Original Article

Short-term effectiveness of an individual counseling program for impaired fasting glucose and mild type 2 diabetes in Japan: a multi-center randomized control trial

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The aim of this study is to evaluate the short-term effectiveness of our individual-based counseling program and tools among individuals in ordinary Japanese communities with impaired fasting glucose (IFG) and mild type 2 diabetes. A total of 233 eligible participants (age 30-69 years) in 14 local study centers were randomly assigned to an intervention group (INT, N=119) and a control group (CONT, N=114). During the 4-month intervention, the INT received 4 individual counseling sessions and one reminder on life style modification. The CONT received only an explanation of blood test results and general information on diabetes. Baseline characteristics did not differ significantly between groups. Percentages of participants with desirable changes in glycemic level and weight were significantly higher in INT than CONT: fasting plasma glucose reduction of more than 10 mg/dL (39% in INT vs. 26% in CONT, p=0.045), hemoglobinA_1c reduction greater than 0.3% (14% vs. 4%, p=0.01), and weight reduction of more than 4 kg (13% vs. 4%, p=0.025). Decreases in total energy intake and percentage of heavy alcohol drinkers (more than 46 g/day) were significantly greater in INT than CONT. The increase in percentages of participants who engaged in leisure time physical activity more than 12 times per month was significantly greater in INT than CONT. Our program resulted in life style modification and glycemic level improvement in the short-term among individuals with IFG and mild type 2 diabetes. Results indicated that the program was sufficiently effective and feasible for implementation in ordinary communities.

Key Words: randomized controlled trial, health education, program evaluation, hyperglycemia, public health

INTRODUCTION

The number of individuals with diabetes worldwide was predicted to dramatically increase from the 135 million cases in 1995 to 300 million by 2025.[1] In Japan, the National Survey of Diabetes, which was conducted in 1997 and 2002 by the Ministry of Health, Labor and Welfare, showed that persons over 20 years of age with a hemoglobinA_1c (HbA_1c) value of more than 5.6% or who were being treated for diabetes increased from 13.7 million at the first survey to 16.2 million at the second survey and that the prevalence increased with age.[2-3] Recently the Japanese population has been aging so rapidly[4] that additional increases in diabetic patients and in the micro- and macro-complications of diabetes are anticipated.

Large long-term studies have demonstrated that in a research setting intensive instruction and programs on life style modifications for individuals with impaired glucose tolerance could prevent or delay development of type 2 diabetes.[5-7] However, the development of practical programs suitable for the existing health care system or life styles within individual communities is inadequate, and the effectiveness of such programs on a public health basis is not sufficiently clear.[8] We newly developed an individual-based counseling program and tools for persons with impaired fasting glucose (IFG) and mild type 2 diabetes that utilized as much as possible existing human or material resources in Japanese communities, such as nurses or dieticians at the front line of public health. To determine the effectiveness of our program on a short-term basis, we conducted a multi-center randomized controlled trial in 14 communities and companies.

MATERIALS AND METHODS

Recruitment of participants

In 1998 we sent the study protocol to approximately 200

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Manuscript received 5 July 2006. Initial review completed 21 June 2006. Revision accepted 29 December 2006.

public health centers of local governments or health management sections of private companies around the Kinki area in midwestern Japan. Of those, 21 centers expressed interest in participating. We met with those centers to provide details of the study and to standardize intervention methods. Finally, 14 centers became local study centers (5 from local governments, 9 from private companies).

In Japan, local governments or private companies perform annual health check-ups by law on everyone 40 years of age or older. The examination usually includes measurement of plasma glucose, with the approximate time after the last meal recorded. Measurement of HbA_1c depends on the policy of each local government or company. Data from these annual health check-ups were used to screen for eligible study participants.

Participants were recruited by local study centers on the basis of results of fasting plasma glucose (FPG), post-prandial glucose (PPG) or HbA_1c from these annual health check-ups for the past 2 years. Since plasma glucose was not always measured after an overnight fast at these annual check-ups, inclusion criteria included subjects who had either post-prandial or overnight fast measurements. The inclusion criteria for overnight FPG was based on the diagnostic criteria for diabetes (normal: <110 mg/dL, diabetes: >= 140) established by the World Health Organization (WHO) in 1985.[9] For classification of PPG, we referred to the manual for the annual health check-ups implemented by law in Japan (normal: <140 mg/dL, requiring counseling for diabetes: between 140 and 200, requiring treatment for diabetes: >= 200).[10] Plasma glucose, especially PPG, fluctuates widely. Therefore, we formulated inclusion criteria using data from each participant's health check-ups for the past two years and added a margin of 10-20 mg/dL to the WHO criteria and classifications from the manual to ensure enrollment sufficient for the purpose. Furthermore, with regard to PPG, subjects were separated according to whether tested within 3 hours or after 3 hours from the last meal. Because no clear criteria existed as to the relationship of HbA_1c to diabetic status, we formulated our own criteria. Variations in HbA_1c values between laboratories in Japan were found to be large in 1997 (coefficient of variation in normal range of HbA_1c was about 8 %). [11] The upper limit for the normal range of HbA1c also varied widely (66% of laboratories defined it to be from 5.8 to 6.0%).[11] We aimed to recruit subjects around the upper limit of the normal range and therefore established the margin at approximately 10% of the upper limit.

Inclusion and exclusion criteria

Subjects must be males or females from 30 to 69 years of age. Results of one health check-up in the past 2 years should include one of the following: 1) FPG between 110 and 160 mg/dL, 2) PPG between 150 and 210 mg/dL within 3 hours after a meal, 3) PPG between 130 and 210 mg/dL more than 3 hours after a meal or 4) HbA_1c between 5.6 and 6.7%. Otherwise, inclusion criteria could be satisfied by any of the following results at two consecutive yearly health check-ups: 1) FPG between 100 and 109 mg/dL, 2) PPG between 140 and 149 mg/dL within 3 hours after meals, 3) PPG between 120 and 129 mg/dL more than 3 hours after meals, or 4) HbA_1c between 5.4 and 5.5%.

Exclusion criteria were based on the following: being treated for diabetes; having a history of hormonal diseases, renal function failure, hepatic disease, pancreatic disease, anemia, angina, myocardial infarction, stroke, or post-gastrectomy; and being considered an inappropriate study subject as judged by the doctor at the administrative office. Participants with FPG of more than 200 mg/dL during the study were asked to discontinue participation and to seek further medical care.

Data collection

Individuals who satisfied the inclusion criteria were invited to each local center. After nurses explained the study purposes and protocol, those who wanted to participate signed an informed consent form.

Participants received two assessments, before and after the intervention, including blood tests after an overnight fast and assessment of diet and physical activity. Blood tests were also performed at the 2nd month of the 4-month intervention. Nurses took blood samples after an overnight fast, performed anthropometric measurements and recorded the subject's medications and disease histories. Blood tests included FPG, HbA_1c, total cholesterol, HDL cholesterol and triglycerides. Samples were sent to the same laboratory. Measurement methods were uniform during the entire study period. In the baseline assessment before the intervention, participants who met any exclusion criteria were then excluded.

Nurses or dieticians had received training to standardize administration of the dietary survey, and conducted a dietary survey by a quantitative food frequency questionnaire (FFQ). In the FFQ, 91 food items were included, and frequency of intake was recorded according to servings of each item per week or per month. In addition, the amount of each food item per serving was quantified with food models to calculate total energy intake or nutrients. Responses in the FFQ were calculated by computer software specific for this FFQ, based on the standard tables of food composition in Japan.[12-14]

Participants filled out self-reporting questionnaires that included information on parental diabetes; tobacco use; frequency, time and kind of leisure time physical activity; or counts on a pedometer for 2 weekdays.

Randomization and design

In total, 233 eligible individuals were randomly assigned to an intervention group (INT) or a control group (CONT) stratified by centers (Fig 1). The duration of the intervention was 4 months. The INT received individual counseling sessions 4 times (at 0, 1, 2, 4 months) and 1 reminder on life style modification (3rd month). The CONT received general information about diabetes and results of their blood tests at baseline and at the 2nd and 4th months. For ethical reasons, we arranged for the CONT subjects who were interested to receive the same program after the 4-month intervention. The ethical committee of the Shiga University of Medical Science approved the study protocol.

Intervention program

Our goal for the dietary intervention was to correct any

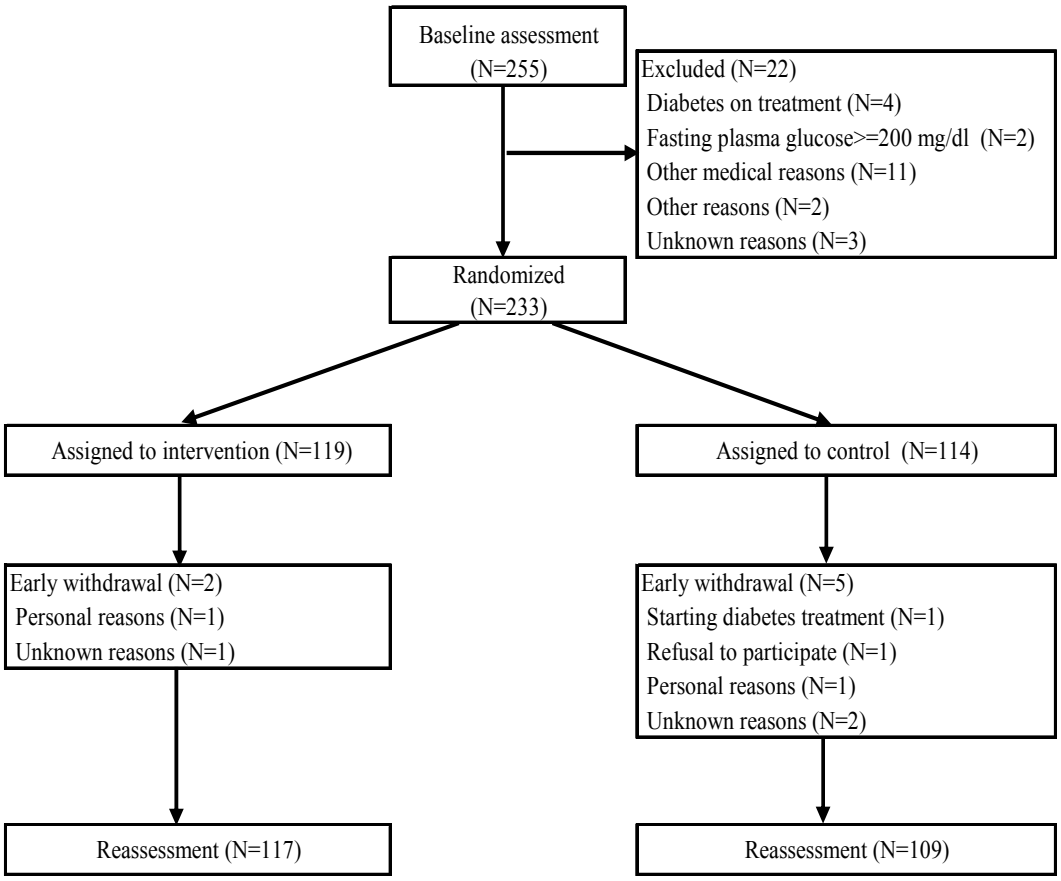

Figure 1. Flow chart of participants

imbalance in macro-nutrients and reduce total energy intake among participants with a body mass index (BMI) of more than 22 kg/m^2. Recommendations for macro-nutrients were based on the Japan Diabetes Society (JDS) guidelines for diabetic patients.[15] These included carbohydrate intake comprising 55-60% of total energy intake and fat intake comprising less than 25% of intake. We also defined the appropriate intake of several food groups as follows: vegetables, more than 300 g/day; fruit, approximately 80 kcal/day; milk, approximately 200 ml/day; alcohol, less than 23 g/day (corresponding to approximately 1 conventional Japanese unit of alcohol, "1gou"); and confectioneries (including soft drinks), less than 100 kcal/day.

Our goal for physical activity was to encourage sedentary participants to increase basal physical activity. We recommended a gradual increase in physical activity in daily life rather than in leisure time, mainly through walking more. The final goal was set at a total pedometer count of more than 10,000 per day. In subjects having sufficient motivation and spare time, we recommended low intensity exercise, such as walking or resistance exercise, three or four times per week for periods of 20-30 minutes.

Based on the JDS guidelines for weight,[15] we recommended that subjects achieve a BMI of 22 kg/m^2 and aimed at weight reduction of 1 kg per month among participants with a BMI greater than 22 kg/m^2.

Our program aimed at motivating each individual to correct imbalances in life style voluntarily by providing practical advice. On the basis of our recommendations related to diet, physical activity and obesity, nurses or dieticians abstracted practical problems related to the life style of each participant from the baseline assessment before the first session. At the first session (0 month), they discussed these issues with the INT participant and allowed him to voluntarily decide on personal goals. Typical examples of goals were "replacing high fat meat with fish or soy products", "not eating noodles with rice", "keeping pedometer counts 10,000 or more per day" or "walking past 1 bus stop when taking a bus in commuting". They gave the participant appropriate self-report forms for his personal goals such as a recording sheet of food intake or pedometer counts. At the second session (1st month), the nurse or dietician checked the self-report forms to determine if personal goals had been achieved. If so, the participant was advised to continue to maintain the goals and, if possible, set further goals. Conversely, when difficulties in reaching goals became evident, goals were again discussed so that a decision could be made to continue with or change current goals. At the third (2nd month) and fourth sessions (4th month), similar procedures were followed.

We prepared a series of support tools specific for this program that included a pamphlet, a series of quizzes, 15 pages of explanatory material, including diagrams or illustrations as teaching aids, a summary sheet of data or of the interview and several self-report forms on diet or physical activity. We also provided each center with pedometers, a self-monitoring kit for blood glucose and

photographs of dishes commonly consumed with energy and nutrient content.

Sample size calculation and statistical analysis

A sample size of more than 84 participants per group was estimated to be necessary, assuming an absolute reduction in FPG of 5 mg/dL (standard deviation of 10 mg/dL), a two-sided alpha of 0.05 and a power of 0.9.

Percentages of participants who achieved desirable goals in FPG, HbA_1c and weight were compared between groups by the chi square test on the basis of the intention-to-treat principle of analysis. Wilcoxon rank sum test and the two-sample McNemar test were used to compare changes in continuous and categorical variables between groups, respectively.[16-17] Wilcoxon signed rank sum test and McNemar test were also used to compare continuous and categorical variables, respectively, between pre- and post-intervention within each group.

Current alcohol drinkers were defined as those who consumed alcohol more than once a week. Current cigarette smokers were those who smoked more than 1 cigarette a day. Leisure time physical activity meant regular physical activity more than once a month. We excluded participants with missing data from the analysis except in the intention-to-treat analysis. Total energy intake, excluding alcohol, was adopted to calculate percentages of nutrients in total energy.

RESULTS

Baseline characteristics did not differ significantly between the INT and CONT groups (Table 1). At the baseline assessment before the intervention, percentages of

Table 1. Baseline characteristics (mean ± one standard deviation) of participants by assigned groups, 1999, Japan

	Intervention	Control
N	119	114
Male/Female (no.)	84 / 35	82 / 32
Age (years)	50.7 ± 8.7	51.1 ± 7.9
Parental diabetes (%)	29	29
Weight (kg)	64.6 ± 9.7	64.3 ± 10.1
Body mass index (kg/m^2)	24.5 ± 3.1	23.9 ± 2.9
Fasting plasma glucose (mg/dL)*	122 ± 19	122 ± 19
HemoglobinA_{1c} (%)	5.6 ± 0.7	5.5 ± 0.6
Serum total cholesterol (mg/dL)†	218 ± 32	217 ± 33
Serum triglycerides (mg/dL)‡	155 ± 127	141 ± 125
Serum HDL cholesterol (mg/dL)†	54 ± 13	57 ± 15
Systolic blood pressure (mmHg)	134 ± 20	135 ± 19
Diastolic blood pressure (mmHg)	81 ± 12	83 ± 11
Blood pressure lowering medications (%)	8	4
Cholesterol lowering medications (%)	7	14
Total energy intake (kcal/day)	2106 ± 632	2044 ± 546
Total energy intake excluding alcohol (kcal/day)	1954 ± 570	1894 ± 497
Carbohydrate (g/day)	283 ± 87.1	268 ± 68.3
% of total energy intake excluding alcohol	58.2 ± 6.2	57.1 ± 7.9
Protein (g/day)	76.4 ± 23.8	77.2 ± 26.9
% of total energy intake excluding alcohol	15.7 ± 2.5	16.1 ± 2.5
Fat (g/day)	53.9 ± 22.0	54.1 ± 23.8
% of total energy intake excluding alcohol	24.5 ± 5.4	25.3 ± 6.9
Saturated fat (g/day)	14.3 ± 6.2	14.4 ± 8.1
% of total energy intake excluding alcohol	6.5 ± 1.7	6.6 ± 2.4
Monounsaturated fat (g/day)	19.6 ± 8.8	19.7 ± 9.3
% of total energy intake excluding alcohol	8.9 ± 2.4	9.2 ± 3.0
Polyunsaturated fat (g/day)	14.1 ± 5.7	14.1 ± 6.2
% of total energy intake excluding alcohol	6.4 ± 1.6	6.7 ± 2.1
Total dietary fiber (g/day)	10.7 ± 3.9	10.6 ± 4.1
Soluble dietary fiber (g/day)	1.7 ± 0.8	1.6 ± 0.7
Insoluble dietary fiber (g/day)	8.6 ± 3.0	8.6 ± 3.3
Current alcohol drinkers§ (%)	66	68
Current alcohol consumption ≥ 46 g/day (%)	20	18
Alcohol consumption in current alcohol drinkers (g/day)	33.1 ± 29.8	31.5 ± 27.6
Current cigarette smokers‖ (%)	39	40
Pedometer counts (/day)	8677 ± 3602	8837 ± 3991
Pedometer counts (/day) ≥ 10000 (%)	36	37
Leisure time physical activity¶ ≥ 1 time/month (%)	52	54
Leisure time physical activity¶ ≥ 12 times/month (%)	14	17
Leisure time physical activity¶ ≥ 240 minutes/month (%)	39	42
Walking >=1 time/month (%)	20	18
Doing other physical activities ≥ 1 time/month (%)	35	40

Plus-minus values are means ± SD. No significant differences in any baseline characteristics between groups. * To convert values for glucose to millimoles per liter, multiply by 0.056. † To convert values for cholesterol to millimoles per liter, multiply by 0.026. ‡ To convert values for triglycerides to millimoles per liter, multiply by 0.011. § Current alcohol drinkers were those who consumed alcohol more than once a week. ‖ Current cigarette smokers were those who smoked more than 1 cigarette a day. ¶ Leisure time physical activity meant regular physical activity more than once a month.

Table 2. Comparison of changes from the baseline after 4 months intervention in anthropometry and clinical parameters by assigned groups, 1999, Japan

	Intervention	Control	*p* value
Intention to treat analysis			
N	119	114	
Weight loss ≥ 4.0 kg (%)	13	4	0.025
Fasting plasma glucose reduction ≥ 10 mg/dL (%)	39	26	0.045
HemoglobinA_{1c} reduction ≥ 0.3% (%)	14	4	0.01
On treatment analysis			
N*	117	109	
Weight (kg)	-1.6 ± 2.0‖	-1.0 ± 1.9‖	0.002
Body mass index (kg/m^2)	-0.6 ± 0.7‖	-0.4 ± 0.7‖	0.002
Fasting plasma glucose (mg/dL)†	-7 ± 13‖	-5 ± 12‖	0.067
HemoglobinA_{1c} (%)	0 ± 0.4	0.1 ± 0.2‖	0.042
Serum total cholesterol (mg/dL)‡	-10 ± 26‖	-8 ± 23‖	0.54
Serum triglycerides (mg/dL)§	-1 ± 123	-3 ± 126	0.36
Serum HDL-cholesterol (mg/dL)‡	-1 ± 9	-1 ± 10‖	0.54
Systolic blood pressure (mmHg)	-7 ± 15‖	-7 ± 14‖	0.88
Diastolic blood pressure (mmHg)	-3 ± 9‖	-4 ± 8‖	0.56

Plus-minus values are means ± SD. * Number of available data was limited in following variables, intervention (fasting plasma glucose: 114, hemoglobinA_{1c}:116, serum triglycerides: 113), control (fasting plasma glucose: 105, serum triglycerides: 105). † To convert values for glucose to millimoles per liter, multiply by 0.056. ‡ To convert values for cholesterol to millimoles per liter, multiply by 0.026. § To convert values for triglycerides to millimoles per liter, multiply by 0.011. ‖ p value < 0.05 in comparing continuous variables between pre- and post-intervention within groups by Wilcoxon signed rank sum test.

participants according to FPG levels were as follows: FPG of 140 mg/dL or more (16%); FPG between 126 and 139 mg/dL (23%); FPG between 110 and 125 mg/dL (30%); FPG between 100 and 109 mg/dL (21%); FPG of 99 mg/dL or less (9%) Thirty-six percent of participants had a BMI of more than 25 kg/m^2. Early withdrawal was 2% in INT and 4% in CONT (Fig 1).

After the 4-month intervention, a significantly higher percentage of INT subjects than CONT subjects achieved desirable goals for FPG, HbA_1c and weight: FPG reduction of more than 10 mg/dL (39% in INT vs. 26% in CONT, p=0.045), HbA_1c reduction of more than 0.3% (14% vs. 4%, p=0.01), and weight reduction of more than 4 kg (13% vs. 4%, p=0.025) (Table 2). Mean reductions of HbA_1c, weight and BMI were also significantly greater in INT than CONT, and reduction in mean FPG was of borderline statistical significance.

The decrease in energy, carbohydrate and saturated fat intake was significantly greater in INT compared with CONT (Table 3), but changes in percentages of any nutrient within total energy intake, excluding alcohol, did not differ significantly between groups nor did changes between pre- and post-intervention within groups. The percentage of heavy alcohol drinkers (more than 46 g/day) decreased significantly greater in INT than CONT. The mean amount of alcohol consumed among current alcohol drinkers (consuming alcohol either at baseline assessment or reassessment) decreased 6.3 g/day in INT. Decrease was negligible in CONT.

In comparison with CONT, the percentages of participants who engaged in leisure time physical activity more than 12 times per month and walking more than once a month as a leisure time physical activity increased significantly. Although not significant, the increase in the percentages of INT who engaged in leisure time physical activity more than once per month and more than 240 minutes per month was greater compared with CONT. The increase in pedometer counts was approximately twice that in INT than in CONT, but without significance.

DISCUSSION

Our intervention program for life style modification improved the glycemic level after 4 months among participants with IFG and mild type 2 diabetes. Only a few intervention studies with a similar setting have been performed. Racette *et al*. conducted a non-randomized controlled trial of subjects with IFG or mild type 2 diabetes; results for FPG were similar between groups at the 4th month of the 12-month intervention (FPG decrease; intervention: 7 mg/dL, control: 5 mg/dL).[18] In a randomized controlled trial lasting for 5 months in subjects with IFG or mild type 2 diabetes, Takata *et al*. found that 6 times as many participants in the intervention group as the control group had a HbA_1c improvement greater than 0.2%.[19] This result was similar with that of HbA_1c in our study. However, these results cannot be easily compared with ours because of the smaller sample size in the study by Racette *et al*. and the difference in content of the intervention between our investigation and that of Takata *et al*.

Total energy intake and the absolute amount of intake of each macro-nutrient decreased, but the percentages of nutrients within the total energy intake, excluding alcohol, did not change in either group. Thus, our program led participants to decrease total energy intake without altering the nutrient balance. Nutrient composition among participants was similar to that of subjects of the same age as reported by the National Nutrition Survey of Japan at the same time as our study,[20] and mean BMI in the INT was approximately 1 kg/m^2 higher. Therefore, we do not believe that the nutrient balance among participants was poor, but that a decrease in total energy intake was needed for weight reduction.

Weight reduction was 2.5% from baseline in INT. Although this is smaller than that reported in previous large

Table 3. Comparison of changes from the baseline after 4 months intervention in nutrition and physical activity by assigned groups, 1999, Japan

	Intervention	Control	*p* value
N*	117	109	
Total energy intake (kcal/day)	-191 ± 460¶	-34 ± 434	0.008
Total energy intake excluding alcohol (kcal/day)	-158 ± 424¶	-35 ± 388	0.026
Carbohydrate (g/day)	-24.6 ± 67.2¶	-1.2 ± 52.5	0.012
% of total energy intake excluding alcohol	-0.1 ± 5.5	0.7 ± 6.4	0.31
Protein (g/day)	-4.5 ± 20.1¶	-2.9 ± 22.9	0.53
% of total energy intake excluding alcohol	0.2 ± 2.4	-0.3 ± 2.4	0.10
Fat (g/day)	-4.6 ± 15.4¶	-2.4 ± 20.2	0.20
% of total energy intake excluding alcohol	-0.2 ± 4.5	-0.7 ± 5.1	0.43
Saturated fat (g/day)	-1.4 ± 4.7¶	-0.6 ± 8.3	0.05
% of total energy intake excluding alcohol	-0.2 ± 1.5	-0.1 ± 2.3	0.48
Monounsaturated fat (g/day)	-1.9 ± 6.1¶	-1.0 ± 7.7	0.23
% of total energy intake excluding alcohol	-0.2 ± 1.9	-0.3 ± 2.1	0.53
Polyunsaturated fat (g/day)	-1.0 ± 4.2¶	-0.7 ± 4.7	0.71
% of total energy intake excluding alcohol	0.1 ± 1.5	-0.2 ± 1.4	0.07
Total dietary fiber (g/day)	-0.4 ± 3.6	-0.7 ± 3.4	0.49
Soluble dietary fiber (g/day)	-0.2 ± 0.7	-0.2 ± 0.7	0.88
Insoluble dietary fiber (g/day)	-0.1 ± 2.9	-0.4 ± 2.8	0.38
Current alcohol drinkers† (%)	5	4	0.76
Current alcohol consumption ≥ 46 g/day (%)	-10#	0	0.037
Alcohol consumption in current alcohol drinkers‡ (g/day)	-6.3 ± 16.7¶	0.2 ± 21.6	0.13
Current cigarette smokers § (%)	3	0	0.11
Pedometer counts (/day)	1135 ± 5451	489 ± 2836	0.63
Pedometer counts (/day) ≥ 10000 (%)	6	5	0.97
Leisure time physical activity ≥ 1 time/month ‖ (%)	15#	7	0.24
Leisure time physical activity ≥ 12 times/month ‖ (%)	20#	6	0.022
Leisure time physical activity ≥ 240 minutes/month ‖ (%)	15#	7	0.27
Walking ≥ 1time/month (%)	24#	9#	0.006
Doing other physical activities ≥ 1time/month (%)	0	-1	0.88

Plus-minus values are means ± SD. * In assessment of diet after intervention, 4 participants (intervention: 2, control: 2) could not participate. Number of available data for nutrition (total energy intake, nutrients, dietary fiber, alcohol) was as follows, intervention: 115, control: 107. Regarding the pedometer counts after intervention, 25 participants (intervention: 10, control: 15) did not do pedometer counts. Number of available data on pedometer counts was as follows, intervention: 107, control: 94. † Current alcohol drinkers were those who consumed alcohol more than once a week. ‡ Change in alcohol consumption was calculated among individuals who were current alcohol drinkers at least either at baseline assessment or reassessment. Number of available data was 86 in the intervention group, 83 in the control group. § Current cigarette smokers were those who smoked more than 1 cigarette per day. ‖ Leisure time physical activity meant regular physical activity more than once a month. ¶ p value < 0.05 in comparing continuous variables between pre- and post-intervention within groups by Wilcoxon signed rank sum test. # p value < 0.05 in comparing categorical variables between pre- and post-intervention within groups by McNemar test.

studies,[5-6] we feel that it is still reasonable because approximately 60% of participants were not overweight according to the WHO classification of obesity and because the dietary and exercise component of our intervention program was probably less stringent than in the other programs. Our results did show that moderate life style changes could result in weight reduction even among ethnic groups with a relatively low BMI, such as the Japanese. Recently, WHO recommended that a lower cut-off point for Asian people for public health action should be added to the present WHO classifications of BMI, considering the ethnic variety in the effects of obesity on type 2 diabetes or cardiovascular diseases.[21] It recommended a BMI of 23 kg/m^2 as the cut-off point of overweight for Asians overall, and also proposed that each country should identify the most useful public health action point based on reliable data from that country. We consider that counseling on weight reduction should be given to Japanese people with both a BMI of more than 24 kg/m^2 and any other risk factors for cardiovascular diseases.

Our program induced participants to begin walking and to increase physical activity. Walking is easy to do anytime and anywhere, and is suitable for most people as a leisure time activity or a physical activity in daily living. This study showed that walking is an effective and feasible way to increase physical activity.

Effect of alcohol intake on the risk of the development of type 2 diabetes is not well known .[22-23] In this study, the number of heavy alcohol drinkers decreased in INT, which might mean that reducing alcohol consumption is directly or indirectly related to improvement of the glycemic level.

This study has several limitations. First, our study was short-term, so it could not be determined if effectiveness and feasibility could be sustained over the long-term. Second, the instructions given to the INT might have been transmitted to the CONT and motivated the CONT to undertake some life style modifications because participants in both groups belonged to the same community. This might lead to underestimation of the difference between groups in each parameter, but we feel that underestimation was not very great because we did not provide

CONT participants with any systematic advice on diet and physical activity. Third, we did not perform an oral glucose tolerance test (OGTT) for screening or defining end-points, although many studies do use the OGTT and have shown larger differences between groups in 2-hour plasma glucose after glucose load than with FPG.[6,7,24-26] Scientifically OGTT provides more precise information, but performing the OGTT for the present study would not be feasible in most communities because of time and cost constraints. Recently, the American Diabetes Association recommended lowering the lower limit of IFG to FPG of 100 mg/dL.[27] With our screening process, 9% of participants had a baseline FPG of 99 mg/dL or less, but despite this we consider this screening process to be more feasible than use of the OGTT. Fourth, our FFQ was not validated, so the degree of systematic or measurement error in this FFQ is unknown. A large measurement error might lower the statistical power in testing the difference between groups and time points. However, since such errors would occur similarly in both groups in a randomized controlled trial, we do not feel that it is a serious problem in estimating differences between groups.

In conclusion, the present study showed short-term effectiveness and feasibility of our individual-based program in ordinary Japanese communities. The present study included participants with mild type 2 diabetes who do not need medication as well as those with IFG. Since the first step in treatment of both conditions is to modify life style, it seemed reasonable to use the same program and tools for both groups of patients. In addition, only a very small percentage of subjects withdrew from the study, indicating that our program was sufficiently feasible for implementation in the average Japanese community.

It would be possible to implement this program within the present health care system, but it would be difficult to provide it to all persons at risk for type 2 diabetes or with mild type 2 diabetes because of limited human and material resources in public health. We think individual-based programs should be applied to the population at higher risk for type 2 diabetes and with mild type 2 diabetes who do not need medication. For those at milder risk for type 2 diabetes, population-based strategies should be implemented.

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Original Article

Short-term effectiveness of an individual counseling program for impaired fasting glucose and mild type 2 diabetes in Japan: a multi-center randomized control trial

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個人諮詢課程對日本空腹葡萄糖不良及輕微第 2 型糖尿病患者之短期效果：一個多中心隨機控制試驗

本研究目的為評估我們的個人化諮詢課程及工具，對有空腹葡萄糖不良(IFG)及輕微第 2 型糖尿病的一般日本社區個人之短期效果。 在 14 個研究中心中共有 233 名合格的參與者（年齡在 30-69 歲），隨機分派為介入組(INT，N=119)及控制組(CONT，N=114)。四個月的介入期間，INT 接受四次個人諮詢課程及一次的生活型態改變提示。CONT 僅接受一次血糖測試結果的解釋及糖尿病的基本資訊。兩組研究初始的特性沒有顯著差異。參與者血糖值及體重改變符合期望的百分比，INT 顯著的較 CONT 高：空腹血漿葡萄糖降低超過 10 mg/dL(INT 39% vs. CONT 26%，p=0.045)、糖化血色素降低高於 0.3%(14% vs. 4%，p=0.01)、體重降低超過 4 公斤(13% vs. 4%，p=0.025)。總熱量攝取量及重度酒精攝取（一天超過 46 公克）百分比的降低，INT 顯著的高於 CONT。參與者每個月從事休閒活動超過 12 次增加的百分比，INT 顯著高於 CONT。我們的課程可導致 IFG 及第 2 型糖尿病之個人的短期生活型態改變及血糖值改善。結果指出這個課程在一般社區具有可行性，且有足夠效果。

關鍵字：隨機控制試驗、衛生教育、課程評估、高血糖、公共衛生。