Effect of Delivery of Diabetic Meals as an Educational Tool for Self-Management of Japanese Type 2 Diabetes Mellitus.

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Short Communication

Effect of Delivery of Diabetic Meals as an Educational Tool for Self-Management of Japanese Type 2 Diabetes Mellitus

Saori FUJIMOTO,[1,2] Chikako TOGAWA,[1] Toyomi YAMAMURA,[1] Mikuko MATSUDA,[1,2] Kayoko OYABU,[3] Tatsushi KOMATSU,[4] Kanji WATANABE,[2] Shuichi MIYATANI,[2] Shizuo KAJIYAMA[1] and Saeko IMAI[† 2]

[1]Kajiyama Internal Clinic, 25-1-136, Oiwake-cho, Saiin, Ukyo-ku, Kyoto 615-0035, Japan ; [2]Department of Clinical Nutrition, Faculty of Comprehensive Rehabilitation, Osaka Prefecture University, 3-7-30, Habikino, Habikino, Osaka 583-8555, Japan ; [3]Department of Health Science, Kio University, 4-2-2, Koryo-cho, Kitakatsuragi-gun, Nara 635-0832, Japan ; [4]Faculty of Human Life and Science, Doshisha Women's College of Liberal Arts, Teramachi, Imadegawa,Kamigyo-ku, Kyoto 602-0893, Japan

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1 Introduction

If nothing is done, medical costs for treatment of patients with diabetes mellitus will reach $ 40.8 billion a year by 2010 in Japan. Numerous studies have shown the beneficial effects of dietary intervention and increased physical activity on diabetes mellitus and other cardiovascular risk factors. It is essential to effect good metabolic control to prevent chronic complications of diabetes mellitus.[1-4]

Educating patients can influence behavior, which, in turn, can modify metabolic control, influencing changes in glycemic control, blood pressure, lipid levels, physical activity, body weight, lifestyle and self-monitoring skills. However, there are many patients that have little success in their diet or even if patients could achieve their dietary goals it is difficult to maintain a proper diet for a long period of time.[5,6] In Japan, diabetic patients often stay in hospital for 1 or 2 weeks for diabetes education, primarily to learn about diet. However, most patients were not pleased this methods since the high costs and suspension of work and daily life. In addition, many patients have a tendency to revert to their previous dietary habits and lifestyles. In 2008, methods of efficient self-management training will be required in public health programs in Japan and all health insurance organizations will be responsible to educate and improve medical characteristics of patients with metabolic syndrome or other health problems. In order to educate many patients efficiently, previous studies have shown that a telemedicine[7] or internet-based blood glucose monitoring system can be effective for diabetes management.[8] However, most elderly Japanese patients are not yet familiar with the use of the internet, while education through telemedicine, although an effective psychological support, may not be suitable for teaching about diet.

To establish a more efficient dietary education for diabetes self-management, we previously devised a diabetic meal delivery system for 4 months for type 2 diabetes patients.[9] Using this system, the patients were able to learn about diet and kept good glycemic control for over 12 months. The knowledge learned made it easier for them to maintain a good diet without requiring a stay in hospital. However, it was not a convenient system in economic terms or in self-management education since it depended too much on delivery meals. Appropriate education should provide the patient with knowledge and skills that allow the patient to carry out self-care on a routine basis. For this to be possible, it is necessary that the patient understands this complexity, and be able to take part in the treatment.

Further studies are required to examine how many meals or how long the diabetic meals need to be delivered in order to maintain optimal glycemic control and behavior modification. Therefore we can use the diabetic delivery meals as a practical educational tool, providing only 4 dinners per week for 4 weeks to investigate the effects of diabetic meal delivery as an educational tool on glycemic control in Japanese outpatients with type 2 diabetes mellitus.

[†] Corresponding author, Email : poooch@rehab.osakafu-u.ac.jp

2 Subjects and Methods

2.1 Patients and dietary intervention

Patients diagnosed with type 2 diabetes who fulfilled the WHO criteria for diabetes were recruited from outpatients visiting the Kajiyama Clinic between 2004 and 2007. Patients were excluded if they had any significant diseases that were likely to affect the outcome or compliance with this study. The exclusion criteria were as follows: heart failure, renal failure, or serious physical or mental conditions. A total of 83 adults with type 2 diabetes who attended the clinic (62.2 ± 11.0 years; means ± SD), range 36-83 years) were assigned into three groups by the stratified randomization method that considered age, gender, and duration of diabetes. Each group received one of the following diabetic interventions.

The diabetic meal delivery group (group M) had diabetic meals delivered to their homes, 4 dinners a week for 4 weeks (total 16 meals). The patients replace 4 normal dinners per week for 4 weeks with the diabetic meals to learn the appropriate diet and prepare other meals by themselves. The meals were designed for diabetes patients and consisted of 1,200 to 1,800 kcal, 16 % protein, 60-64% carbohydrates, 20-25 % fat of calories, and 9 g of salt. The meals were cooked and chilled immediately to 3℃ prior to delivery. The cost of the delivery meal was paid for by a grant and usual clinical examinations were paid by health insurance and the patients themselves. If a patient agreed to participate in the diabetic meal delivery study, the subject had three individual sessions with a dietitian at the start of intervention and after 4 and 12 weeks. The sessions were interactive and included a focus on self-management of type 2 diabetes, especially on diet. The participants were encouraged to measure and record food and weight. The individual diet counseling group (group D) involved patients having consultations with same dietitian every 4 weeks (4 sessions over 12 weeks). The educational counseling covered such topics as diabetes risk factors, its complications, diet and physical activity. The discussions were individualized and focused on specific individual problems and self-management, mainly relating to diet. The goals and plans were to equip the subjects with skills and knowledge of diet and exercise to initiate behavioral changes. The subjects were encouraged to make easy goals to achieve for themselves by thinking about practical goal such as "to eat vegetables first in each meal, and walk 6,000 steps everyday". The dietitians also addressed coping skills for improving psychosocial functions to aid their behavior change. The patients were also encouraged to measure and record their weight at home before and after intervention. The family members were invited to join the education counseling as much as possible since family participation and support are important. The control education group (group C) involved the patients receiving their usual outpatient management every 4 weeks. At baseline, the control group was given general information about lifestyle and diabetes risk by either a doctor or nurse at every visit. The message was to make changes in dietary habits and increase physical activity. The dietary state before and after intervention over 6 days per patient in group M and D was obtained using a food record in which calorie intake was calculated by using Eiyokun (Kenpakusya, Tokyo, Japan). The study protocol was approved by the Ethics Committee of the School of Comprehensive Rehabilitation at Osaka Prefecture University and all participants gave written informed consent prior to enrollment in the study. No changes were made to oral blood glucose-lowering agents, antihypertensive and lipid-lowering therapies during the study in all groups.

2.2 Laboratory analysis

Laboratory data, body weight and body mass index (BMI; kg/m^2) were collected for all groups at baseline and every 4 weeks, for all participants who completed the entire education program. Fasting blood samples were collected in the morning after an overnight fast from all participants every 4 weeks. HbA_{1c} levels were determined by a latex cohesion method (JCA-BM2250, KYOWA MEDEX, Co., Ltd., Tokyo, Japan). Fasting blood glucose (FBG) levels were examined by the hexokinase method (JCA-BM12, Shino Test, Co., Ltd., Tokyo, Japan). Total cholesterol (T-C) and triglyceride (TG) levels were determined by enzyme assay. HDL cholesterol (HDL-C) levels by a direct method (Labospect 008K, Bio Majesty JCA-BM 8060, JEOL, Ltd., Tokyo, Japan) and LDL cholesterol (LDL-C) levels by an enzymatic method (Bio Majesty JCA-BM 8060, JEOL, Ltd., Tokyo, Japan).

2.3 Statistical analysis

The characteristics of the study participants were calculated and expressed as means ± SD. Statistical analyses were performed using SPSS version 14.0 (SPSS Inc., Chicago, IL). Differences between the three groups in baseline were determined by one-way analysis of variance (ANOVA). The Bonferroni/Dunnett post hoc test was used to determine the significance of continuous data and the χ^2-test for significance of the categorical variables. Repeated-measures ANOVA was used to determined the difference between the groups and over time. When a significant difference was found by

Table 1 Baseline clinical characteristics of the three study groups

	group M (Meal delivery) (n=27)	group D (Dietitian counseling) (n=29)	group C (Control) (n=27)	P
Gender (males / females)	8 / 19	15/14	13/14	0.207
Age (yrs)	61.0 ± 11.1	62.0 ± 11.2	63.5 ± 11.1	0.720
BMI (kg/m^2)	24.6 ± 5.3	24.4 ± 3.9	24.0 ± 3.4	0.877
Duration of diabetes (yrs)	9.9 ± 8.8	10.7 ± 10.8	12.4 ± 6.8	0.566
Systolic blood pressure (mmHg)	126 ± 14	128 ± 15	133 ± 11	0.220
Diastolic blood pressure (mmHg)	72 ± 7	73 ± 7	73 ± 11	0.776
HbA_{1c} (%)	8.5 ± 1.9	8.6 ± 1.7	8.6 ± 2.1	0.942
Fasting plasma glucose (mg/dl)	165 ± 46	180 ± 69	193 ± 68	0.300
T-C (mg/dl)	212 ± 27	213 ± 33	217 ± 41	0.858
HDL-C (mg/dl)	64 ± 17	59 ± 16	62 ± 16	0.279
LDL-C (mg/dl)	124 ± 25	120 ± 31	128 ± 35	0.599
TG (mg/dl)	134 ± 96	150 ± 87	142 ± 89	0.706
Diabetes treatment:				0.223
Diet only	7	10	6	
Oral hypoglycemic agents	17	13	16	
Oral hypoglycemic agents + Insulin	3	6	5	
Energy goals (kcal)	1,444 ± 178	1,541± 208	1,493 ± 175	0.163

Data are means ± SD or n.

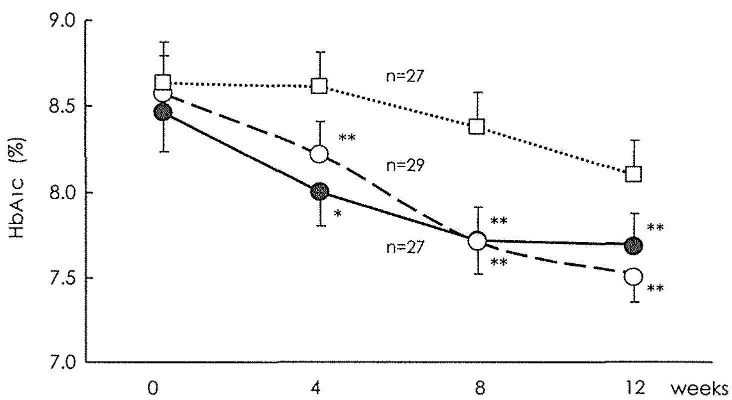

Fig. 1 HbA_{1c} levels after intervention in group M (closed circle), D (opened circle) and C (opened square). The data are expressed as means ± SE. *Significant difference from the baseline ($p < 0.05$), ** ($p < 0.01$).

Table 2 Results of laboratory data from baseline to the endpoint in subjects in the three study groups

	Baseline	4 wks	8 wks	12 wks
FBG (mg/dl)				
group M	165 ± 46	153 ± 54	166 ± 61	161 ± 66
group D	180 ± 69	145 ± 36*†	153 ± 40*	148 ± 41*
group C	193 ± 68	189 ± 74	178 ± 65	174 ± 53
T-C (mg/dl)				
group M	212 ± 27	211 ± 32	205 ± 35	205 ± 32*
group D	213 ± 33	202 ± 30*	200 ± 31*	200 ± 33*
group C	217 ± 41	211 ± 35	205 ± 33	209 ± 37
HDL-C (mg/dl)				
group M	64 ± 17	61 ± 15	59 ± 15	62 ± 15
group D	57 ± 16	56 ± 15	56 ± 14	56 ± 15
group C	62 ± 16	60 ± 16	60 ± 14	59 ± 14
LDL-C (mg/dl)				
group M	124 ± 25	123 ± 30	122 ± 29	120 ± 27
group D	120 ± 31	115 ± 29	113 ± 28	114 ± 33
group C	128 ± 35	123 ± 33	117 ± 29	123 ± 31
TG (mg/dl)				
group M	134 ± 96	143 ± 72	135 ± 88	128 ± 71
group D	150 ± 88	123 ± 58	120 ± 57	113 ± 47*
group C	142 ± 89	146 ± 82	125 ± 63	140 ± 63

Data are means ± SD. Baseline vs after intervention; *p<0.05.

Dietitan counseling vs Control; †p<0.05.

repeated-measures ANOVA, paired t-tests with Bonferroni correction were applied to identify specific differences. A p-value of less than 0.05 was considered statistically significant.

3 Results

The clinical characteristics of the three intervention groups are shown in Table 1. There were no significant differences in the clinical background of the subjects in the three groups with respect to gender, age, body mass index (BMI), diabetes duration, blood pressure, laboratory data, diabetic treatments and energy goals. There was a higher proportion of women in group M (n=19) compared with other two groups (n=14) although this difference was not significant.

Our primary outcome was glycemic control, as indicated by HbA_{1c} levels. Fig. 1 displays HbA_{1c} results at baseline, 4 weeks, 8 and 12 weeks after intervention in the three groups. In group M, HbA_{1c} levels improved from 8.5 ± 1.9% at baseline to 8.0 ± 1.2% immediately after intervention ($p < 0.05$) and 7.7 ± 1.2%, 7.7 ± 1.2% in 8 ($p < 0.01$) or 12 weeks ($p < 0.01$) after intervention respectively. Similar results were found for the patients in group D, HbA_{1c} decreased from 8.6 ± 1.7% to 8.2 ± 1.3% ($p < 0.01$) soon after intervention and to 7.5 ± 1.2% at 12 weeks after intervention ($p < 0.01$). This improvement with time was significant overall ($p < 0.01$). In contrast, in group C, HbA_{1c} levels slowly tended to decrease from 8.6 ± 2.1% at baseline to 8.1±1.0% at 12 weeks after intervention, which did not reach statistical significant ($p = 0.147$). HbA_{1c} levels were not statistically significant overall between groups. Table 2 shows the changes in laboratory data from baseline to 12 weeks after intervention in the three groups. FBG levels decreased significantly throughout in group D ($p < 0.05$), they were significantly lower than that in group C at 4 weeks after intervention ($p < 0.05$). Analysis of the lipid profile results showed an improvement T-C levels in group M and D, and TG levels in group D. T-C levels decreased significantly in M group after 12 weeks ($p < 0.05$) while in D group decreased overall throughout the study period ($p < 0.05$). TG levels were significantly decreased in D group after 12 weeks ($p < 0.05$). On the other hand, no significant changes were observed in serum lipids levels in C group. The reduction of LDL-C levels did not reach statistical significance in all groups. Also there were no significant differences in BMI or blood pressure during the period in all groups. BMI tended to decrease from 24.6 ± 5.3 to 24.0 ± 5.1, 24.4 ± 3.9 to 23.9 ± 3.7, 24.0 ± 3.4 to 23.8 ± 3.0 at 12 weeks after intervention in group M, D and C, respectively. Systolic blood pressure changed slightly from 126 ± 14mmHg to 127 ± 10mmHg, 128 ± 15mmHg to 121 ± 12mmHg, 133 ± 11mmHg to 126 ± 12mmHg in group M, D and C, respectively. Diastolic blood pressure changed from 72 ± 7mmHg to 73 ± 7mmHg, 73 ± 7mmHg to 69 ± 10mmHg and 73 ± 11mmHg to 71 ± 8mmHg at 12 weeks after intervention in group M, D and C, respectively.

Dietary intake decreased significantly after intervention in group M, such as energy intake from 1,700 ± 339kcal to 1,437 ± 330kcal ($p < 0.01$), protein intake from 76 ± 21g to 62 ± 19g ($p < 0.01$), fat intake from 51 ± 18g to 43 ± 19g ($p = 0.087$) and carbohydrate intake from 228 ± 62g to 184 ± 44g ($p < 0.01$). Dietary energy, total protein and carbohydrate intake also decreased significantly in group D, such as 1,736 ± 477kcal to 1,427 ± 200kcal ($p < 0.01$), protein intake from 73 ± 21g to 64 ± 11g ($p < 0.05$), fat intake from 49 ± 20g to 41 ± 7g ($p = 0.056$), carbohydrate intake from 252 ± 76g to 195 ± 24g ($p < 0.01$). Dietary intakes before and after intervention did not differ between the two intervention groups. On the other hand, daily vegetable intake increased from 268 ± 100g to 408 ± 178g in group M ($p < 0.05$), and from 244 ± 53g to 373 ± 80g in group D after intervention ($p < 0.01$).

4 Discussion

In the previous study, we demonstrated that delivery of the diabetic meals led to improved glycemic control equal to individual dietary counseling. Intervention with the diabetic meal delivery for 4 months had a beneficial effect on HbA_{1c} levels similar to that seen with individual dietary counseling during 12 months.[9] Our previous results have important clinical implications, given that medical costs for diabetic patients are increasing and self-care for patients is considered to be of great benefit.[10] In addition, improving glucose control reduced the economic costs associated with diabetic complications.[11]

In this study we used the diabetic delivery meals minimally as an educational tool to encourage patients to independent self-management of their diet for 12 weeks. Firstly, the patients were able to learn and experience dietary changes as a result of receiving and eating the diabetic meals as an educational tool soon after intervention. This led to immediate behavioral changes in each participant regarding self-management of their diet. Many were able to evaluate that their daily food portions were too large and therefore decreased the portions of rice or meat while increasing portions of vegetables. Dietary mean energy intake was reduced

15% and carbohydrate intake decreased 19% after intervention in group M. Mean energy and carbohydrate intake also decreased 18% and 23% respectively after intervention in group D. Also, the patients in M and D group received medical data, with the majority showing improved glycemic control soon after intervention, as a consequence of increased self-efficacy. After the experience of the short period of diabetic meal delivery, patients gained dietary skills and knowledge and continued to consume a proper diet as self-management. Secondly, delivery of meals was suitable for patients who had limited economic means. It costs approximately $2,100 a week to stay in hospital for diabetic education, whereas diabetic meal delivery costs only $123 for 4 dinners for 4 weeks.

However, there were several limitations to our study. We are aware that the group of patients is relatively small. Some patients hesitated to join this study because of particular food preferences. Secondly, our study needs to involve follow-up care after the 3-month assessment, as the results may have been achieved. To ensure good outcomes, post-educational programs that enable consultations regarding diet should be considered and initiated at regular intervals by dietitians. The patients of D group showed significant decreased in FBG, HbA_{1c}, T-C and TG. The observed difference in incidence between intervention groups and the control group indicated that the intervention needs to be individual and performed consistently in order to be effective in self-management, especially regarding diet. This result showed the importance of the counseling given to patients by dietitians and its role in increasing understanding about how to efficiently and consistently self-manage dietary regimes. Dietitians are an essential part of the diabetes care team along with physicians and nurses. Our study provides evidence that minimum use of diabetic meal delivery as an educational tool is as effective as individual counseling for the self-management of diabetes. The method was practical for diabetic outpatients who were not able to stay in hospital for diabetes education or receive counseling by dietitians. The lower HbA_{1c} levels, T-C, TG, and LDL-C concentrations at 12 weeks period after intervention might lead to a lower incidence of cardiovascular disease in type 2 diabetes, remains to be elucidated. This in turn contributes to better long-term metabolic control which adds to the prevention of chronic complications.

In conclusion, this study provides evidence that intervention of delivery of diabetic meals as an educational tool in Japanese patients with type 2 diabetes is as effective as individual diet counseling by dietitians for maintaining glycemic control in a short period of time.

Acknowledgement

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List of List of abbreviations:

BMI	Body mass index
FBG	Fasting blood glucose
HbA_{1c}	Glycated hemoglobin A_{1c}
HDL-C	High density lipoprotein cholesterol
LDL-C	Low density lipoprotein cholesterol
T-C	Total cholesterol
TG	Triglyceride