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Randomized Controlled Trial of Two Forms of Self-Management Group Education in Japanese People with Impaired Glucose Tolerance

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Summary **The aim of this study was to determine the effectiveness of education on diabetes prevention in subjects with impaired glucose tolerance. A total of 100 subjects of impaired glucose tolerance with hemoglobin A1c (HbA1c) levels ≥5.5 to <6.1% were assigned randomly to either support or control groups. All subjects received education in 8 sessions over a 6-month period. The support group consisted of 10 members collaborating with a dietitian or a nurse who learned coping skills by employing a participant-centered approach. Participants in the support group were required to keep a diary that monitored weight, food intake and blood glucose levels, while the control group attended several lectures. Subjects assigned to the support group had a reduction in mean HbA1c levels from 5.77 ± 0.36% at baseline to 5.39 ± 0.24% at the endpoint (p<0.01). Weight, total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), and triglyceride (TG) levels also decreased (p<0.01) in the support group, whereas subjects in the control group had no observable reduction in these indices. After intervention, participants of the support group had improvements in their 2-h post-meal blood glucose levels. Support group education can be effective for improving glycemic control in participants when carried out in collaboration with educators and other team members.**

Key Words: **diabetes prevention, glycemic control, self-management education, support group**

Introduction

Due to the huge financial burden associated with diabetes, health care systems are increasingly seeking efficient methods that prevent diabetes and provide diabetic care. It is well recognized that impaired glucose tolerance is a risk factor for cardiovascular disease [*1*]. In 2007, the International Diabetes Federation recommended tighter monitoring of post-prandial blood glucose levels in people with diabetes. In order to optimize diabetes control and reduce the risk of complications, these guidelines emphasized that people with diabetes should closely monitor their post-prandial blood glucose levels to ensure these are less than 140 mg/dl 2 h after eating [*2*]. As there is evidence that intensive behavioral interventions generally lower the risk

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of diabetes in people with impaired glucose tolerance [*3*–*5*], strategies for people with intermediate hyperglycemia or impaired glucose tolerance are needed urgently in order to reduce cardiovascular risk. Education in self-management of diabetes plays an important role in enabling patients to achieve glycemic control. This in turn, reduces the risk of diabetes and associated complications including microvascular and macrovascular diseases, thereby leading to an improvement in the quality of life [*6*, *7*]. Diabetes patients who are not able to receive diabetes education have more than a four-fold increase in the risk of developing major diabetes complications compared to patients who receive educational interventions [*8*]. In the past, diabetes education tended to focus on gaining knowledge in order to improve self-management. However, knowledge itself does not improve glycemic control, nor does it produce behavioral changes [*9*]. To achieve long-term self-management, changes in the attitudes and motivation of participants are more important than simply increasing knowledge. Effective education programs must therefore be individualized to a person's lifestyle and medical parameters and, most of all, it is important for educators to respect the individual habits of the participants [*3*]. The most important action for improving impaired glucose tolerance or diabetes is lifestyle modification, primarily through diet and physical activity.

We developed a randomized controlled trial for a diabetes prevention program for self-management among Japanese people with impaired glucose tolerance. This involved these people being part of a support group that employed five key self-management skills, including problem solving, decision making, partnerships with health care providers, taking steps to modify behavior, and utilizing resources [*10*]. The aim of this study was to determine the effect of this support group education that incorporated measurement of blood glucose levels by self monitoring of blood glucose (SMBG). This program was then compared to a control program that involved lecture style education on glycemic control in people with impaired glucose tolerance.

Subjects and Methods

Participants

The subjects of the study were selected from an initial group of 36,258 people who underwent annual health checks over a 3-year period at the Public Health Center of Habikino City in Osaka Prefecture. Criteria for inclusion in the study were subjects of impaired glucose tolerance with hemoglobin A1c (HbA1c) levels ≥5.5% to <6.1% between the ages 40 to 70 years who had no prior history of systematic diabetes education. The subjects were further culled to 1,295 who met these criteria, were sent cards or answered a notice in the city newspaper asking them to participate. A total of 100 subjects between the ages of 47–70 (62.3 ± 5.2 years, mean ± SD), with a mean HbA1c level of 5.71 ± 0.41%, who were willing to participate in the study. No subject had a known mental disability. A 100 participants were enrolled in the study and were assigned randomly to either a support group (n = 50) or a control group (n = 50) following stratification randomization method that considered gender, age and weight. The education staff members involved in the intervention were aware of the group assignments. The study protocol was reviewed and approved by the Ethics Committee of the School of Comprehensive Rehabilitation at Osaka Prefecture University. All participants gave written informed consent prior to enrollment in the study. The subjects received education in 8 sequential sessions delivered at regular time intervals over the 6-month period. Outcome variables included changes in weight, body mass index (BMI), HbA1c, and lipid concentrations which were assessed at baseline and at the end of the 6-month sessions. Each group received one of the following group education sessions. The program was administered at Osaka Prefecture University and City Health Center using classrooms for the groups and also individual consultations. Drug therapies were not changed during the study in either group.

The support group education

Educators, registered dietitians and nurses were trained regarding the curriculum and group dynamics before enrolling participants in the study. The group diabetes education program was carried out over a 6-month period and was composed of 8 sessions consisting of 3 h classes, mainly about diet. Group size was set at eight to ten members in order that the sessions were manageable without diminishing the opportunity for expression and individualization within each group. Support in each class was provided by the same dietitian or nurse. Each class consisted of lectures of less than 1 h presented by either a physician who specialized in diabetes, a dentist and dental hygienists, or registered dietitians and physical trainers, while some classes lasted 2 h and involved group support education, group dynamics and individual consultations. Dietary skills taught by dietitians included portion control, eating order (vegetables first and carbohydrates last) and glycemic index, dental care by dentists, and practical day-to-day exercises by physical trainers. Dietary energy goals were calculated by ideal body weight (kg) times 30 kcal for non-obese participants, or ideal body weight (kg) times 25 kcal for obese participants. In particular, the importance of diet self-management was emphasized during two cooking classes held in the first and fifth months of the education period. All participants in the cooking classes measured their blood glucose before and 2 h after the meals by SMBG. The participants were encouraged to use monitoring diaries that involved recording body weight measurements in the morning and evening every day. The participants were set a

goal of reducing body weight by 5% and to graph their individual changes. The primary learning and behavioral outcomes included self-reporting of diet and exercise as well as achieving the behavioral goals. These outcomes were discussed and reported in each class, with support being offered by the educators. In particular, the behavioral goals for diet and exercise were initiated at the first session and evaluated at every follow-up session. As indicated, the curriculum content was participant-centered and structured to address knowledge, skills and attitudes that encouraged, supported, and promoted self-management, thereby ensuring long-term behavior was maintained. Interactive instruction primarily consisted of problem solving for difficulties keeping to diets, meal planning or exercise plans and were expressed and discussed with group members during every class. Educators of each group wrote and gave feedback during all the classes, after monitoring the diaries of each participant, with an emphasis on support and encouragement that focused on positive and neutral reinforcement. The content was sequential, with each session building on the foundation achieved in the previous sessions.

Dietary intake was assessed by food records collected over three days at both baseline and at the end of the study, with pictures taken of each meal. At baseline and study endpoint, all the participants were also required to fill out the Dutch Eating Behaviour Questionnaire (DEBQ), which is an assessment of an individual's eating behavior structure, with separate scales for emotional, external and restrained eating. Emotional eating is eating in response to states of emotional arousal such as fear, anger or anxiety. External eating is eating in response to external food cues such as the sight and smell of food or eating in response to food-related stimuli, while restrained eating is overeating after a period of slimming when the cognitive resolve to diet is abandoned. Physical activity was also measured during the study period by using Kens Activity Monitor Life Corders® (Suzuken, Japan).

Control group education

The group diabetes education program was composed of 8 sessions consisting of 3 h education and individual consultations over a 6-month period and was designed to give lectures to meet the individual needs of the participants. The lectures were given by diabetes specialists, dentists and dental hygienists, dietitians, nurses and physical trainers and included topics such as what is diabetes mellitus and its complications, reducing weight and increasing physical activity, appropriate calories, how to understand nutrition indications on food packages, what to eat at restaurants and daily exercise. The information was basically the same as that provided to the support group, such as how to make qualitative changes in diet and physical activity and to set goals or make plans. However, these lectures were not participant oriented and the educators were not trained specially in group dynamics or coping skills prior to the intervention. Dietary intake was assessed by the Food Frequency Questionnaire (FFQ) at baseline and at the end of the education sessions. Physical activity during the study period was measured using Kens Activity Monitor Life Corders® (Suzuken, Japan).

Measurements

Laboratory data, body weight and BMI were collected on all the participants in both groups who completed the entire education program at baseline and after 6 months. Clinical results of interest included glycemic control assessed by changes in HbA1c and fasting blood glucose (FBG), measured by standard laboratory methods. Lipid concentrations, including total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C) and triglyceride (TG) were measured by enzyme assays.

Statistical analysis

The characteristics of the study participants were calculated and expressed as means ± SD. Changes within each educational group were calculated by determining differences between baseline and after 6-month, with the significance of the mean differences analyzed using paired Student's *t* tests. Comparisons between the two groups were conducted using the χ^2-test for categorical variables and two-sample *t* tests for continuous variables. All analyses were performed using SPSS 15.0 for Windows (SPSS Inc., Chicago, IL). A *p*-value of less than 0.05 was considered statistically significant.

Results

Of the 100 study subjects assigned to the two groups, 92 (92%) completed the entire 6-month sessions. Eight participants (four in each group) withdrew from the study for family or work reasons. The characteristics of the study groups, including gender, age, weight, BMI, HbA1c, FBG, TC, LDL-C, TG and HDL-C are summarized in Table 1. With the exception of HDL-C, the baseline data on the subjects who completed the entire program did not differ significantly between the two groups.

For subjects in the support group who completed the program, weight and BMI decreased significantly after intervention from 57.0 ± 11.2 kg to 54.4 ± 10.9 kg, and 23.5 ± 3.4 to 22.5 ± 3.3, respectively ($p<0.01$). The primary metabolic syndrome characteristic, waist circumference, decreased in the support group from 88.3 ± 10.9 cm to 83.7 ± 10.4 cm. Body weight and BMI also decreased significantly in the control group, from 57.8 ± 10.6 kg to 56.8 ± 10.5 kg and 24.1 ± 3.8 to 23.6 ± 3.9, respectively

Table 1. Baseline characteristics of the two study groups

	Support group (n = 50)	Control group (n = 50)	p
Gender (male/female)	9/41	8/42	0.790
Age (years)	63.2 ± 5.4	61.4 ± 4.8	0.074
Weight (kg)	57.0 ± 11.2	57.8 ± 10.6	0.914
BMI (kg/m^2)	23.5 ± 3.4	24.1 ± 3.8	0.875
HbA1c (%)	5.78 ± 0.35	5.64 ± 0.44	0.075
FBG (mg/dl)	99 ± 9	100 ± 13	0.822
TC (mg/dl)	234 ± 30	232 ± 36	0.721
LDL-C (mg/dl)	143 ± 28	135 ± 32	0.172
TG (mg/dl)	142 ± 80	178 ± 137	0.116
HDL-C (mg/dl)	70 ± 19	63 ± 16	0.038

Data are expressed as either means ± SD or n.

Table 2. Results of laboratory data at baseline and study endpoint in subjects in the two study groups

	Baseline (n = 46)	After 6-month (n = 46)
HbA1c (%)		
Support group	5.77 ± 0.36	5.39 ± 0.24*†
Control group	5.64 ± 0.45	5.73 ± 0.35
FBG (mg/dl)		
Support group	100 ± 9	96 ± 10*†
Control group	99 ± 13	107 ± 20
TC (mg/dl)		
Support group	234 ± 29	220 ± 32*
Control group	230 ± 37	221 ± 36
LDL-C (mg/dl)		
Support group	143 ± 28	126 ± 28*
Control group	131 ± 35	125 ± 31
TG (mg/dl)		
Support group	144 ± 83	112 ± 53*†
Control group	183 ± 139	169 ± 120
HDL-C (mg/dl)		
Support group	70 ± 19	68 ± 16
Control group	62 ± 16	63 ± 16

Data are expressed as means ± SD. Baseline vs endpoint; * p<0.01. Support group vs Control group at study endpoint; † p<0.01.

(p<0.01). The changes in HbA1c, FBG and serum lipid concentrations are presented in Table 2. As this table shows, subjects assigned to the support group had a significant reduction in mean baseline HbA1c of 0.38% by the end of the study (p<0.01), whereas subjects assigned to the control group had no observable reduction but a slight increase in HbA1c at the study endpoint. FBG, TC, LDL-C and TG levels also improved significantly by the end of the study in the support group (p<0.01). Furthermore, HbA1c, FBG and TG levels were significantly lower in the support group than the control group after 6-month (p<0.01). Forty-five (98%) subjects in the support group had lower HbA1c levels and 37 (80%) had decreased LDL-C levels after 6-month. The participants showed a significant reduction from 177 ± 31 mg/dl to 162 ± 32 mg/dl (p<0.05) in the two-hour post-meal blood glucose levels after intervention in the support group.

Energy intake assessed by food records decreased significantly in the support group from 2,014 ± 356 kcal to 1,770 ± 380 kcal per day (p<0.01), whereas no reduction was observed in the control group (1,521 ± 272 kcal to 1,482 ± 211 kcal per day assessed by FFQ). In the support group, consumption of rice and grains (409 ± 102 g to 326 ± 90 g), eggs (52 ± 29 g to 36 ± 22 g) and salt (11.6 ± 2.1 g to 10.4 ± 2.5 g) decreased, while consumption of green vegetables (127 ± 56 g to 236 ± 102 g) and other vegetables (170 ± 55 g to 231 ± 83 g) increased (p<0.01) during the study period. Eating behavior assessed by DEBQ demonstrated that external eating and restrained eating improved in the support group after the intervention (p<0.01). All the participants engaged in regular exercise at least three days a week, however, energy expenditure did not change after the intervention and was not different in the two groups.

Discussion

This study is the first randomized controlled trial for diabetes prevention education among Japanese people with impaired glucose tolerance. This study demonstrates that support group education was very effective for improving glycemic control in Japanese people with impaired glucose tolerance. Compared to the control group, the improvement in glucose control in the support group was marked, while lipid concentrations were also observed to decrease significantly. The average weight loss of approximately 5% in the support group, although not large, led to an improvement

in metabolic control. These results indicate a successful outcome that was enhanced by supportive education delivered in a group setting, utilization of a participant-centered approach, stimulation by other team members and close collaboration between participants and educators [*11*, *12*]. All components of self-management used a written action plan and included educational efforts, individualized exercise programs, realistic dietary goals and team communication. All these components were necessary to express individuality in every class. The plan was written from the perspective of the participants and incorporated their goals in a manner that was concise and easy to achieve [*13*]. In the present study, the support group education program was successful because the process was guided by considering the self-efficacy and readiness to change of the participants. In addition, monitoring diaries were used to ensure the desired outcomes were achieved [*14*]. Food records and taking pictures of each meal for three days at both baseline and at the end of the study complemented the changes in behavior and resulted in a significant reduction in dietary intake in the support group.

Our study demonstrated the importance of support group education that focused especially on SMBG. All participants measured their blood glucose levels by SMBG prior to and two hours after meals to determine BG levels before and after intervention. The effect of the SMBG measurements was to increase enthusiasm in the participants by obtaining "real-time" information on BG levels. The SMBG measurements also helped the participants directly, as they realized the importance of diet, what and how to eat, in addition to becoming more aware of post-meal hyperglycemia. This study used SMBG as an effective and practical tool for people with impaired glucose tolerance. On the other hand, no changes in glycemic control or lipid concentrations were observed in the control group, and no reduction was observed in dietary intake. The FFQ proved to be ineffective for initiating changes in behavior or dietary intake and possibly underestimated actual dietary intake in this study.

Some limitations to our study should be noted. There were several obstacles to the self-management programs, such as a lack of time, finances, health care provisions, confidence or self-efficacy, motivation and non-supportive family and friends. The mean age of the participants who agreed to take part in our study was over 60 years and the majority was females (83%). Although we held education classes on Saturdays and Sundays to attract people of working age and males, most of the participants were retirees. Only 22% of the participants were under 60 years of age. Specific evaluations of health care programs to be administered to younger people, especially males, are therefore needed for diabetes prevention management and metabolic control to succeed. One possible way to allow people who are still working to participate in the education sessions is to have the sessions sponsored by companies. These sessions could be held during lunch time or after five o'clock at the workplaces. However, people who have restricted finances or lack motivation may soon be drawn into support group education as part of the policy of the Japanese government to increase spending on health care. This policy is to be introduced at the start of 2008 and has the aim of reducing the prevalence of the metabolic syndrome and type 2 diabetes in the population by 25% by 2015. A further benefit for many participants in the support group is the friendships created that endured even after the program had ended. This particularly impacted on participants who have little or no family support or who lacked the confidence to achieve and sustain their goals over the long term. The majority of people with Impaired Glucose Tolerance or diabetes mellitus exhibit no symptoms, and therefore it is important to maintain their motivation over time. The low dropout rate in our study indicates that people with Impaired Glucose Tolerance are willing to participate in education programs if the programs are made readily available and if they perceive the benefits of changing their lifestyle.

Secondly, our study needs to involve follow-up care after the 6-month assessment, as the results may have been achieved, in part, by the subjects' awareness of being in a research study [*15*, *16*]. To ensure good outcomes, post-educational programs that enable consultations regarding diet, such as telephone calls, e-mails, or sending digital photos of meals, should be considered and initiated at regular intervals by educators and health providers.

In conclusion, our study showed that support group education can be a more cost-effective method of providing diabetes prevention education, without pharmacologic intervention, when it is carried out in collaboration with educators and team members. In addition, increasing evidence suggests that reducing post-meal plasma glucose levels may be more important for achieving HbA1c goals in the short term. However, studies of longer duration are needed in order to prevent diabetes or postpone the onset of diabetes in people with Impaired Glucose Tolerance.

Acknowledgment

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Abbreviations

BMI, body mass index; FBG, fasting blood glucose; HbA1c, hemoglobin A1c; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; TC, total cholesterol; TG, triglyceride.

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