

# Effect of a newly-devised nutritional guide based on self-efficacy for patients with type 2 diabetes in Japan over 2 years: 1-year intervention and 1-year follow-up studies

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## Keywords

Nutritional guidance, Self-management, Type 2 diabetes

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*J Diabetes Investig* 2017; 8: 195–200

doi: 10.1111/jdi.12571

## ABSTRACT

**Aims/Introduction:** We devised a new system called “Educational Guidance” (E-Guide) for nutritional education based on self-efficacy. The present study aimed to examine the effects of E-Guide use on glycemic control among patients with type 2 diabetes.

**Materials and Methods:** We carried out an interventional and observational study that included 74 patients with type 2 diabetes. The extent of glycemic control in the 39 patients who received guidance through the E-Guide (E-Guide group) was compared with that of 35 patients who received conventional nutritional guidance (control group). We carried out a 1-year follow-up survey (subanalysis) based on the electronic health records of 18 patients from the E-guide group and 19 patients from the control group. These patients continued treatment at Hikone Municipal Hospital, Hikone, Shiga, Japan. Changes in glycosylated hemoglobin levels, body mass index and medication dose were examined from time of enrollment to the end of the 1-year intervention, and during the 1-year follow-up.

**Results:** Decreases in glycosylated hemoglobin levels were more pronounced in the E-Guide group than in the control group during the intervention period ( $P < 0.05$ ). The levels further decreased during the follow-up period ( $P < 0.01$ ). In the E-Guide group, body mass index decreased significantly throughout the follow-up period ( $P < 0.001$ ). Additionally, increased medication doses were significantly less common in the E-Guide group than in the control group ( $P < 0.01$ ).

**Conclusions:** Intervention based on our “E-Guide” is more useful and powerful than the conventional methods for glycemic control and self-care behavior among patients with type 2 diabetes in Japan.

## INTRODUCTION

Type 2 diabetes mellitus has emerged as a major public health challenge, with an estimated 415 million adults diagnosed with type 2 diabetes mellitus worldwide, and that number is likely to increase to 642 million by 2040 if not controlled<sup>1</sup>. In Japan, the prevalence of type 2 diabetes mellitus has increased over the past few decades, and the total number of patients with

diabetes is estimated to have increased from 7.4 million in 2002 to 9.5 million in 2012. Furthermore, diabetes has become an important cause of mortality and morbidity<sup>2</sup>.

Several risk factors for type 2 diabetes mellitus, including obesity, smoking habits, hypertension, physical activity levels and family history, have been identified<sup>3</sup>. Lifestyle modification (diet and exercise) is the most essential treatment strategy to combat these risk factors. However, a previous study showed that adherence to lifestyle modification is significantly lower than that to medication<sup>4</sup>. Patients and providers differ substantially in their perceptions and attitudes to lifestyle modifications for the management of diabetes, which can lead to confusion

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Received 20 April 2016; revised 23 July 2016; accepted 8 August 2016

and conflict<sup>4</sup>. Despite the favorable effects of behavioral modifications on the risk for type 2 diabetes mellitus, lifestyle modification is a complicated process<sup>5</sup>. Therefore, establishing an effective strategy based on behavioral changes for diabetes prevention or treatment remains an issue<sup>6</sup>.

The American Diabetes Association has recommended patient-centered communication, which is important in the clinical management of diabetes<sup>7,8</sup>. One of the key factors in attaining active self-care is self-efficacy, which is a construct based on social cognitive theory that focuses on self-confidence for a given behavior<sup>9</sup>. Several authors have documented associations between self-efficacy and self-care for diabetes<sup>10–12</sup>. We hypothesize that adopted psychological techniques, including self-efficacy in nutritional guidance, have beneficial effects for glycemic control in patients with type 2 diabetes mellitus compared with conventional methods. However, many providers are not able to identify and evaluate psychological problems, and provide the psychological support their patients require<sup>4</sup>. For conventional methods, dietitians or physicians provide one-way knowledge and behavioral targets for lifestyle modifications. However, even if short-term improvements in glycemic control and bodyweight can be expected using these methods, good long-term control is usually not achieved<sup>13</sup>.

Therefore, we established a modified nutritional education program, called the “Educational Guidance” program (E-Guide), based on psychological techniques that include self-efficacy, coaching<sup>14,15</sup>, self-management programs<sup>16</sup> and a solution-focused approach<sup>17</sup>. The E-Guide protocol is shown in Figure 1. First, patients plan the action target alone. We carried out an evaluation of the degree of achievement of their planned action target, calorie intake and nutrient balance during each visit.

The present study comprised two segments spread across 2 years: (i) a 1-year intervention; and (ii) a 1-year follow-up. The primary objective of the present study was to determine the degree of glycemic control in patients with type 2 diabetes mellitus by comparing outcomes after a 1-year intervention between patients who received nutritional guidance through the E-Guide (E-Guide group) or conventional methods (control group). The secondary outcomes were changes in glycemic and weight control during the 1-year follow-up, which was carried out subsequently.

## MATERIALS AND METHODS

### Participants

We studied 74 Japanese patients with type 2 diabetes mellitus (44 men and 30 women) with no history of heart failure, cirrhosis, malignancy, chronic renal failure or other serious diseases, including drug abuse or major psychiatric illness. In total, 39 patients received guidance through the E-Guide (E-Guide group), and 35 patients received conventional nutritional guidance (control group). The subanalysis (1-year follow-up survey) was carried out for 18 patients in the E-Guide group and 19 patients in the control group. Patients from both the groups

continued their treatment at Hikone Municipal Hospital, Hikone, Shiga, Japan. Almost half of the patients with type 2 diabetes mellitus who showed improvement during the 1-year treatment period at our hospital were referred to the original clinic.

The present study was approved by the ethical committee of Hikone Municipal Hospital and complied with the principles of the Declaration of Helsinki (registration number: 22-5 and 25-7), and informed consent was obtained from all participants. Height and bodyweight were measured using a digital scale.

### 1-year Intervention

All participants were individually advised about their lifestyle modifications and weight control by physicians every 2 months for 1-year. The targeted glycated hemoglobin (HbA1c) level by the end of the educational sessions was <7.0%, which is the glycemic threshold to prevent onset and progression of diabetic microangiopathy<sup>18</sup>. In the E-Guide group, a patient-centered approach and combinations of behavior modifications (self-efficacy, motivational interviewing, coping strategies, goal setting, developing action plans, barrier identification and relapse prevention, among others<sup>19</sup>) were applied. The following goals were set: maintaining caloric intake with <25% of calories derived from fats (dietary balance); quitting smoking, snacks or alcohol; and increasing exercise. Patients set their action targets for lifestyle modification themselves, and we evaluated the degrees of achievement for their action target, energy intake and dietary balance during each intervention appointment. Additionally, dietary intake and nutrient balance were assessed based on dietary records, and all participants were asked to record all food items and drinks consumed during the 2 days before every intervention. Adherence to dietary intake was defined as the percentage of calorie intake compared with the calorie intake indicated by the physician during the intervention period.

### 1-year follow-up survey

During the follow-up period, all participants underwent only periodical medical examination that included instructions on lifestyle modification once every 1–2 months from physicians. We carried out the 1-year follow-up survey based on the electronic health records to examine changes in HbA1c levels, body mass index (BMI) and medication dose, and we compared differences between the E-Guide and control groups.

### Statistical Analysis

Dietary records were analyzed using the Japanese food exchange list<sup>20</sup>. Statistical analysis software (Ekuseru-Toukei 2015; Social Survey Research Information Co. Ltd., Tokyo, Japan) was used to carry out data analyses. Data were expressed as mean  $\pm$  standard deviation or number (percentage). Intergroup comparisons were carried out by two-sample *t*-tests for quantitative variables (age, height, bodyweight, BMI, diabetes duration and HbA1c level), and by the  $\chi^2$ -test or



Fisher's exact test for qualitative variables (sex and medications) accordingly. Intragroup comparisons were carried out by paired *t*-tests. During the 1-year follow-up period, comparisons of intragroup changes were made by one-way analysis of variance (ANOVA) for repeated measurements of BMI and HbA1c levels, and Bonferroni post-hoc tests were carried out to examine the differences among mean values for significant findings.  $P < 0.05$  was considered statistically significant.

Table 1 shows the baseline characteristics of the E-guide and control groups. No significant differences were observed in the mean age, BMI, HbA1c levels, diabetes duration and medications between the two groups. There were no significant differences in the disease duration (E-Guide group  $1.7 \pm 3.2$  years, control group  $1.4 \pm 3.1$  years) or intervention frequencies (E-guide group  $4.0 \pm 1.1$  times, control group  $5.3 \pm 1.0$  times) between the two groups. HbA1c levels and BMI decreased in both groups during the 1-year intervention study (HbA1c 7.9–6.5%,  $P < 0.001$ ; and 8.2–7.2%,  $P < 0.001$ ; BMI 26.8–26.0 kg/m<sup>2</sup>,  $P < 0.001$ ; and 26.4–25.5 kg/m<sup>2</sup>,  $P < 0.001$ ; Table 2). Although HbA1c levels at baseline were not significantly different between the two groups (7.9% vs 8.1%,  $P = 0.425$ ), the levels at the end of interventions were significantly lower in the E-Guide group than in the control group (6.5% vs 7.2%,  $P < 0.001$ ). Furthermore, the degree of improvement in HbA1c levels was significantly higher in the E-Guide group than in the control group (–1.4% vs –0.9%,  $P < 0.05$ ).

	E-Guide	Control	<i>P</i> -value
<i>n</i> (male/female)	39 (26/13)	35 (18/17)	0.183
Age (years)	57.3 ± 10.4	62.2 ± 12.3	0.067
Height (cm)	163.6 ± 8.1	162.4 ± 10.7	0.577
Bodyweight (kg)	71.9 ± 11.5	70.4 ± 14.8	0.612
BMI (kg/m <sup>2</sup> )	26.8 ± 3.2	26.6 ± 4.0	0.798
HbA1c (%)	7.9 ± 1.1	8.1 ± 0.9	0.425
Duration of diabetes (years)	1.7 ± 3.2	1.6 ± 3.1	0.903
Medications, <i>n</i> (%)			
Sulfonylureas	13 (33.3)	17 (48.6)	0.183
α-Glucosidase inhibitors	5 (12.8)	2 (5.7)	0.297
Metformin	5 (12.8)	1 (2.9)	0.502
Glinides	14 (35.9)	10 (28.6)	0.117
DPP4 inhibitors	10 (25.6)	4 (11.4)	0.207

Based on the results from dietary records, no significant difference was observed in the total caloric intake between the two groups ( $1,564.6 \pm 212.1$  kcal vs  $1,596.7 \pm 323.4$  kcal,  $P = 0.749$ ), and dietary intake adherence rates for both groups were impressive ( $97.9 \pm 14.6\%$  vs  $98.4 \pm 15.0\%$ ,  $P = 0.923$ ). In the E-Guide group, the most frequent action target was stopping consumption of snacks including a decrease in frequency and quantity (57.9%), and the other action targets were dietary

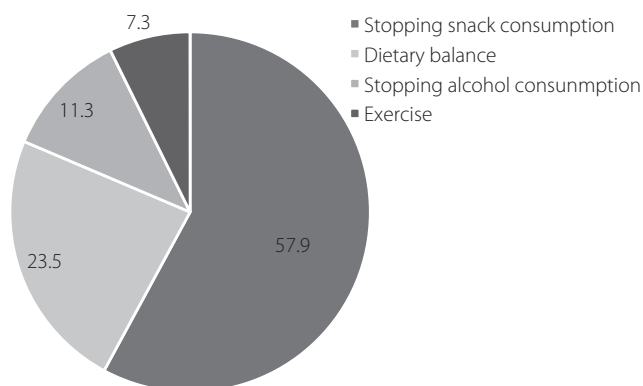
**Table 2** | Changes in glycated hemoglobin and body mass index in the intervention study

	E-Guide (n = 18)	Control (n = 19)
HbA1c (%)		
Baseline	7.9 ± 1.1	8.2 ± 0.9
Post	6.5 ± 0.3***	7.2 ± 0.6***
BMI (kg/m <sup>2</sup> )		
Baseline	26.8 ± 3.2	26.4 ± 4.0
Post	26.0 ± 3.1***	25.5 ± 4.1***

Data are expressed as mean ± standard deviation. \*\*\* $P < 0.001$  (vs baseline). BMI, body mass index; E-Guide, "Educational Guidance" program; HbA1c, glycated hemoglobin.

balance (improved nutrient balance and increased vegetable intake, among other actions; 23.5%); stopping alcohol consumption, including a decrease in frequency and quantity; 11.3%); and exercise, such as walking and resistance exercise (7.3%). The mean attainment rates for the action targets were high ( $79.5 \pm 18.5\%$ ), and the details are shown in Figure 2. There was no significant relationship between the kind of the action target and improvement of glycemic control. This is likely because the practice degree for each aim was selected and determined by the patients themselves. The percentage of patients with increased medications from baseline to the end of the interventions was not significantly different by  $\chi^2$ -test.

The results of the 1-year follow-up survey, which show mean changes in HbA1c and BMI levels in the two groups, are shown in Figure 3. Although significant changes in HbA1c levels within



**Figure 2** | The action targets set by patients in the modified nutritional education program, called the "Educational Guidance" program, group. The most frequent action target was stopping consumption of snacks, including a decrease in frequency and quantity, and the other action targets were dietary balance (improved nutrient balance and increased vegetable intake, among other actions); stopping alcohol consumption, including a decrease in frequency and quantity; and exercise, such as walking and resistance exercise. The mean attainment rates for the action targets were  $79.5 \pm 18.5\%$ , and the individual attainment rates were as follows; stopping consumption of snacks ( $84.4 \pm 18.6\%$ ), dietary balance ( $81.9 \pm 7.3\%$ ), stopping alcohol consumption ( $75.3 \pm 21.5\%$ ) and exercise ( $61.6 \pm 23.7\%$ ).

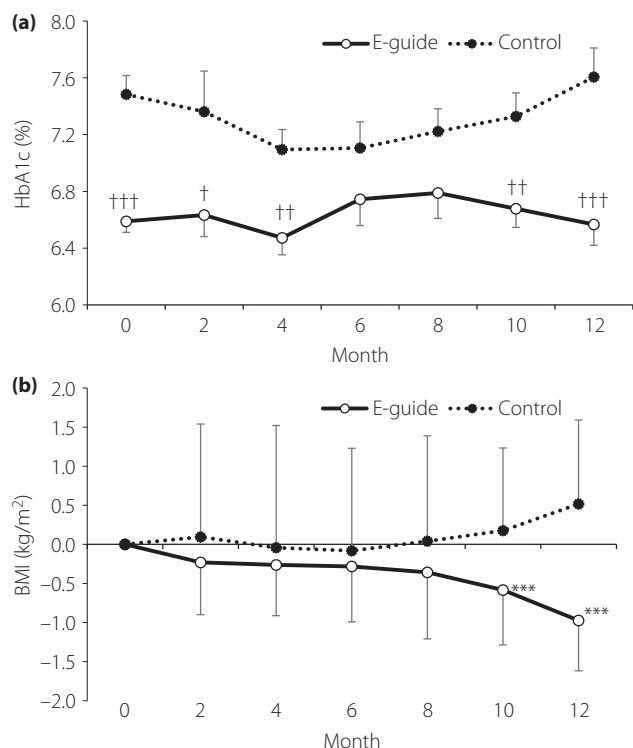
each group were not observed during the follow-up period, HbA1c levels in the E-Guide group were significantly lower than those in the control group at 0, 2, 4, 10 and 12 months (6.6% vs 7.5%,  $P < 0.001$ ; 6.6% vs 7.4%,  $P < 0.05$ ; 6.5% vs 7.1%,  $P < 0.01$ ; 6.7% vs 7.6%,  $P < 0.01$ ; and 6.6% vs 7.6%,  $P < 0.001$ , respectively). Furthermore, the mean HbA1c level during the follow-up period was also significantly lower in the E-Guide group than that in the control group (6.6% vs 7.3%,  $P < 0.01$ ). Based on the results of the repeated-measures ANOVA, a progressive increase in BMI was observed in the control group during the follow-up period. However, a progressive decrease in BMI and a significant decrease in BMI were observed at months 10 and 12, respectively, compared with that at baseline in the E-Guide group ( $P < 0.001$ ) during the follow-up period. Additionally, the rates of increased medications were significantly lower in the E-Guide group than in the control group (33.3% vs 83.3%,  $P < 0.01$ ).

## DISCUSSION

The present results indicate that patients with type 2 diabetes mellitus who underwent nutritional intervention with the empowerment approach using our E-Guide showed greater improvement in their HbA1c levels and BMI than those that used conventional nutritional interventions. The E-Guide utilizes psychological approaches, such as self-efficacy<sup>9</sup>, coaching<sup>14,15</sup>, self-management programs<sup>16</sup>, and solution-focused approaches<sup>17</sup> for communication and as instruction for nutritional guidance. This study reports that nutritional guidance based on psychological approaches impacts glycemic control in patients with type 2 diabetes mellitus.

Several studies have examined the relationships between self-efficacy and health literacy, and their effects on self-care behaviors and glycemic control<sup>11,12,21,22</sup>. Gao *et al.*<sup>12</sup> suggested that diabetes self-care had a direct effect on glycemic control, and self-efficacy had an indirect effect on HbA1c levels. Similarly, in a systematic meta-analysis, patients with diabetes who were involved in self-management education programs showed reductions in HbA1c levels (summary effect size 0.45, 95% confidence interval 0.17–0.74)<sup>16</sup>. These studies show that knowledge alone is not enough to empower patients to incorporate the necessary self-care skills into their daily lives. Therefore, it is recommended that diabetes education include some psychosocial factors, such as the patient's self-efficacy, which might have a significant effect on a patient's adherence to self-care behaviors. In the present study, HbA1c levels significantly decreased in the E-Guide group during the intervention period, and appropriate levels were maintained during the 1-year follow-up period, compared with those of the control group. Furthermore, rates of medication increase were significantly lower in the E-Guide group than in the control group. These results strongly support the effectiveness of the E-Guide.

In a previous study, it was suggested that disease duration and frequent counseling influenced glycemic control<sup>23</sup>. Nakagawa *et al.*<sup>23</sup> reported that HbA1c levels decreased more significantly in patients with short disease durations (<1 year,



**Figure 3** | Mean changes in (a) glycated hemoglobin (HbA1c) and (b) body mass index (BMI) in the follow-up survey. The modified nutritional education program, called the “Educational Guidance” program (E-Guide), group (solid line) and control group (dotted line) are shown. Months 0, 2, 4, 6, 8, 10 and 12 in the follow-up period are shown on the x-axis. Mean differences  $\pm$  standard error are shown. (b) BMI at month 0 in the follow-up survey was not significantly different between the E-Guide group and the control group.  $^{\dagger}P < 0.05$ ,  $^{\dagger\dagger}P < 0.01$ ,  $^{\dagger\dagger\dagger}P < 0.001$  (vs control),  $^{***}P < 0.001$  (vs month 0).

–2.09%) than in those with long disease durations (>6 years, –0.99%,  $P < 0.001$ ), as well as in patients who received more frequent counseling (>4 times, –1.99%) compared with those who received less frequent counseling (<2 times, –0.67%,  $P < 0.001$ ). Although they emphasized the importance of short disease durations and high counseling frequencies, the duration and frequencies even in our control group are similar to those of the group that improved in the Nakagawa study. The present study showed that better glycemic and bodyweight control were obtained using the E-Guide; therefore, we would like to emphasize that our E-Guide is effective.

During the 1-year intervention, although the medication doses and adherence rates to dietary calorie intake in both groups were good, the degree of improvement in HbA1c levels was significantly higher in the E-Guide group than that in the control group. This could be for a few reasons. First, patients in the E-Guide group planned the action target themselves and continued self-monitoring. The mean attainment rates for the action targets were higher in the E-Guide group. The action target attainment rate significantly correlated with the degrees

of improvement of both HbA1c and BMI ( $P < 0.05$ ,  $P < 0.01$ , respectively) in our previous studies (Yamamoto T, Moyama S, Kimura A, Furikado H, Kuroe A, Yano H, unpubl. data). The chosen action targets were mainly stopping snack consumption, and the decrease in quantity and/or frequency of snacks might have contributed to glycemic control. Second, physical activity levels might have increased. Adeniyi *et al.*<sup>24</sup> suggested that physical activity levels were significantly associated with self-efficacy, and low physical activity levels were seen in patients with chronic illness and low self-efficacy. In the present study, a similar effect was observed, and it is likely that decreased HbA1c levels resulted from increased physical activity.

We would like to emphasize that we used psychological techniques, including self-efficacy, coaching and the solution-focused approach, in the new nutritional guide and have examined the influence on glycemic control. Only few such studies have been carried out. However, several limitations should be considered while interpreting our findings. First, we did not quantify self-efficacy and physical activity. Second, relatively few participants were enrolled. Third, the present study was carried out at a single institution in Japan. Further studies including more institutions and participants are required to determine whether the present results are reproducible.

In conclusion, the present study shows that compared with conventional methods, the intervention based on the nutritional guidance, which we called the “E-Guide,” might serve as a useful nutrition educational tool for glycemic control in patients with type 2 diabetes mellitus in Japan.

## ACKNOWLEDGMENTS

This study was supported by a research grant in 2010 from The Japan Dietetic Association. We thank Editage ([www.editage.jp](http://www.editage.jp)) for English language editing.

## DISCLOSURE

The authors declare no conflict of interest.

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