Randomized Controlled Trial of a New Dietary Education Program to Prevent Type 2 Diabetes in a High-Risk Group of Japanese Male Workers

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OBJECTIVE — The aim of this study was to assess the effectiveness of a new dietary education (NDE) program in reducing plasma glucose (PG) levels in Japanese male workers at high risk for type 2 diabetes through a randomized controlled trial.

RESEARCH DESIGN AND METHODS — We randomly assigned 173 high-risk men (mean age, 55 years) to either the NDE or the control (conventional dietary education) group. Each subject in the NDE group received two individualized interventions especially aimed at reducing total energy intake at dinner by modifying dietary intake. The control group received conventional group counseling. An "overintake/underintake fraction" for total energy intake was used to measure the status of dietary intake. Our hypothesis was that the NDE group would have a 10% decrease in 2-h PG 1 year after the start of the education. Outcome measures were compared with ANCOVA by adjusting for baseline values.

RESULTS — The NDE group had a significantly lower total energy intake at dinner and daily than the control group. The adjusted differences in changes from baseline in the absolute value of the "overintake/underintake fraction" were −15.3% (95% CI −24.6 to −6.0%, $P = 0.002$) for the NDE group and −6.0% (−9.8 to −2.2%, $P = 0.002$) for the control group. The NDE group had a decreased 2-h PG after 1 year, whereas that value was increased in the control group. The adjusted difference in the percent change of 2-h PG was significant (−15.2%, −22.0 to −8.4%, $P < 0.001$).

CONCLUSIONS — The NDE was shown to reduce glucose levels in high-risk subjects for type 2 diabetes.

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The incidence of type 2 diabetes is increasing worldwide, and its prevalence in adults was estimated to rise to 5.4% by 2025 (1). With the change in recent years from the traditional Japanese lifestyle to a western lifestyle, the prevalence of type 2 diabetes has drastically increased with estimates of no fewer than 6,900,000 cases in Japan (2). This disease leads to vascular complications that result in considerable morbidity and premature mortality (3). Type 2 diabetes incurs serious health problems among the Japanese (4). Dietary education at an early stage may play a key role in preventing diabetes. Considering the poor quality of life that can result from diabetes, effective dietary education that would delay or avoid progression to diabetes in those at high risk is clearly important.

Management of diabetes in primary care has been well studied (5–7). In addition, the effects of dietary education as an intervention in high-risk subjects have been the topic of several reports (8–11). Many Japanese male workers tend to eat and drink a great deal late at night, and changing the habit of excess energy intake during this period might reduce the risk for diabetes. For the purpose of attaining and maintaining optimal blood glucose levels and of modifying dietary intake as appropriate for prevention, we developed a new dietary education (NDE) program based on information on an individual's dietary energy intake for breakfast, lunch, and dinner. Information was obtained through use of the semiquantitative food frequency questionnaire that included lists of 65 food items for each meal (FFQW65) (12). Our aim was to assess the effectiveness of the NDE in reducing plasma glucose (PG) levels in Japanese male workers at high risk for type 2 diabetes through a randomized controlled trial and, at the same time, to implement an evidence-based nutritional program.

RESEARCH DESIGN AND METHODS

The randomized controlled study was designed to assess the effectiveness of the NDE in reducing PG to test the hypothesis that subjects participating in the NDE would have a 10% reduction in the 2-h PG level in the 75-g oral glucose tolerance test (2-h PG, primary end point) 1 year after the start of the education (described in Dietary intervention section) compared with a control group that received conventional dietary education. Enrollment and treatment of

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Abbreviations: FFQW65, food frequency questionnaire (65 items); FPG, fasting plasma glucose; ITT, intent to treat; JDS, Japanese Diabetes Society; NDE, new dietary education; PG, plasma glucose; RDA, recommended dietary allowance.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

subjects were conducted in accordance with the Helsinki Declaration, and all study subjects gave written informed consent.

Eligibility and exclusion criteria

Study subjects were male workers at high risk for type 2 diabetes, aged 35–70 years, and living in a metropolitan area of Tokyo, Japan. The Japanese Diabetes Society (JDS) Committee has classified the glycemic state into three categories based on fasting plasma glucose (FPG) and 2-h PG (13). Because the JDS strongly recommended considering patients with 1-h PG values of ≥10 mmol/l as borderline, to capture patients at an early stage for risk of diabetes in addition to those above-described definitions, we treated patients with 1-h PG ≥10 mmol/l as borderline in the present study. Our definition was as follows: normal, FPG <6.1 mmol/l, 2-h PG <7.8 mmol/l, and 1-h PG <10 mmol/l; diabetes, FPG ≥7.0 and/or 2-h PG ≥11.1 mmol/l; and borderline, all remaining values between normal and diabetes. Borderline individuals are considered to be high-risk individuals. Subjects were recruited primarily during an annual health checkup in a health examination center located in the center of Tokyo from February 2000 to January 2001. The examination included anthropometrics, blood pressure measurements, and an oral glucose tolerance test. Eligible subjects were those diagnosed as borderline. Subjects taking hypoglycemic agents, cholesterol-lowering drugs, or antihypertensive drugs were excluded. Furthermore, those who refused to participate in the dietary questionnaire survey were excluded. A total of 173 subjects were then randomly assigned to either the NDE group (86 patients) or the control group (87 patients).

Dietary intervention

Each subject in the NDE group received individualized counseling using a booklet explaining the concepts of the NDE. The policies of the NDE were to provide the subject with information on his actual dietary practices as revealed by the FFQW65, to increase his motivation to improve dietary practices, and to help him to recognize his need for behavior modification. The FFQW65, a self-administered semiquantitative food frequency questionnaire, consists of 65 food items for each meal with colored illustrations showing portion sizes. Relatively high validity (correlation coefficient $r = 0.64$) and reproducibility ($r = 0.76$) for daily energy intake were obtained (12). From the responses to the FFQW65, energy intake for each meal was estimated according to food groups corresponding to the JDS food exchange book (14). Furthermore, latent problems (e.g., too much eating late at night) could be clarified. The counseling aimed to help individuals reduce total energy intake by modifying dietary intake and to adopt habits appropriate for prevention of diabetes. The dietary education program was comprised of two parts. The first part consisted of an individual dietary counseling session 1 month after the baseline health checkup, and the second part was administered by mail 6 months after the health checkup. Dietary counseling was tailored to each subject on the basis of FFQW65 results with a booklet illustrating "recommendations for meals" corresponding to the recommended dietary allowance (RDA) for total energy intake by the JDS. RDA was calculated based on the individual's height, unit kilocalorie (usually 25–30 kcal), which was defined by physical activity level based on occupation, and age. Then, the following "overintake/underintake fraction" was used to measure the individual's status of dietary intake:

$$\left(\frac{\text{Actual total energy intake}}{\text{RDA}} - 1\right) \times 100(\%)$$

Furthermore, to optimize total energy intake in a day, the NDE aimed to reduce total energy intake at late night. Based on the assessment by the FFQW65, the NDE group knew their actual food intake pattern and recognized how it differed from the recommended pattern. This program also aimed to keep protein energy around 15–20%, fat energy around 20–25%, carbohydrate energy around 55–60% of the total energy intake, and to optimize the intake of whole-grain products, vegetables, fruits, low-fat milk, beans, fish, meat, and eggs and maintain the intake of alcohol at an appropriate level. These standards followed the recommendations of the Japanese Diabetes Society (14) and American Diabetes Association (15). The nutritionist encouraged the subject to recognize latent dietary problems and to set his own goals for improvement and attempted to enhance motivation for dietary improvement.

The importance of education in self-management was emphasized in recommendations for the treatment and prevention of diabetes (16). For the second part of the program, the following four items were mailed to each NDE subject accompanied by a letter encouraging the subject to improve his dietary habits: *1*) self-administered checklist consisting of 10 items that assessed dietary intake; 2) information related to improving dietary behavior; *3*) examples of menus corresponding to the subject's RDA; and *4*) information to confirm the necessity of blood glucose control. On the other hand, each control group subject was given general oral and written information about results of the health examination and results of the FFQW65 but without a detailed explanation. The control group received only conventional group counseling using a leaflet with general information for prevention of lifestyle-related diseases.

Outcome measures

The primary outcome measure was the percent change from baseline in 2-h PG values 1 year after initiation of dietary education.

The change from baseline in the absolute value of "overintake/underintake fraction" for total energy was used as a secondary outcome measure.

Statistical analyses

Enrolled subjects were randomly assigned to the NDE group or the control group by the study nurse with the use of a randomization list (random permutated blocks with length 4). This process was blinded to other staff members as well as to the subjects. The sample size needed for the study was determined based on information to detect the difference in primary end point with a significance level of 5% and power of 90%. Subjects who withdrew from the study and for whom there were no data on outcome measures were excluded from the main analysis. Difference between groups for baseline characteristics of the subjects who completed the trial were assessed by the Student's *t* test and Wilcoxon's rank-sum test. Outcome measures were compared using ANCOVA by adjusting for baseline values. The Spearman's correlation coefficient was used for examining the rela-

Table 1—*Baseline characteristics of the subjects who completed the 1-year follow-up*

Parameters	NDE group	Control group
n	79	77
Age (year)	55.2 ± 7.4	54.9 ± 6.7
Body mass index	24.5 ± 3.0	24.2 ± 2.7
PG (mmol/l)		
FPG*	**6.1 ± 0.55**	**5.5 ± 0.55**
1 h after oral glucose challenge	10.7 ± 1.8	10.6 ± 1.6
2 h after oral glucose challenge†	**8.2 ± 1.5**	**7.3 ± 1.7**
Serum lipids (mg/dl)		
Total cholesterol	201.3 ± 32.0	199.5 ± 37.0
HDL cholesterol	52.2 ± 12.2	52.8 ± 15.2
Triglycerides	128.6 ± 64.0	127.1 ± 71.1
Liver function (IU/l)		
Alanine aminotransferase	25.9 ± 7.8	24.0 ± 7.7
Aspartate aminotransferase	31.7 ± 19.9	26.9 ± 14.3
Blood pressure (mmHG)		
Systolic	122.3 ± 14.4	121.1 ± 14.3
Diastolic	77.4 ± 10.2	76.4 ± 10.8
Absolute value of the "overintake/underintake fraction" for total energy intake (%)		
Breakfast	25.4 ± 16.4	23.6 ± 12.9
Lunch	13.8 ± 9.3	12.8 ± 11.6
Dinner	60.5 ± 33.6	62.0 ± 37.1
Daily	21.6 ± 15.0	19.9 ± 14.9
Smoking status (%)		
Yes	22 (28)	30 (39)
No	57 (72)	47 (61)

Data are means ± SD and *n* (%). *$P < 0.05$; †$P < 0.01$ for the comparison with the NDE group by two-tailed Wilcoxon's rank-sum test. Data in bold are statistically significant.

tionship between the percent changes in glucose values (fasting, 1-h PG, and 2-h PG) and the change in the absolute value of the "overintake/underintake fraction" by the NDE group and control group.

Because the subjects who dropped out before the end of the 1-year intervention period were not included in the main analysis, an "intent-to-treat" (ITT) approach (17) was used. Specifically, we introduced a binary outcome measure of "reduced/not reduced" that could apply to all randomized subjects, where reduction was defined as "percent change of glucose level >10%," and the subjects without data on the outcome measure were assigned to "not reduced." Then, for each of the glucose values, the odds ratio (crude and adjusted for baseline value) of reduction in the NDE group compared with the control group was estimated by logistic regression models for the subjects used in the main analysis and for all randomized subjects. Incidence of type 2 diabetes during the first year of intervention adjusted for the baseline 2-h PG value was also examined for ITT.

All tests for significance were two-sided with a 5% significance level. All statistical analyses were performed using SAS version 8.12 for Windows (SAS Institute, Cary, NC).

RESULTS — Of the 173 randomized subjects (86 NDE group, 87 control group), 156 (90.2%) completed the 1-year follow-up, and their data were analyzed. Of the remaining 17 subjects, 1 changed his job (NDE group), 5 retired (1, NDE group; 4, control group), 1 canceled his follow-up checkup for financial reasons (control group), and 10 could not be located (6, NDE group; 4, control group). All subjects were asked to complete the FFQW65 before the health checkup, and all subjects cooperated.

The baseline characteristics of NDE and control group subjects who completed the 1-year follow-up are presented in Table 1. At baseline, characteristics did not differ statistically between groups except for FPG ($P < 0.05$) and 2-h PG ($P < 0.01$).

For dietary intake, as shown in Table 2, the adjusted difference in the change from baseline in the absolute value of "overintake/underintake fraction" for total energy intake was significant for dinner (−15.3%, 95% CI −24.6 to −6.0%, $P = 0.002$) and daily (−6.0%, −9.8 to −2.2%, $P = 0.002$). The Spearman correlation coefficient between the percent change in 2-h PG and the change from baseline in the absolute value of the "overintake/underintake fraction" was significant at dinner in the NDE group ($r = 0.36$, $P = 0.001$).

Although the baseline level of 2-h PG was significantly different between the two groups, the adjusted difference in the percent change of 2-h PG was also significantly different (−15.2%, 95% CI −22.0 to −8.4%, $P < 0.001$) (Table 2, Fig. 1).

As described above, the 17 withdrawn subjects were excluded from the main analysis. Therefore, to check their potential influence on trial results, we conducted ITT analysis (17). The crude and adjusted odds ratios of reduction in the NDE group compared with the control group and their 95% CI estimated using logistic regression models were similar; only the difference in the 2-h PG was statistically significant. The proportion of subjects showing significant reduction in the main analysis in the NDE group for 2-h PG was 48% (38 of 79) vs. 16% (12 of 77) for the control group. In the analysis that included all randomized subjects, on the other hand, the proportion of subjects showing reduction in the NDE group was 44% (38 of 86) vs. 14% (12 of 87) in the control group. Adjusted odds ratio was 4.1 (95% CI 1.9–9.0, $P < 0.001$) in the main analysis and 5.0 (2.4–10.8, $P < 0.001$) in the analysis for all randomized subjects. These results did not exhibit any statistical evidence of bias due to exclusion of the withdrawn subjects.

CONCLUSIONS — This study provides evidence that an increase in 2-h PG can be prevented by an individualized counseling and diabetes education program using the FFQW65 for male workers at high risk for type 2 diabetes. The 2-h PG was reduced by ~15% (adjusted) compared with the control group. The ef-

Table 2—*Percent changes in 2-h PG and changes from baseline in the absolute value of "overintake/underintake fraction" for total energy intake 1 year after initiation of dietary education in the NDE group and the control group*

Variable	NDE group	Control group	Adjusted* difference between the groups: Mean	95% CI	Two-tailed *P* value
n	79	77			
Percent changes in plasma glucose (%)					
Fasting	−0.5 ± 0.9	2.2 ± 0.9	−1.8	−4.2 to 0.6	0.153
1-h PG	−5.2 ± 2.6	−3.3 ± 2.3	−3.7	−9.9 to 2.5	0.242
2-h PG	−8.2 ± 1.9	11.2 ± 3.0	−15.2	−8.4 to −22.0	<0.001
Change from baseline in the absolute value of "overintake/underintake fraction" for total energy intake (%)					
Breakfast	0.4 ± 1.5	−2.1 ± 0.9	2.6	−0.7 to 5.8	0.126
Lunch	0.4 ± 1.1	1.0 ± 1.2	−0.5	−3.8 to 2.7	0.746
Dinner	−3.0 ± 4.1	11.7 ± 3.7	−15.3	−24.6 to −6.0	0.002
Daily	−1.8 ± 1.5	4.0 ± 1.4	−6.0	−9.8 to −2.2	0.002

Data are mean ± SD unless otherwise indicated. *Adjusted for baseline value by ANCOVA.

fect was confirmed by analysis according to the ITT principle (17), even though some NDE group subjects did not follow dietary recommendations.

To prevent diabetes, early detection of risk and care to maintain normal PG levels might be effective. Improvement in lifestyle relative to diet and exercise (8–10) or lifestyle and drugs (11) plays an important role. Studies in China (8), Finland (9), New Zealand (10), and the U.S. (11) provide evidence that changes in lifestyle, including dietary intake, can be effective in preventing diabetes. In the Chinese study (8), an attempt to determine whether a change in diet or a change in exercise habits was the more effective showed no difference in outcome between the two interventions. In the Finnish study (9), they did not separate the effects by diet and exercise but assessed changes in lifestyle that were as extensive as possible for each subject. In the New Zealand study (10), the effects on body weight and glucose tolerance of a 1-year intervention for reducing dietary fat were examined. In the U.S. study (11), the effectiveness of a lifestyle intervention and treatment with metformin for subjects at high risk for diabetes was discussed. In our intervention study, we concentrated on assessing the effect of NDE on glucose tolerance based on a randomized controlled trial. Our results were similar to those of the above-mentioned studies. Specifically, as for 1-year changes in 2-h PG from baseline, there was an ~6% reduction (baseline and change in 1 year were 8.8 and −0.83 mmol/l for the intervention group and 8.8 and −0.28 mmol/l for the control group, respectively) in Finland, a 9% reduction (baseline and change in 1 year were 7.5 and 0.01 mmol/l for the intervention group and 7.9 and 0.74 mmol/l for the control group, respectively) in New Zealand, an ~27% reduction in China (baseline and change in 6 year were 9.03 and 3.96 mmol/l for the dietary intervention group and 9.03 and 1.48 mmol/l for the control group, respectively), and a 15.2% reduction (adjusted, Table 2) in our study. Because our study was designed to verify the primary end point of 2-h PG, the fact that the difference in the incidence of diabetes between the two groups was not significant is not of concern. Also, the time frame of 1 year was very short to show such a difference in incidence.

To prevent the continuation of the recent increase in the prevalence of diabetes

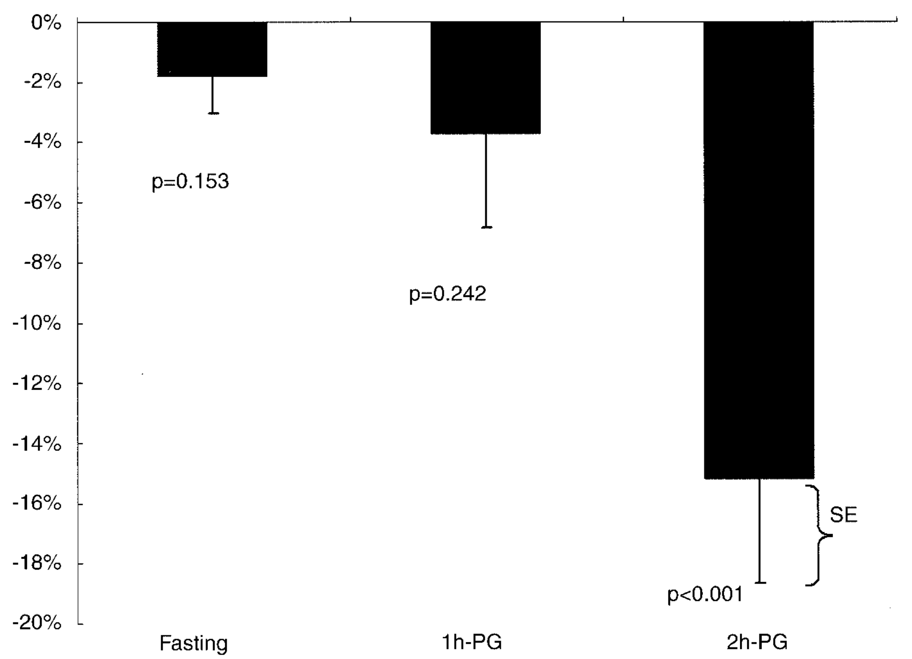

Figure 1—*Difference in the mean percent changes from baseline in 2-h PG after 1 year between the NDE group and the conventional dietary education (control) group (adjusted for baseline value).*

(2,13), an effective dietary education measure is warranted. Our study was directed toward assessing the effectiveness of the NDE in reducing PG levels in high-risk subjects for type 2 diabetes among Japanese men by correcting total energy intake through adequate instruction. Compared with the control group, total energy intake both at dinner and daily was relatively lower in the NDE group, although the magnitude of these reductions was not significant. Furthermore, dietary changes were correlated with changes in PG in the NDE group. These results indicated the effect of the NDE in reducing the blood glucose level. To optimize total energy intake each day, the NDE aimed to reduce total energy intake late at night. The intake of energy during the day rather than at night improves insulin resistance, resulting in a reduced blood glucose level. The rationale for this can be explained by the study of Lindsay et al. (18), which indicated that when a fasting blood glucose level reaches 7.8 mmol/l or more, the total amount of insulin secretion after a meal begins to decrease.

One may wonder why only two education events could result in a reduction of 2-h PG. Three reasons can be cited. Namely, the subject was given specific information about his actual dietary habits through use of the FFQW65 and could manage to maintain the current level rather than experience an increase as shown in the control group. Furthermore, the program focused on increasing motivation and encouraging the subject to recognize the need for behavior modification through his own efforts. The rader chart of "ratio of actual-to-RDA" for total energy intake by meals and illustrations of portions might have helped the subjects modify their food intake pattern through recognition of their own dietary problems. In fact, many subjects successfully managed to maintain a balance of total energy intake. For instance, energy intake for oil and alcohol was decreased in the NDE group ($P > 0.05$), and those differences were significantly correlated to the percent change of 2-h PG. Spearman correlation coefficients for oil were as follows: dinner, $r = 0.33$, $P = 0.003$ and daily $r = 0.23$, $P = 0.044$. For alcohol daily, the Spearman correlation coefficient was $r = 0.28$, $P = 0.013$. These provide evidence for the effect of the NDE on dietary intake.

Our study has a limitation in that the subjects were all Japanese male workers. The value of this dietary intervention for specific populations or in countries other than Japan is likely but unknown, especially when different risk factors for diabetes may exist in various areas. However, the strategy of our program, particularly the focus on maintaining balance in dietary intake among the three meals daily, could reasonably be extended to countries other than Japan. Furthermore, although our definition of the high-risk group was less stringent than that of the IGT because we used 2-h PG as the outcome measure and examined the effect of the NDE by a randomized controlled trial, the same result may apply using the IGT definition. The effect of the interventions was assessed after 1 year because an earlier assessment could be biased as a result of changes made only because subjects were conscious of being studied. As for the influence of other risk factors such as smoking, we did an additional analysis that included smoking as a covariate. The distribution of smokers at baseline was not different between the NDE and control groups. However, the adjusted difference in the percent change of 2-h PG was still significant (−14.9%, 95% CI −8.1 to −21.7%, $P < 0.001$). However, three subjects stopped smoking within 1 year in the NDE group. Therefore, we excluded them and confirmed the result. The adjusted difference was almost concordant (−14.9%, −8.0 to −21.8%, $P < 0.001$). Although our study design was a randomized controlled trial, we cannot deny the influence of unknown factors, such as physical exercise.

In conclusion, the NDE can reduce glucose levels by effecting changes in the total energy intake of subjects at high risk for type 2 diabetes. The NDE with the strategy for maintenance of balance in dietary intake among the three daily meals and using the FFQW65 may play an important role in the prevention of diabetes for high-risk groups in the early stages.

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