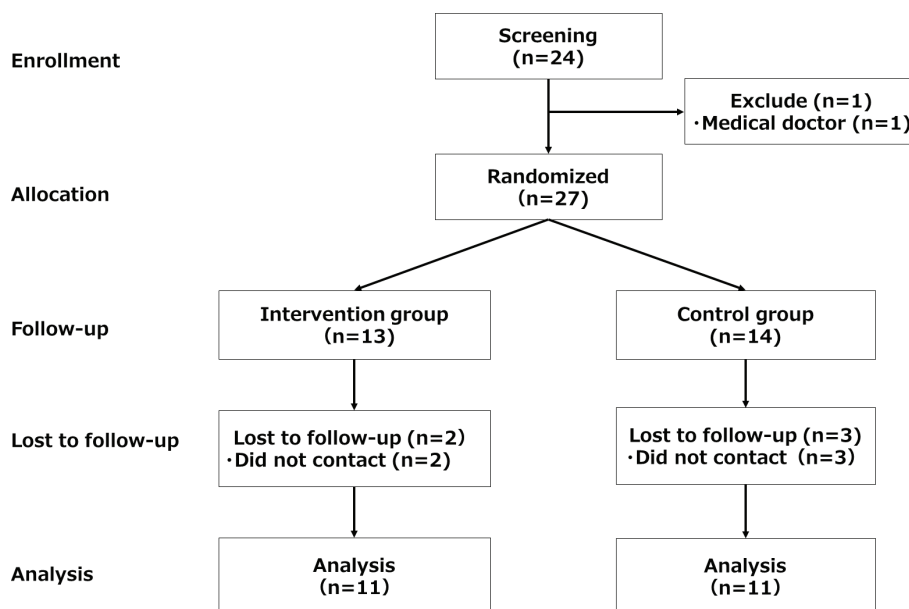


Fig. 2. Flow diagram of the CGM-SDM study. CGM: continuous glucose monitoring; SDM: shared decision-making.

Table 2. Characteristics of participants

Variables	Intervention group (N = 13)	Control group (N = 14)	P value
Age group, %			
20s	1 (7.7)	0 (0.0)	0.631
30s	3 (23.1)	2 (14.3)	
40s	4 (30.8)	6 (42.9)	
50s	5 (38.5)	4 (28.6)	
60s and above	0 (0.0)	2 (14.3)	
Sex, %			
Female	13 (100.0)	11 (78.6)	0.222
Male	0 (0.0)	3 (21.4)	
Medical institution, %			
Hospital	11 (84.6)	9 (64.3)	0.385
Clinic	2 (15.4)	5 (35.7)	
Teaching experience, %			
None	0 (0.0)	3 (21.4)	0.105
1–2 years	1 (7.7)	1 (7.1)	
3– <5 years	0 (0.0)	2 (14.3)	
≥5 years	12 (92.3)	8 (57.1)	
CGM teaching experience, %			
None	2 (15.4)	4 (28.6)	0.404
<6 months	0 (0.0)	2 (14.3)	
1–2 years	2 (15.4)	3 (21.4)	
3– <5 years	4 (30.8)	1 (7.1)	
≥5 years	5 (38.5)	4 (28.6)	
Diabetes certification, %			
CN/CNS/CDEJ/LCDEJ	11 (84.6)	12 (85.7)	>0.999
None	2 (15.4)	2 (14.3)	

CGM, continuous glucose monitoring; CN, certified nurse; CNS, certified nurse specialist; CDEJ, certified diabetes educator of Japan; LCDE, local certified diabetes educator.

in confidence score after the intervention ( $1.4 \pm 1.5$  vs.  $2.6 \pm 1.5$  points;  $P < 0.001$ ) (Table 3). There were no significant differences in the attitude and knowledge score between the groups. The consultation style scores did not differ between the groups after the intervention. The evaluation of the SDM guide tool yielded relatively positive results (mean total score of  $3.8 \pm 0.8$  points out of 5 points) and ‘assisting patients in thoroughly understanding the advantage and disadvantage of CGM’ was high (mean  $4.1 \pm 0.6$  points).

## Discussion

This study is the first to investigate the effects of the SDM guide tool on confidence in diabetes management using CGM among diabetes nurses. The findings indicate that the intervention improved overall confidence scores in diabetes management using CGM among diabetes nurses. Interestingly, the intervention increased confidence scores not only in nurses with low confidence but also in those with high confidence compared to the control group.

The reasons for the intervention’s increase in confidence scores among nurses with high baseline confidence are unclear. It is possible that the program’s structured design, which includes SDM-based four steps and repeated learning through five scenarios, may explain these results. However, there were no significant changes in attitude scores before and after the intervention. This lack of change in attitude scores may be explained by a ceiling effect, as there were high attitude scores at baseline. Although the intervention increased knowledge scores in both groups, there was no significant difference between the groups. These results may be due to the small sample size and lack of statistical power. Further examination is required to confirm these issues.

HbA1c is an excellent measure for assessing diabetes population health, specifically for predicting the risk of micro and macro vascular complications. However, CGM is a valuable tool in tailoring diabetes treatment plans on an individual basis.<sup>15</sup> Encouraging patient participation in decision-making is a fundamental

**Table 3.** Confidence, attitude, knowledge, and consultation style regarding diabetes management using CGM, and selection of CGM device in participants

Variables	Intervention group (n = 11)				Control group (n = 11)				P value (Int. vs. Cont.)
	n	Pre	Post	delta	n	Pre	Post	delta	
Confidence score, points									
All	11	4.4 ± 2.7	7.0 ± 1.5*	2.6 ± 1.5	11	4.3 ± 3.0	5.8 ± 1.8*	1.4 ± 1.5	<0.001*
High confidence (≥5 points)	6	6.6 ± 0.6	7.9 ± 0.9*	1.5 ± 0.5	5	7.1 ± 1.1	7.2 ± 1.2	0.0 ± 0.7	0.003*
Low confidence (<5 points)	5	1.8 ± 1.3	5.9 ± 1.5*	4.0 ± 1.0	6	1.9 ± 1.4	4.6 ± 1.4*	2.5 ± 0.8	0.024*
Attitude score, point									
Attitude score, point	11	8.3 ± 0.9	8.6 ± 0.8	0.5 ± 0.8	11	7.8 ± 0.7	7.7 ± 1.2	-0.1 ± 1.3	0.253
Knowledge score (out-of-16), points									
Knowledge score (out-of-16), points	11	10.1 ± 3.3	13.5 ± 2.3*	3.4 ± 2.7	11	10.8 ± 3.2	12.5 ± 2.1*	1.6 ± 1.6	0.081
Consultation style score, points									
s1 (paternalism)	11	2.0 ± 1.2	1.9 ± 1.0	-0.1 ± 0.7	11	1.9 ± 0.9	1.9 ± 0.8	0.0 ± 0.8	0.776
s2 (near paternalism)	11	2.8 ± 1.7	2.8 ± 1.5	0 ± 1.4	11	2.7 ± 0.9	3.3 ± 0.9	0.5 ± 0.7	0.264
s3 (informed consent)	11	2.5 ± 1.3	2.8 ± 1.5	0.4 ± 1.2	11	2.6 ± 0.8	2.9 ± 1.0	0.3 ± 0.9	0.844
s4 (shared decision making)	11	2.9 ± 1.4	2.7 ± 1.6	-0.2 ± 1	11	2.6 ± 1.1	2.9 ± 1.0	0.3 ± 0.9	0.272
s5 (informed decision making)	11	2.8 ± 1.2	3.0 ± 1.4	0.2 ± 1.3	12	3.0 ± 1.2	3.1 ± 0.8	0.1 ± 1.3	0.869

\*P < 0.05 (Pre vs. Post, or Int. vs. Cont. group). CGM, continuous glucose monitoring.

principle for fostering a patient-centered care experience, holding the potential to enhance care experiences and responsiveness in diabetes management.<sup>16</sup> Although numerous studies have explored SDM for diabetes management, covering areas include diabetes prevention for prediabetes,<sup>17,18</sup> young adults with T1D,<sup>7,19</sup> T2D,<sup>20–23</sup> and exercise.<sup>24,25</sup> There is currently a gap in the literature regarding SDM, specifically in the selection of CGM devices.

The program described in this study comprised four steps and addressed five different situations: Initially, the identification of patient concerns (e.g. pain) motivated the patient to choose CGM. In the second step, sharing information about CGM through a comparison table provides crucial insights into the decision-making of the patient. In the third step, nurses build trust by earnestly addressing patient queries concerning CGM. Patients are often concerned about factors such as device attachment site, size, and skin reactions. Making the wrong choices in these aspects could decrease treatment adherence and satisfaction. The fourth step involves inquiring about patient preferences and facilitating SDM. It is particularly important to provide patients with adequate time for contemplation, especially when they are undecided. The use of the SDM guide tool in the five different scenarios is expected to facilitate active conversations with patients regarding CGM choices. However, this study did not investigate the extent to which nurses engaged in meaningful conversations with patients using this tool or the extent to which the tool enhanced the quality of interactions. Future research should explore the effectiveness of this tool and its effect on facilitating meaningful conversations with patients.

#### Clinical implications

Numerous CGM studies emphasize the importance of a standardized glucose pattern report, such as an ambulatory glucose profile report, to facilitate effective SDM sessions. Diabetes nurses are tasked with continuously evaluating the appropriate use of CGM in patients. They should remain vigilant during each visit regarding potential changes in cognitive abilities, physical fitness, insurance coverage, and other age-related factors that may affect the effective use of CGM. Additionally, diabetes nurses must assess the patient's performance for CGM system; differences between CGM and blood glucose monitoring data, interpret glucose trend information for insulin dose adjustments, provide guidance on site selection and care, and ensure a comprehensive understanding of alarm functions.<sup>26</sup> Psychosocial factors might influence the effectiveness of CGM in diabetes management. Despite the proven biomedical benefits of CGM, variability in usage exists. Limited research exists on these factors; however, studies have highlighted issues such as frustration, feeling overwhelmed, and negative social reactions that affect CGM success. Patient expectations, tech-savviness, and the underestimated effort needed for CGM skills also influence adoption and sustained use.<sup>27</sup> Some patients may experience psychological stress when they are aware that their rtCGM usage is being monitored, whereas others prefer to check their blood glucose levels only when they perform a scan. To achieve a TIR >70% in adults with T1D, 12 or more scans must be performed per day.<sup>28</sup> Scans are suggested around three meals: before and after snacks, at waking and bedtime, and before and after physical activities, to achieve optimal TIR.

A clinician-training program, aligned with established guidelines, holds promise for effective implementation of

SDM.<sup>29</sup> Similarly, personal health record (PHR) technology, when designed with an interconnected architecture, has the potential to streamline SDM, and incorporating the SDM process into PHR technology can enhance the overall value of PHRs.<sup>30</sup> Digital therapeutic platforms operating on patient-centered strategies facilitated by multidisciplinary teams and SDM contribute to health-care advancements.<sup>31</sup> Further research, particularly incorporating digital therapeutic platforms, is essential to validate the effectiveness of this SDM-training program.

### Strengths and limitations

The strengths of this study lie in its randomized controlled trial design and the use of a validated questionnaire. However, several limitations include the small sample size, exclusion of Medtronic Guardian 3, absence of subjective SDM assessments, such as the SDM-Q-9,<sup>32</sup> and omission of checking the CGM introduction rate in individual hospitals/clinics. Additionally, the limited generalizability of the findings should be recognized because all participants were nurses.

In conclusion, this SDM-based training program may be effective in increasing confidence in diabetes management using CGM among diabetes nurses. The choice of CGM involves the essential collaboration of physicians, and it is not solely within the purview of nurses to make decisions regarding the approach. These factors can be considered barriers to promote SDM. The latest CGM systems introduced in the USA include the Abbott FreeStyle Libre 3 and Dexcom G7. These advanced systems have updated features and enhanced accuracy, and promising individuals with diabetes have improved their overall experience with CGM. For instance, the Abbott FreeStyle Libre 3 offers rtCGM with minute-by-minute data transmission to a smartphone app, a brief 60-min warm-up period, and a 14-day duration. Conversely, the Dexcom G7 rtCGM features the shortest warm-up period of 30 min, predictive low alerts and alarms, a sensor duration of 10 days, and a generous 12-h grace period for seamlessly replacing finished sensors between sessions. Future research, including updating of the CGM, is required to confirm these findings.

### Ethical standards and guidelines

This study conformed to the standards of the Declaration of Helsinki.

Approval of the research protocol: The present study was approved by the ethics committee of the National Hospital Organization Kyoto Medical Center (No.23-039, Approval Date.19/Sep/2023).

Informed consent or substitute for it was obtained from all participants for being included in the study.

Approval date of Registry and the Registration No. of the study/trial: Trial registration number: University

hospital Medical Information Network (UMIN) Center: UMIN000052495).

Animal studies: N/A

### Disclosure of potential conflicts of interest

The authors declare no conflicts of interest associated with this manuscript.

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**\*Naoki Sakane**

I-1 Mukaihata-cho, Fukakusa  
Fushimi-ku, Kyoto 612-8555, Japan  
Tel.: +81-75-641-9161  
Fax: +81-75-643-4325  
Email: nsakane@gf6.so-net.ne.jp