Evaluation of a Diabetes Patient Education Program Consisting of a Three-Day Hospitalization and a Six-Month Follow-Up by Telephone Counseling for Mild Type 2 Diabetes and IGT

Hiroshi FUKUDA*¹, Takashi MUTO*¹ and Ryuzo KAWAMORI*²

*¹Dept. of Public Health, School of Medicine, Juntendo University, Tokyo

*²Dept. of Medicine, Metabolism and Endocrinology, School of Medicine, Juntendo University, Tokyo

Abstract

The purpose of this study was to evaluate the efficacy and feasibility of a newly developed diabetes patient education program consisting of a three-day hospitalization and a six-month follow-up by telephone counseling for patients with mild type 2 diabetes or impaired glucose tolerance (IGT) by a randomized controlled trial (RCT) method. Fifty-two patients with mild type 2 diabetes or IGT (HbA1c<8) were randomly assigned to either an intervention group or a control group. The current care was continued for the control group and the new education program was provided in addition to the current care for the intervention group. Changes in weight, blood glucose in a 75g-oral glucose tolerance test (75g-OGTT), and HbA1c were measured in June 1997 as baseline data and again in Dec. 1997. Scores for knowledge of diabetes, dietary habits, physical activity, health practice index, diabetes quality of life (DQOL), and self-efficacy were also obtained. After six months, the intervention group showed a statistically significant weight loss and blood glucose reduction in the 75g-OGTT test, but the control group did not. A significant improvement in lifestyle was observed in the intervention group, especially in terms of dietary habits and physical activity. The knowledge test scores increased in both groups. There were no significant differences in HbA1c, DQOL, or self-efficacy between the two groups. The results of this study show that the combination of a three-day hospitalization and a six-month follow-up by telephone counseling is effective in metabolic control and improvement of lifestyle for patients with mild type 2 diabetes or IGT. The reasons for the effectiveness were considered to be that 1) changes in lifestyle were based on autonomous decision-making; 2) regular, consistent counseling was provided by the nurse in charge of each patient; 3) extended follow-up is more effective than initial education in preventing a rebound of weight or metabolic control.

Key words: randomized controlled trial, type 2 diabetes, IGT, patient education, telephone counseling

Introduction

The number of diabetes patients in Japan has increased rapidly. The number of people with suspected diabetes in Japan exceeded 6,900,000 in 1997, according to the Ministry of Health and Welfare (1). Due to these statistics we determined the following: primary prevention for patients with mild diabetes is considered important (2). The ultimate goal of diabetes treatment

is to prevent complications from arising from this chronic illness (3). Behavior-oriented patient education to encourage self-management of lifestyle is essential for achieving this goal. Recent research has shown the efficacy of various methods, namely, self-management record keeping, autonomous decision-making, small-group strategies, and a monthly follow-up by telephone (4-12). However, few education programs using a combination of these methods have been reported.

Various diabetes patient education programs have been conducted in hospitals in Japan. In most general hospitals, the length of educational hospitalization is about two weeks (13). This period is longer than that in specialized diabetes hospitals in the U.S. (14). This difference is considered due to the difference in insurance systems and in the social demographics of the

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Reprint requests to: Hiroshi FUKUDA,

Dept. of Public Health, School of Medicine, Juntendo University

2-1-1 Hongo, Bunkyo-ku, Tokyo, Japan 113-8421

TEL: +81(3)5802-1049 FAX: +81(3)3814-0305

e-mail: hiro@mend.juntendo.ac.jp

patients between hospitals. The period of initial education is important in terms of metabolic control (15), but it is difficult to ensure that an education program is effective for busy people or for patients with mild type 2 diabetes or IGT who do not consider their disease to have serious implications. Recently, short-term hospitalization for mild diabetes has been introduced in a few hospitals in Japan, but the educational effect and risk of interruption of visits to an outpatient clinic after hospitalization have not been clarified (16,17). The interruption ratio of treatment varies among facilities from 4%-40% after one year, but is generally high in patients receiving diet therapy alone, such as patients with mild type 2 diabetes or IGT (18-20).

Patients' educational needs are becoming increasing diverse. The authors clarified that 20-30% of the patients needed short-term hospitalization or correspondence courses as follow-up in a needs assessment conducted for 940 diabetic outpatients in a general hospital in 1996 (21). Only 5% of such patients needed long-term educational hospitalization. It appears necessary to introduce new education programs for patients with mild type 2 diabetes or IGT, such as short-term hospitalization or the extended follow-up to prevent a rebound of weight loss or to stabilize metabolic control. In addition, to the best of our knowledge, few studies have been conducted using an RCT method to evaluate lifestyle intervention for patients with type 2 diabetes or IGT in Japan (22).

Consequently, we developed a patient education program involving a three-day hospitalization and a six-month follow-up by telephone counseling for patients with mild type 2 diabetes or IGT at a medium-sized hospital in the metropolitan area. This education program was named "MIRAI", which stands for "Diabetes Mellitus intervention program for glucose reduction and lifestyle improvement". The word "mirai" also means "future" in Japanese. The purpose of the present research is to evaluate the efficacy and feasibility of the MIRAI program in terms of patients' knowledge, behavior, and metabolic control by an RCT method.

Research Design and Methods

Study Design & Patient Selection

The study was designed as a simple randomized control trial (Figure 1). The subjects were recruited from among the outpatients at Saitama-Kyodo Hospital, which is a medium-sized general hospital with 345 beds in the metropolitan area of Japan. Patients who satisfied certain criteria were recruited between Jan. 1997 and May 1997. The study inclusion criteria required that volunteers be diagnosed as having type 2 diabetes or IGT but not be receiving drug or insulin therapy for diabetes, be 40-70 years old, and have HbA1c of less than 8. Patients with any serious complication, e.g. anamnesis of cerebral hemorrhage, myocardial infarction, renal failure, or eyeground apoplexy, were excluded. Patients having types of anamnesis or using drugs that were considered likely to affect metabolic control were also excluded, e.g. patients with post gastrectomy anamnesis, or those taking prednis. There were 266 patients with mild type 2 diabetes or IGT who met the criteria. These subjects were asked to participate in briefing sessions by mail and telephone. The briefing sessions were held six times in June 1997. Informed consent was obtained from the patients who participated in the program. Sixty-eight patients participated in the briefing sessions. Fifty-two patients consented to participate in the current

Fig. 1 Research design for evaluating the diabetes patient education program "MIRAI"

research, and were randomly assigned to either the intervention group or the control group.

Patients' current ambulatory treatment was continued for both the control group and the intervention group and the educational intervention program MIRAI was provided for the intervention group alone. An examination was conducted and self-checking sheets was filled in when the baseline data was obtained in June, 1997, and again six months later. The same intervention was also provided for the control group for ethical reasons from January, 1998 onwards.

Educational intervention program

The diabetes education program MIRAI was developed by an interdisciplinary team consisting of physicians, nurses, dieticians, and clerks. The interdisciplinary approach is an effective means of conducting patient education, in that it enables patients to obtain accurate and comprehensive information on their disease, as well as promoting good relationships among members of the teaching staff (23). After reviewing the type 2 diabetes patient education programs previously reported in Japan (14,16,17,24-30), we developed our education program and teaching materials based on the results of our assessment of educational needs among type 2 diabetes outpatients in June, 1996 (1).

Our education program MIRAI was designed for patients with mild type 2 diabetes or IGT who are not receiving drug or insulin therapy and whose main aim is the improvement of dietary or exercise habits. The program consists of two components: a three-day hospitalization and a six-month follow-up with telephone counseling (Table 1). The period of hospitalization was kept short so that even busy people could participate easily. During the hospitalization, a complete physical examination was conducted, focusing on diabetes and arteriosclerosis, and initial education was provided (Table 2). The initial education included basic lectures on diabetes mellitus, diet therapy, exercise, and the overall concept of MIRAI. After the lectures, a group discussion was conducted. Finally, each patient set his or her own lifestyle targets concerning diet and daily activities before discharge. An original textbook of cartoon illustrations was used to supplement the lectures. The textbook also included a column for the telephone counseling schedule and lifestyle targets, a schedule of sending self-checking sheets after discharge. A nurse was assigned to each patient, and the assignments remained the same throughout the period of telephone counseling.

Table 1 Content of the Diabetes Patient Education Program "MIRAI" and roles of patients and staff

	Patients	Hospital staff
1. Three-day hospitalization	1)Receive complete physical examination 2)Receive initial education 3)Set targets for improvement of lifestyle by themselves 4)After discharge, visit their doctor and receive explanation and advice	1)Conduct complete physical examination for diabetes (physician) 2)Provide initial education on self-management of lifestyle (nurse, dietician) 3)Manage small-group discussion on lifestyle targets (nurse) 4)Explain the result of examinations and encourage the patient (physician)
2. Six-month follow-up with telephone counseling	1)FAX or mail self-checking sheet to the hospital 2)Phone their nurse in charge and talk about their lifestyle and problems with reference to self-checking sheet (once a month, 20-min. session) 3)Set targets for next month 4)After six months of telephone counseling, visit their doctor and discuss the efficacy of this program	1)Correct self-checking sheets and return them to patients (nurse, dietician) 2)Conduct case-conferences for individual patients (all staff) 3)Counsel patients by telephone with reference to self-checking sheet (nurse) 4)Discuss the efficacy of this program (physician)

Table 2 Schedule of the three-day hospitalization

First day	
10:00	Admission, photography of patients Submission of meal record and interview sheet Completion of self-checking sheet Stature, weight, and body fat ratio are measured.
13:00	Lunch
14:00	Diabetes knowledge test
14:30	Lectures "About diabetes" "Ergotherapy for diabetes" by nurse
17:00	Walking and pulse measurement practice
18:00	Supper
Second day	
8:00	Examinations for diabetes and arteriosclerosis (double master ECG, ophthalmoscope, nerve conduction velocity check etc.)
13:00	Lunch
14:00	Lecture "Diet therapy for diabetes" by dietitian
17:00	Group discussion and setting of targets for dietary habits
18:00	Supper
Third day	
8:30	75g-OGTT test
9:00	Lecture "Self-management of lifestyle" by nurse
10:00	Group discussion and setting of targets for lifestyle Reserved out-patient clinic
13:00	Lunch
14:00	Carotid artery echo check
15:00	Discharge from hospital

During the next six months, the nurse assigned to each patient provided telephone counseling (20 minutes/ session, once a month) based on a self-checking sheet, to encourage patients to adopt an appropriate lifestyle. Participants faxed or mailed their check sheets to the hospital once a month. A dietitian, physician, or nurse examined each check sheet and, after a staff conference, sent it back to the patient. Participants initiated each scheduled counseling session by telephoning the nurse in charge. If a patient forgot about a counseling session, a nurse telephoned the patient regarding that session only once. During each counseling session, the patient discussed his or her anxieties concerning recuperation, conducted a self-evaluation of food intake, physical activity, etc, and set new lifestyle targets for the next month. After discharge and when the program ended, the patient consulted a physician and received an explanation of the examination results and advice on recuperation lifestyles.

Evaluation Index

The evaluation index used in this study took into account 1)biological indicators; 2)knowledge, attitude, and behavior; 3)quality of life (QOL) and self-efficacy.

As biological indicators, weight, body fat ratio, diastolic blood pressure (DBP), glucose and insulin levels determined by a 2-hour 75g glucose tolerance test, HbA1c, glycosylated albumin (GA), and serum lipid, i.e. total cholesterol (T-cho), HDL-cholesterol (HDL), and triglyceride (TG) were used. HbA1c values were determined by standardized high performance liquid chromatography (HPLC) methods, measuring only stable HbA1c. The normal ranges for each indicator were as follows: HbA1c 4.3-5.8%, GA 11.8-16.2%, T-cho 130-220mg/dl, HDL 35-70mg/dl, TG 30-150mg/dl. As a preliminary examination to investigate insulin resistance, we regarded the whole body as one metabolic system, and practically calculated the ratio of Σ insulin/ Σ glucose at 75g-OGTT (31,32).

The diabetes knowledge test was a 25-item questionnaire designed to measure the patients' cognitive knowledge of diabetes based on a diabetes treatment guide (33). The number of correct answers was summed to obtain the knowledge score. Attitude was assessed using a 16-item questionnaire scored with a self-efficacy scale. The validity of the questionnaires was established by previous studies in Japan (34).

The health practice index used was also measured by Morimoto's Health Practice Index with eight-point full marks, adapted for a Japanese population based on Breslow's Health Practice Index (35). A self-checking 40-item questionnaire based on the "Meal Exchange List for diabetes" (36) was used to evaluate eating habits. In addition, a dietitian conducted an objective evaluation based on the three-day meal record, and compared the results with those of the self-evaluation.

Physical activity was assessed using a short questionnaire, the validity of which was established by previous studies in Japan (37). We also obtained the patients' self-reported pedometer counts.

QOL was assessed using a DQOL questionnaire which was developed by the DCCT Research Group (38). However in Japan, validity of this index was not shown, so we translated and used it as a preliminary in this research.

Patient Satisfaction was assessed practically only in the intervention group, using 20-item questionnaire as follows

designed to measure patients' feasibility and satisfaction with this program: duration of hospitalization, examination, textbook, self-checking sheet, lectures, telephone counseling, nurse, physician, dietician, and cost of participation.

Statistical Methods

Data was analyzed using Stat View ver. 4.5J. To calculate the baseline data, the Chi square test was used to analyze differences in the frequency of sex between the intervention group and the control group. The unpaired t-test was used to analyze differences in continuous variables between the groups. The significance of the changes in metabolic control or lifestyle improvement between that of the baseline and 6 Mo later in both groups was analyzed using the paired t-test. And also, the significance of the differences in improvement during the six months between the intervention group and the control group was calculated in unpaired t-test. Differences were considered statistically significant if the p-value was less than 0.05. All results are expressed as mean $\pm$ SD.

Results

Patient Demographics at Baseline

A total of 52 patients were randomly assigned to the two groups. One patient was excluded from the intervention group due to lung cancer, and one was excluded from the control group due to cerebral hemorrhage. Twenty-six patients in the intervention group and 24 patients in the control group completed the educational program. Patient demographics at baseline is shown in Table 3. The majority of the patients were middle-aged. There were no significant differences between the groups at baseline. No patients with retinopathy, nephropathy, neuropathy or any serious complications were observed in either group at baseline.

Metabolic Impact

A reduction in blood glucose values and insulin values after six months was observed in the intervention group but not in the

Table 3 Patient characteristics at baseline

	intervention group	control group	p value
N(M/F)	26(10/16)	24(10/14)	NS*
Diagnosis(diabetes/IGT)	12/14	10/14	NS*
Age (yr)	59.7 $\pm$ 9.0	56.7 $\pm$ 10.3	NS
Duration of mobility (yr)	3.3 $\pm$ 4.3	2.8 $\pm$ 4.0	NS
Height (cm)	157.0 $\pm$ 7.1	156.2 $\pm$ 7.7	NS
Body weight (kg)	61.7 $\pm$ 10.7	61.2 $\pm$ 11.4	NS
BMI	25.0 $\pm$ 4.1	25.0 $\pm$ 4.0	NS
Body fat ratio (%)	27.6 $\pm$ 8.0	28.1 $\pm$ 8.1	NS
Σ glucose (mg/dl)	966.7 $\pm$ 259.3	927.7 $\pm$ 244.2	NS
Σ insulin (μ U/ml)	181.5 $\pm$ 147.4	197.6 $\pm$ 110.9	NS
HbA1c (%)	6.0 $\pm$ 0.9	6.2 $\pm$ 1.0	NS
Tcho (mg/dl)	213.2 $\pm$ 32.8	228.8 $\pm$ 33.5	NS
TG (mg/dl)	138.2 $\pm$ 78.5	132.4 $\pm$ 74.9	NS
HDL (mg/dl)	48.8 $\pm$ 18.0	52.6 $\pm$ 13.9	NS
Diastolic blood pressure (mmHg)	81.1 $\pm$ 10.3	76.2 $\pm$ 9.1	NS
Diabetes knowledge (points)	66.8 $\pm$ 14.1	67.0 $\pm$ 17.2	NS
Dietary habit (points)	42.8 $\pm$ 16.7	43.8 $\pm$ 13.6	NS
Physical activity (points)	13.2 $\pm$ 7.1	9.0 $\pm$ 7.6	NS
Health practice index (points)	5.8 $\pm$ 1.6	5.0 $\pm$ 1.7	NS
Self efficacy (points)	8.6 $\pm$ 3.3	8.7 $\pm$ 3.2	NS
DQOL (points)	78.5 $\pm$ 6.4	78.9 $\pm$ 5.6	NS

P value was calculated in unpaired t-test between the intervention group and the control group.

NS= not significant, $p \geq 0.05$, * Chi-square P value

Σ glucose= sum of blood glucose (Σ glucose), Σ insulin (sum of insulin)

control. There was a significant difference in the glucose value curves for 90 minutes and 120 minutes at 75g OGTT and in the insulin value curves for 90 minutes in the intervention group only (Figure 2). Therefore, Σ glucose and Σ insulin were also significantly different only in the intervention group (Table 4). As a preliminary examination to investigate insulin resistance, the results showed that the ratio of Σ insulin/ Σ glucose was 0.213 at baseline and 0.183 six months later in the intervention group, and 0.188 at baseline and 0.182 six months later in the control group (μ U/ml)/(mg/dl). The difference between the data obtained at baseline and that obtained six months later was not significant in either group.

Similar to the results for blood glucose, there were significant differences between the data obtained at baseline and that

Table 4 Comparison of metabolic impact between intervention and control groups

	intervention group				control group				p value A vs B
	baseline	6 Mo later	differences between baseline and 6Mo later (A)	p value baseline vs 6Mo later	baseline	6 Mo later	differences between baseline and 6Mo later (B)	p value baseline vs 6Mo later	
body weight (kg)	61.7 $\pm$ 10.7	59.1 $\pm$ 10.3	-2.6	<0.001	61.2 $\pm$ 11.4	60.7 $\pm$ 11.7	-0.5	NS	<0.001
BMI	25.0 $\pm$ 4.0	24.0 $\pm$ 3.8	-1.0	<0.001	25.0 $\pm$ 4.0	24.8 $\pm$ 4.1	-0.2	NS	<0.001
body fat ratio (%)	27.6 $\pm$ 8.0	27.0 $\pm$ 7.7	-0.6	NS	28.1 $\pm$ 8.1	30.5 $\pm$ 10.0	+2.4	<0.001	<0.001
Σ glucose (mg/dl)	927.7 $\pm$ 244.2	843.4 $\pm$ 186.0	-84.3	<0.05	966.7 $\pm$ 259.3	1010.8 $\pm$ 320.4	+44.1	NS	<0.01
Σ insulin (μ U/ml)	197.6 $\pm$ 110.9	154.2 $\pm$ 127.0	-43.4	<0.05	181.5 $\pm$ 147.4	184.0 $\pm$ 108.3	+2.5	NS	NS
HbA1c (%)	6.00 $\pm$ 0.92	5.79 $\pm$ 1.04	-0.21	<0.05	6.16 $\pm$ 0.98	6.03 $\pm$ 1.14	-0.13	NS	NS
GA (%)	16.9 $\pm$ 3.0	16.1 $\pm$ 3.0	-0.8	<0.001	16.8 $\pm$ 3.0	16.8 $\pm$ 3.4	0	NS	<0.05
Tcho (mg/dl)	213.2 $\pm$ 32.8	213.0 $\pm$ 32.6	-0.2	NS	228.8 $\pm$ 33.5	242.0 $\pm$ 37.6	+13.2	<0.05	NS
TG (mg/dl)	138.2 $\pm$ 78.5	108.7 $\pm$ 45.7	-29.5	<0.05	132.4 $\pm$ 74.9	137.8 $\pm$ 58.0	+5.4	NS	<0.05
HDL (mg/dl)	48.8 $\pm$ 18.0	56.0 $\pm$ 17.9	+7.2	<0.001	52.6 $\pm$ 13.9	52.4 $\pm$ 15.1	-0.2	NS	<0.001
Diastolic blood pressure (mmHg)	81.1 $\pm$ 10.3	77.0 $\pm$ 9.7	-4.1	<0.05	76.2 $\pm$ 9.1	73.9 $\pm$ 10.2	-2.3	NS	NS

"P value baseline vs 6Mo later" was calculated in paired t-test between the baseline and 6Mo later at each group.

"P value A vs B" was calculated in unpaired t-test between the differences of intervention group (A) and control group (B).

Σ glucose=sum of blood glucose, Σ insulin=sum of insulin, NS =not significant ($p \geq 0.05$)

P value was calculated in paired t-test between the baseline and 6Mo later at each value.
*p < 0.05 **p < 0.01

Fig. 2 Blood glucose and insulin values at 75g-OGTT

obtained six months later in HbA1c, GA, DBP, HDL, and TG only in the intervention group. As regards T-cho, there was no significant difference in the intervention group, but the T-cho value was significantly higher after six months in the control group.

Mean weight after six months was significantly lower than the baseline value only in the intervention group. Mean body fat ratio after six months was significantly higher than the baseline value only in the control group (Table 4). If we define weight loss as a loss of more than 1kg, 82% of the intervention group lost weight, but only 52% of the control lost weight.

Table 4 also shows the comparison of the intervention and the control groups on improvement of biological indicators during the education program. The intervention group showed a significantly greater reduction in body weight, BMI, body fat ratio, Σ glucose, GA, and TG. The HDL value also improved more significantly in the intervention group than in the control. There was no significant difference in Σ insulin, but p value was 0.051.

Behavior, Knowledge, Attitude, and QOL

There was a significant difference in diabetes knowledge and in the dietary habits score evaluated by patients between the baseline and six months later in both the intervention group and the control group. However, in the dietary habits score evaluated by a dietician, as well as in physical activity, pedometer count, and health practice index, a significant difference was observed only in the intervention group. For self-efficacy and DQOL, no significant differences were observed (Table 5).

As between-group analysis, the intervention group showed a significantly greater improvement in dietary habits score, physical activity, pedometer count, and health practice index. There were no significant differences in diabetes knowledge, self-efficacy or DQOL (Table 5).

Patient Satisfaction

The returned questionnaires from the intervention group

Table 5 Comparison of behavior change between intervention and control groups

scale(points)	intervention group				control group				p value A vs B
	baseline	6 Mo later	differences between baseline and 6Mo later (A)	p value baseline vs 6Mo later	baseline	6 Mo later	differences between baseline and 6Mo later (B)	p value baseline vs 6Mo later	
Diabetes knowledge	66.8 ± 14.1	80.0 ± 11.6	+13.2	<0.001	67.0 ± 17.2	77.0 ± 7.9	+10.0	<0.01	NS
Dietary habits evaluated by patient	52.3 ± 18.8	80.9 ± 10.8	+28.6	<0.001	49.7 ± 20.7	58.9 ± 12.6	+9.2	<0.01	<0.001
Dietary habits evaluated by dietician	42.8 ± 16.7	62.1 ± 17.0	+19.3	<0.01	43.8 ± 13.6	46.3 ± 12.6	+2.5	NS	<0.001
Physical activity	13.2 ± 7.1	17.2 ± 9.5	+4.0	<0.01	9.0 ± 7.2	7.8 ± 7.1	-1.2	NS	<0.01
Pedometer count	5230 ± 2420	7580 ± 2400	+2350	<0.001	5390 ± 2230	4800 ± 2700	-590	NS	<0.001
Health practice index	5.8 ± 1.6	7.1 ± 1.0	+1.3	<0.01	5.0 ± 1.7	4.8 ± 1.5	-0.2	NS	<0.01
DQOL	78.5 ± 6.4	80.4 ± 5.4	+1.9	NS	78.9 ± 5.6	80.2 ± 6.3	+1.3	NS	NS
Self-efficacy	8.6 ± 3.3	8.8 ± 3.4	+0.2	NS	8.7 ± 3.2	8.8 ± 3.2	+0.1	NS	NS

"P value baseline vs 6Mo later" was calculated in paired t-test between the baseline and 6Mo later at each group.

"P value A vs B" was calculated in unpaired t-test between the differences of intervention group (A) and control group (B).

NS =not significant ($p \geq 0.05$)

showed that the majority of the participants were satisfied with the educational program especially with regard to the duration of hospitalization, lectures during hospitalization, telephone counseling, and correspondence with the nurse or physician in charge. However, the level of patient satisfaction with the self-checking sheet was comparatively low, because it took too much time to fill in.

Discussion

Efficacy of This Program

In this research, we evaluated the efficacy of a newly developed diabetes patient education program consisting of a three-day hospitalization and a six-month follow-up by telephone counseling for mild type 2 diabetes or IGT. This was the first such program reported in Japan. This education program appears to be as effective as current treatment for increasing patients' knowledge of diabetes, since there were significant increases between the baseline and six months later in both the intervention group and the control group. Moreover, a significant difference between the two groups was seen in biological data behavior indexes, such as dietary habits and physical activity. In short, this program is effective not only in increasing patients' knowledge but also in helping patients to actually change their lifestyle. Munakata considers that health behavior depends on the balance between the health behavior motives and health behavior burdens in the seesaw model of health behavior (39). The health behavior burdens includes factors such as time limitations, geographic limitations, economic limitations, and social support. Because the target patients of this program had only mild type 2 diabetes or IGT, they had few symptoms and little awareness of the implications of their disease. Such patients frequently have few motives for receiving treatment, and tend to interrupt their treatment. Therefore, in such a group, it is more important to reduce the health behavior burdens than to increase health behavior motives. This program greatly reduced the time requirement and financial burden on patients by minimizing the duration of hospitalization. It also greatly reduced time and travel requirements by allowing patients to receive telephone counseling in their own homes. Because these factors decrease the load of health behavior, the efficacy of this patient education program is high. It seems that monthly telephone counseling sessions are an effective means of follow-up because they encourage patients to continue participating in the program. The convenience of such follow-up may contribute to the efficacy of this program in terms of behavior improvement. Moreover, the decision made by each

patient regarding lifestyle targets was respected during the three-day hospitalization and the six-month follow-up. The nurse in charge provided counseling only, and never pushed patients to adopt certain medical targets. To receive telephone counseling, patients called their nurse in charge on the scheduled day. This program therefore respected the patients' independence, which may be another factor contributing to its efficacy. Furthermore, the same nurse in charge provided care for the same patient throughout both hospitalization and telephone counseling. Such a consistent relationship between the patient and the nurse may have improved the patients' confidence, thereby enhancing the efficacy of this program.

In the intervention group, the patients improved their dietary habits and physical activity, so they were able to lose weight. We consider that the patients' weight loss was related to improvements in metabolic control reductions in the glucose and insulin values. In this study, although insulin value decreased in the intervention group, no significant change in the ratio of insulin secretion to glucose was observed in a preliminary examination, so it cannot be concluded that insulin resistance was improved. HbA1c was only slightly reduced in the intervention group, because the symptoms at the baseline of the patients who participated in this study were too mild to exhibit large changes.

Regarding the biological data, the changes in weight and in blood glucose values in the 75g-OGTT test showed a dramatic improvement. We also observed improvements in TG and HDL values as well as blood glucose, however, the improvement in T-cho wasn't clear. We initially expected that this program would be applicable to other lifestyle-related diseases as well as diabetes. However, it seems that modification of the content of the program is necessary in order to achieve significant improvements in biological data for other lifestyle-related diseases such as hyperlipidemia.

For self-efficacy and DQOL, no significant differences between the intervention group and the control group were observed. One possible explanation for this is that the questionnaire was not appropriate to the subjects who participated in this study. DQOL was developed mainly for the purpose of clarifying QOL in IDDM patients (38). We selected patients with mild disease as subjects, too slight an illness to note an improvement of QOL among the subjects. The self-efficacy scale used in this research was suitable for investigating efficacy in terms of general behavior rather than specified behavior such as insulin infusion, and self-monitoring of blood glucose (34). So it was too notional to examine improvement of efficacy in terms of dietary habits or physical activity.

Examination of Validity

Because there were no significant differences between the intervention group and the control group at baseline, the influence of previously known confounding factors was excluded. Therefore, we consider that the randomized assignment in this study was successful in ensuring high internal validity. The findings relative to weight loss and HbA1c are similar or superior to the findings of other studies in Japan (24-30). The reliability of this study was expected to be higher than other studies because of the RCT design. However, the validity of the diabetes knowledge test, dietary habits scale, and DQOL used in this study has not been investigated for studies in Japan so far. Therefore, we are only able to give a preliminary interpretation of the results. Nevertheless, since the questionnaire was developed based on teaching materials that are widely used for diabetes patients in Japan, as well as the results of studies in other countries (33,36,38), we consider the internal validity of the present study to be quite high.

Next, we consider external validity. The subjects of this investigation were patients with mild type 2 diabetes or IGT in a general hospital in the metropolitan area, not in a specialist diabetes hospital. Therefore, we consider that the external validity of this research is high and generalization to other hospitals is possible. However, the participation ratio of this program in the outpatient clinic was 20%. This figure corresponds to the results of a previous needs assessment. Though we couldn't show any differences of patient characteristics between the participants and others in detail, there might not be any remarkable difference in sex, age, or metabolic control because of the study inclusion criteria. It appears that patients who were highly motivated to receive treatment for diabetes in an outpatient clinic participated in this study, resulting in selection bias. Our results should therefore be applied to the case of highly motivated patients. It is necessary to consider patients' motivation before attempting to generalize our results to other situations.

Problems Involved in This Program

In previous studies, based on the patient empowerment

theory, various patient education programs were developed and evaluated by RCT methods (4-12). However, to the best of our knowledge, no program including both short-term hospitalization and telephone counseling based on correspondence methods has been reported so far. Moreover, very few studies have been conducted in Japan using RCT methods to evaluate diabetes patient education. In such situations, the patient education program MIRAI appeared to be not only feasible but also effective for patients with mild type 2 diabetes or IGT. Therefore, it seems this research has important implications.

According to the patients' responses concerning their satisfaction with this program, the number of questions on the self-checking sheet was too large, and the sheet was difficult to fill in. The development of a simple self-checking sheet may improve the feasibility and efficacy of the program. Moreover, the staff manpower requirement for telephone counseling or a correspondence course is high in the current way. Such an education program is not economically viable because the current medical insurance system in Japan does not cover telephone counseling by co-medical staff members or patient education by correspondence course methods. The improvement of such a system is also important so that similar research projects may increase.

Even if the method of short-term hospitalization and telephone counseling is used, it is still difficult to motivate patients with mild type 2 diabetes or IGT who have little consciousness of the implications of their disease. Therefore, further studies using new ideas of patient education programs are required in order to improve the efficacy of these methods for such patients.

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