

Dietitian-supported dietary intervention leads to favorable dietary changes in patients with type 2 diabetes: A randomized controlled trial

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ABSTRACT

Aims/Introduction: It remains to be fully elucidated whether nutrition education by dietitians can lead to specific positive changes in the food choices of patients with diabetes.

Materials and Methods: A total of 96 patients with type 2 diabetes and diabetic kidney disease were randomly assigned to the intensive intervention group that received nutritional education at every outpatient visit and the control group that received nutritional education once a year. The total energy intake, energy-providing nutrients and 18 food groups were analyzed at baseline, and 1 and 2 years after the intervention in 87 patients. Furthermore, the relationship between the changes in hemoglobin A1c, body composition and changes in the total energy or energy-producing nutrient intake was analyzed in 48 patients who did not use or change hypoglycemic agents during the study period.

Results: The total energy intake, carbohydrates, cereals, confections, nuts and seeds, and seasonings significantly decreased, and fish and shellfish intake significantly increased during the study period in the intensive intervention group, whereas these changes were not observed in the control group. The decrease in the total energy intake and carbohydrates after 2 years was significantly greater in the intensive intervention group than in the control group. The change in the total energy and carbohydrate intake showed a significant positive correlation with that in muscle mass. The multivariate analysis showed that the decrease in total energy intake was independently associated with that in muscle mass.

Conclusion: Dietitian-supported intensive dietary intervention helps improve the diet of patients with type 2 diabetes.

INTRODUCTION

In Japan, the increase in type 2 diabetes has been attributed to lifestyle changes. In particular, there has been a significant increase in the number of patients with type 2 diabetes, visceral

obesity and insulin resistance owing to the Westernization of dietary habits. In a randomized controlled trial of the effect of nutritional education by a dietitian on the lifestyle of patients with type 2 diabetes, the intervention group that participated in an intensive lifestyle intervention that promoted weight loss through decreased caloric intake and increased physical activity showed a significant improvement in hemoglobin A1c (HbA1c), as well as weight loss, compared with the control

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group¹. In addition, several meta-analyses reported that dietary and other lifestyle interventions facilitate weight loss², and improve HbA1c, blood lipid levels and blood pressure in patients with diabetes^{3–5}. Based on the above evidence, lifestyle interventions, especially diet therapy, can be considered important tools in the management of type 2 diabetes.

Nutritional education by dietitians has been proven effective in improving metabolic parameters and glycemic control in patients with diabetes^{6,7}. It has also been reported that patients with diabetes who were supported by a dietitian or certified diabetes educator were more knowledgeable about nutrition^{8,9}. In addition, dietary habits, such as consumption of low-calorie foods, a low-fat diet and restriction of salt intake, were significantly associated with good glycemic control, suggesting the important role of dietitians in improving dietary habits⁹. However, to our knowledge, only a few reports have clarified whether intervention by a dietitian in patients with type 2 diabetes with or without diabetic kidney disease (DKD) specifically changes the nutrient and food consumption^{10,11}.

Recently, we reported that frequent nutritional education by dietitians compared with conventional education by dietitians only once a year significantly reduced body fat percentage and HbA1c levels in patients with type 2 diabetes mellitus with or without DKD¹². Therefore, the present study aimed to determine whether frequent nutritional education by dietitians could change food intake, and improve total energy and nutrient intake using the cohort.

MATERIALS AND METHODS

Patients

The entry and exclusion criteria for this trial have been reported previously¹². Briefly, patients with type 2 diabetes mellitus and DKD (chronic kidney disease stages G1–3), aged ≥ 20 years, who were examined in the Division of Endocrinology and Metabolism and the Division of Nephrology at the Jichi Medical University Hospital, Shimotsuke, Japan, between May 2013 and October 2016, and who had not received nutritional education in the past 5 years were included in the present study. The clinical diagnosis of DKD was based on estimated glomerular filtration rate and albuminuria measurements. DKD was clinically defined by a persistently high urinary albumin-to-creatinine ratio ≥ 30 mg/g or sustained reduction in estimated glomerular filtration rate < 60 mL/min/1.73 m². Of the 127 patients who met the enrollment criteria and received an explanation of the purpose and nature of the study, just 102 provided informed consent. After excluding five patients who withdrew their consent and one who had membranous nephropathy as a primary disease, 96 patients were finally enrolled in the study. The patients were randomly assigned into two groups: (i) an intensive intervention group that received nutritional education from a dietitian at each outpatient visit; and (ii) a control group that received nutritional education once a year from a dietitian. Finally, 44 patients in the intensive intervention group and 43 in the control group who completed the 2-year follow-up period were analyzed.

Study design

The intensive intervention group received nutritional education on eating habits at each outpatient visit from a dietitian for 2 years. The control group received nutritional education from a dietitian at the beginning of the study, and 1 and 2 years after the intervention. Nutritional education was provided according to the physicians' instructions. In addition, the physicians prescribed nutritional therapy (e.g., 25–30 kcal/kg ideal weight/day of energy intake, protein, fat and carbohydrate energy ratio, and salt intake) based on the 2012–2013 Diabetes Care Guidelines of the Japan Diabetes Society¹³.

Variable measurements

In both the intensive intervention and control groups, data on HbA1c, body mass index (BMI), body fat percentage, body fat mass, muscle mass, physical activity level (activity factor, a measure of energy expenditure expressed as a multiple of 24 h resting metabolic rate), total energy intake, energy-producing nutrients (protein, fat and carbohydrate) intake, 18 food group intakes and prescribed drugs were obtained at the beginning of the study, and 1 and 2 years after the intervention. These data were examined and assessed as follows: (i) changes over time in the total energy, energy-producing nutrients, and food group intakes in each of the intensive intervention and control groups; (ii) comparison of changes in the total energy and energy-producing nutrients intake between the two groups at the beginning of the study and after 2 years of the intervention; and (iii) relationship between changes in the total energy or energy-producing nutrients intake and changes in HbA1c, BMI or body composition from the beginning of the study to 2 years after the intervention in 48 patients (32 men and 16 women) who did not use or change hypoglycemic agents during the 2-year study period.

Blood biochemistry tests were carried out using an automated analyzer (LABOSPECT 008 a; Hitachi High-Technologies Corp., Tokyo, Japan). The daily nutrient intake of each participant was calculated using a food frequency questionnaire (FFQ) based on food groups, as described previously¹⁴. As the results of the FFQ were correlated well with the results of the 7-day weighed-diet records¹⁵, FFQ can be used as an objective investigation method with both propriety and plasticity^{14,16,17}. The physical activity level was estimated by calculating the weighted sum of hours spent at six levels of activity using the following scores: 1.0 for a basal level of activity, such as sleeping and resting; 1.1 for a sedentary level of activity, such as relaxing in a sitting position; 1.52 for a sedentary level of activity, such as working in a sitting position; 2.46 for slight activity, such as working in a standing position; 4.88 for a moderate level of activity, such as gardening; and 7.26 for a heavy level of activity, such as transporting heavy objects. Body composition was measured using a multifrequency body composition analyzer (MC-190; Tanita Corp., Tokyo, Japan).

Study outcomes

The primary outcome was “changes over time in the total energy, energy-producing nutrients, and food group intakes in

the intensive intervention and control groups.” The secondary outcome was a “comparison of changes in the total energy, and energy-producing nutrients intake between the two groups at the beginning of the study and after 2 years of the intervention” and “association between changes in the total energy or energy-producing nutrients intake and changes in HbA1c or body composition.”

Statistical analysis

Values are presented as the mean \pm standard deviation, median (interquartile range) or percentage. The Kolmogorov–Smirnov test was used to assess the normality of the data. The unpaired *t*-test, Mann–Whitney *U*-test, χ^2 -test, repeated measures analysis of variance and Friedman test were used to compare the factors between the two groups. Spearman’s rank correlation and multivariate logistic regression analysis (forward selection, likelihood ratio) were used to examine the relationship between the changes in the total energy intake or energy-producing nutrients and changes in HbA1c or body composition. Specifically, a multivariate logistic analysis adjusted for age, sex and changes in physical activity during the study period was carried out to examine the association between changes in the total energy, protein, fat or carbohydrate intake, and changes in HbA1c, BMI, body fat percentage, body fat mass and muscle mass, which were separately categorized into two groups based on median values. The sample size was calculated as follows: with <80% power and 5% level,

the target number of patients enrolled to detect a significant difference between the two groups was 74 patients in total, with each group comprising 37 participants.

RESULTS

Baseline characteristics of the patients

The two groups were similar in sex, age, duration of diabetes, HbA1c level, BMI and body fat percentage. The body composition, total energy and energy-producing nutrient intake of the patients at the beginning of the study are shown in Table 1. There were no differences in physical activity level, body fat mass, muscle mass, total energy, protein, fat, and carbohydrate intake between the intensive intervention and control groups. The frequency of nutritional education (mean \pm standard deviation) provided by the dietitians in the intensive intervention group was 12.6 ± 3.3 times.

Changes in the total energy and nutrient intake during the study period

The changes in the total energy and nutrient intake over time in the intensive intervention and control groups are shown in Table 2. In the intensive intervention group, total energy and carbohydrate intake significantly decreased during the study period ($P < 0.05$), whereas no changes were observed in other parameters. However, in the control group, no changes were observed in any of the parameters.

Table 1 | Patient background at the beginning of the study

	Intensive intervention group	Control group	<i>P</i> -value
<i>n</i>	44	43	
Male (%)	68	56	0.235 [‡]
Age (years)	68.0 (62.2–71.0)	65.0 (58.0–71.0)	0.277 [¶]
Albuminuria category, % (A1, A2 and A3) [†]	63, 17, 20	51, 30, 19	0.352 [‡]
Systolic blood pressure (mmHg)	134 (122–141)	133 (124–142)	0.538 [¶]
Diastolic blood pressure (mmHg)	73 \pm 10	76 \pm 14	0.319 [§]
HbA1c (%)	7.0 \pm 0.7	7.1 \pm 0.8	0.395 [§]
eGFR (mL/min/1.73 m ²)	67.7 \pm 18.7	70.2 \pm 16.6	0.517 [§]
Physical activity level (activity factor)	1.49 (1.38–1.66)	1.50 (1.35–1.64)	0.917 [¶]
Body composition			
Body fat mass (kg)	16.6 \pm 7.3	18.1 \pm 7.1	0.355 [§]
Muscle mass (kg)	46.4 (37.3–51.8)	45.5 (36.2–51.6)	0.656 [¶]
Total energy intake and energy-producing nutrients			
Total energy (kcal/day)	1,706 (1,516–2,116)	1,877 (1,509–2,011)	0.653 [¶]
Total energy (kcal/kg/day)	32 \pm 6	31 \pm 5	0.346 [§]
Protein (g/day)	60 (53–74)	64 (54–72)	0.704 [¶]
Protein (%energy)	14 (12–15)	14 (13–15)	0.300 [¶]
Fat (g/day)	50 \pm 16	53 \pm 14	0.402 [§]
Fat (%energy)	25 (20–30)	27 (23–31)	0.122 [¶]
Carbohydrate (g/day)	256 \pm 64	246 \pm 48	0.420 [§]
Carbohydrate (%energy)	57 \pm 8	56 \pm 6	0.617 [§]

Values are expressed as the mean \pm standard deviation, median (interquartile range) or percentage. Some of the data are adopted from our preceding paper¹². eGFR, estimated glomerular filtration rate; HbA1c, hemoglobin A1c; kg, ideal weight. [†]A1, urine albumin level was <30 mg/day; A2, urine albumin level was \geq 30 mg/day, but <300 mg/day; A3, urine albumin level was \geq 300 mg/day. [‡] χ^2 test, [§]*t*-test for two samples. [¶]Mann–Whitney test.

Table 2 | Changes in the total energy and nutrient intake over time during the study period

	At start of study	After 1 year	After 2 years	P-value
Intensive intervention group				
Total energy (kcal/day)	1,805 ± 372	1,738 ± 382	1,660 ± 319	0.024
Protein (g/day)	60 (53–74)	63 (52–70)	61 (56–67)	0.529 [†]
Fat (g/day)	50 ± 16	50 ± 17	50 ± 17	0.953
Carbohydrate (g/day)	251 (202–230)	230 (203–259)	218 (196–247)	0.016 [†]
Control group				
Total energy (kcal/day)	1,877 (1,509–2,011)	1,726 (1,562–1,944)	1,738 (1,471–1,993)	0.846 [†]
Protein (g/day)	64 (54–72)	60 (52–69)	65 (55–74)	0.607 [†]
Fat (g/day)	52 (39–65)	50 (41–58)	51 (42–68)	0.203 [†]
Carbohydrate (g/day)	246 ± 48	245 ± 43	233 ± 50	0.106

Values are expressed as the mean ± standard deviation or median (interquartile range). Repeatedly measured dispersion analysis. [†]Friedman test.

Changes in food group intakes during the study period

The changes in food intake in the intensive intervention and control groups are shown in Tables 3 and 4, respectively. In the intensive intervention group, cereals, confections, nuts and seeds, and seasonings intake significantly decreased, and fish and shellfish intake significantly increased during the study period ($P < 0.05$). However, in the control group, there were no significant changes in any of the parameters, except for fruit intake, during the study period.

Comparison of the changes in the total energy intake and energy-producing nutrients between the intensive intervention and control groups

The comparison of the changes after 2 years from the beginning of intervention in the total energy intake and energy-producing nutrients between the intensive intervention and control groups is shown in Table 5. Decreases in the total energy and carbohydrate intake were significantly greater in the intensive intervention group than that in the control group ($P < 0.05$).

Relationship between the changes in the total energy intake or energy-producing nutrients and changes in HbA1c or body composition

The relationship between the changes in the total energy intake or energy-producing nutrients and changes in HbA1c or body composition was examined in 48 patients (32 men and 16 women, 26 in the intensive intervention group and 22 in control group) who did not use or change hypoglycemic agents during the 2-year study period: nine patients were treated with diet and exercise only, 16 with sulfonylureas, 14 with biguanides, six with alpha-glucosidase inhibitors, five with thiazolidinediones, 18 with dipeptidyl-peptidase-4 inhibitors, two with glucagon-like peptide-1 receptor agonists, one with sodium-glucose cotransporter 2 inhibitors and 13 with insulin preparations.

As summarized in Table S1, changes in the total energy and carbohydrate intakes were significantly positively correlated with changes in muscle mass ($r = 0.376$ and 0.408). In addition,

multivariate logistic regression analyses adjusted for age, sex and changes in physical activity level showed that the decrease in the total energy intake was significantly related to the decrease in muscle mass observed in the subgroup with decreased muscle mass (< -0.025 vs ≥ -0.025 ; odds ratio 0.998, confidence interval 0.996–0.9999, $P = 0.036$). No other items were included in the study. Furthermore, when adjusted for the effect of each hypoglycemic agent, the decrease in muscle mass was independently determined by the decrease in the total energy intake and insulin use (odds ratio 0.998, confidence interval 0.996–0.9999, $P = 0.036$, and odds ratio 0.135, confidence interval 0.024–0.776, $P = 0.025$).

DISCUSSION

In the present study, we randomly assigned patients with type 2 diabetes with or without DKD (chronic kidney disease stages G1–3) into intensive intervention and control groups, prospectively followed them for 2 years, and compared the total energy intake, energy-producing nutrients and 18 food groups between the two groups. The results showed that the total energy and carbohydrate intakes decreased significantly in the intensive intervention group throughout the study period. Furthermore, the decreases in the total energy and carbohydrate intakes after 2 years of intervention were significantly greater in the intensive intervention group than that in the control group.

Similar results were reported by Huang *et al.*¹⁰ They recruited 154 patients with type 2 diabetes, and assigned them randomly to a routine care control group ($n = 79$) and a dietitian-led intervention group ($n = 75$), and compared the nutritional parameters after 1 year of follow up¹⁰. In agreement with the present results, they showed that decreases in the total energy and carbohydrate intakes were significantly greater in the intervention group than that in the control group.

In general, it is difficult to maintain the bodyweight loss achieved by lifestyle modification for a long time. According to a systematic review of 22 articles on weight maintenance after weight loss through lifestyle modifications, the average weight loss during the period was 9.5% of the initial weight. However,

Table 3 | Changes over time in food intake by food group during the study period in the intensive intervention group

Intake by food group (kcal/day)	At start of study	After 1 year	After 2 years	P-value
Cereals	715 ± 290	698 ± 210	636 ± 163	0.036
Potatoes	20 (10–44)	20 (10–30)	15 (5–30)	0.143 [†]
Dark green and yellow vegetables	26 (15–35)	25 (15–44)	28 (19–44)	0.157 [†]
Light vegetables	50 (40–74)	54 (36–71)	51 (39–65)	0.782 [†]
Algae	1.1 (0.7–1.6)	0.8 (0.3–1.9)	0.7 (0.3–1.5)	0.083 [†]
Beans	66 (40–86)	63 (40–93)	46 (27–77)	0.157 [†]
Fish and shellfish	109 ± 53	109 ± 62	121 ± 78	0.036
Meat	152 (91–213)	152 (91–246)	145 (91–244)	0.174 [†]
Eggs	32 (17–52)	32 (11–54)	32 (22–70)	0.664 [†]
Milk	100 ± 73	95 ± 67	88 ± 58	0.445
Fruits	76 (35–82)	47 (7–82)	56 (25–82)	0.254 [†]
Confections	125 (70–219)	86 (50–159)	90 (19–181)	0.040 [†]
Alcoholic	0 (0–101)	0 (0–117)	0 (0–124)	0.234 [†]
Sweetened beverages	0 (0–22)	0 (0–17)	0 (0)	0.166 [†]
Sugars and sweeteners	27 (19–35)	21 (11–33)	29 (12–43)	0.191 [†]
Nuts and seeds	9 (2–30)	4 (0–17)	5 (1–13)	0.017 [†]
Fats and oils	65 (51–100)	63 (49–108)	73 (49–108)	0.126 [†]
Seasonings	46 (32–63)	32 (25–50)	37 (17–51)	0.002 [†]

Values are expressed as mean ± standard deviation or median (interquartile range). Repeatedly measured dispersion analysis. [†]Friedman test.

Table 4 | Changes over time in the food intake by food group during the study period in the control group

Intake by food group (kcal/day)	At start of study	After 1 year	After 2 years	P-value
Cereals	640 (556–747)	678 (563–738)	636 (561–687)	0.068 [†]
Potatoes	20 (10–35)	20 (10, 30)	20 (10–40)	0.864 [†]
Dark green and yellow vegetables	22 (15–32)	22 (14–37)	22 (12–42)	0.980 [†]
Light vegetables	50 ± 24	50 ± 22	46 ± 22	0.313
Algae	0.7 (0.3–1.7)	0.8 (0.5–1.9)	1.1 (0.4–1.9)	0.396 [†]
Beans	93 (53–134)	86 (51–121)	93 (40–136)	0.626 [†]
Fish and shellfish	104 (69–146)	83 (52–118)	91 (59–153)	0.068 [†]
Meat	107 (61–183)	117 (72–171)	126 (91–213)	0.842 [†]
Eggs	32 (11–75)	32 (22–75)	43 (22–75)	0.313 [†]
Milk	111 (70–182)	110 (56–171)	116 (73–177)	0.883 [†]
Fruits	82 (40–85)	82 (23–123)	41 (20–82)	0.008 [†]
Confections	151 (55–217)	87 (55–235)	119 (37–207)	0.908 [†]
Alcoholic	0 (0–55)	0 (0–101)	0 (0–97)	0.163 [†]
Sweetened beverages	0 (0–6)	0 (0–9)	0 (0)	0.986 [†]
Sugars and sweeteners	23 (15–33)	21 (13–34)	20 (10–37)	0.930 [†]
Nuts and seeds	5 (1–13)	6 (1–14)	5 (2–14)	0.759 [†]
Fats and oils	74 (55–97)	82 (45–116)	83 (48–122)	0.730 [†]
Seasonings	38 ± 21	36 ± 18	37 ± 22	0.733

Values are expressed as the mean ± standard deviation or median (interquartile range). Repeatedly measured dispersion analysis. [†]Friedman test.

the average maintenance rate over the next year was just 54%¹⁸. Many reports have shown that dietary interventions are not successful in achieving persistent bodyweight loss. For example, a relatively large study comparing the effects on vascular complications and mortality failed to obtain a significant difference in the mean BMI between the two groups over a median intervention period of 8.5 years¹⁹. To determine

whether frequent dietary intervention effectively reduces bodyweight for an extended period of time, we need to continue intervention for a longer time.

To our knowledge, just a few studies have examined whether nutritional education alters each food group intake in patients with type 2 diabetes. A study compared the efficacy of activity-based personalized nutritional education with that of the

Table 5 | Comparison of the changes after 2 years from the beginning of intervention in the total energy intake and energy-producing nutrients between the intensive intervention and control groups

	Intensive intervention group (n = 44)	Control group (n = 43)	P-value
Changes in the total energy intake (kcal/day)	-145 ± 337	14 ± 379	0.042
Changes in protein intake (g/day)	-2 ± 13	2 ± 18	0.292
Change in fat intake (g/day)	0 ± 15	3 ± 19	0.395
Change in carbohydrate intake (g/day)	-33 ± 55	-8 ± 49	0.033

Values are expressed as the mean ± standard deviation. Unpaired *t*-test.

general instruction for diabetes on the nutritional parameters collected by a dietary survey using the 24 h dietary recall method, in which saccharides, grains and tuber crops intakes were decreased. However, the intake of pulses increased in the activity-based personalized nutrition education group than that in the general instruction group²⁰.

The present study had several limitations. First, the study period was short (3 months). Second, the 24 h dietary recall method, in which the surveyor asked the participants about food intake retrospectively on the previous day or 24 h before the time of the survey, might not be accurate enough to estimate habitual intake. In this respect, the design of the present study, which was followed up for 2 years and used the FFQ, which might be superior to the 24 h dietary recall method in terms of assessing habitual intake¹⁵, should be scientifically more reliable. In the present study, cereals, confections, nuts and seeds, and seasonings intake decreased significantly, whereas fish and shellfish intake increased significantly in the intensive intervention group. In the control group, the fruit intake decreased significantly. These findings show that continuous intervention by a dietitian can favorably influence patients' awareness of food selection over a period of time, thereby reducing the total energy intake and carbohydrates and their related food groups.

Treatment with hypoglycemic agents, including insulin, has been reported to affect bodyweight and composition^{21–23}. Therefore, we examined the relationship between the changes in the total energy intake or energy-producing nutrients and changes in HbA1c or body composition for 48 patients who did not use or change hypoglycemic agents during the 2-year study period. The results showed that the decrease in energy intake was significantly associated with loss of muscle mass, even after adjusting for age, sex and physical activity level. In support of this result, a recent prospective cohort study of 290 Japanese participants reported that inadequate energy intake was associated with decreased muscle mass in older adult patients with type 2 diabetes aged ≥65 years²⁴. Furthermore, a study of 8,165 Korean participants aged ≥30 years reported a positive association between the total energy intake and relative skeletal mass in both men and women, but no significant or only a weak association between single nutrient intake and skeletal muscle mass²⁵. Therefore, when energy restriction is prescribed, changes in body composition and weight should be monitored.

The present study had several limitations. First, dietary surveys cannot be free from reporting biases, because the study was an open-label study. FFQ is also susceptible to underreporting. On average, 11% of men and 15% of women reported an underestimated energy intake²⁶. Second, the study period was too short to detect any effects of the intervention on vascular complications and mortality. Third, although we examined the relationship between the total energy, protein, carbohydrate, and lipid intake and body composition in this study, a more detailed analysis might be required to clarify the effects of nutrients on changes in body composition, such as the differences between animal and vegetable proteins and types of fatty acids. Fourth, as described in our previous paper¹², there were no differences in estimated glomerular filtration rate and albuminuria between the two groups after 2 years of intervention. Because both groups in the present study had a higher percentage of A1 albuminuria, a longer follow-up period might be required to determine the impact of intensive nutrition education on renal function in DKD patients.

The present study shows that frequent intervention by a dietitian can improve food selection, and lower total energy and carbohydrate intakes in patients with type 2 diabetes with or without DKD. In the future, it will be important to establish a longer follow-up period, and clarify whether the intervention by a dietitian can maintain the reduction of diet and body fat content, control blood glucose levels, and suppress the development of complications.

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DISCLOSURE

The authors declare no conflict of interest, except for Nao Kawabata, who received a research grant from the Tanuma Green House Foundation.

Approval of the research protocol: The study protocol was approved by the Jichi Medical University Clinical Research Ethics Committee (No. A16-28). This study was conducted as part of a study on clinical parameters associated with diabetic nephropathy in patients with type 2 diabetes mellitus (SUCCEED).¹²

Informed consent: All the participants gave informed consent.

Registry and the registration no. of the study/trial: The registry was approved by the University Hospital Medical Information Network (UMIN) Clinical Trials Registry on April 17, 2021 (Registration No. UMIN000043955).

Animal studies: N/A.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1 | Relationship between changes after 2 years from the beginning of intervention in the total energy intake or energy-producing nutrients and changes in hemoglobin A1c or body composition.