The Effect of Qi-gong Exercise on the Control of Diabetes Mellitus

糖尿病コントロールにおける気功練習の効果

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Abbreviations:

DM	diabetes mellitus
IDDM	insulin-dependent diabetes mellitus
NIDDM	non-insulin-dependent diabetes mellitus
IGT	impaired glucose tolerance
BG	blood glucose
FBG	fasting blood glucose
CPR	C-peptide
T-Cho	total cholesterol
HDL-Cho	high-density lipoprotein cholesterol
FFA	free fatty acid
BMI	Body Mass Index
TEG	Tokyo University Egogram
CP	Critical Parent personality
NP	Nurturing Parent personality
A	Adult personality
FC	Free Child personality
AC	Adapted Child personality
CMI	Cornell Medical Index-Health Questionnaire
MPI	Maudsley Personality Inventory
MOOD	Mood Inventory
TAS	Toronto Alexithymia Scale
GSES	General Self-Efficacy Scale

Summary:

OBJECTIVE: To examine the effects of Qi-gong exercise, a traditional Chinese health care technique, on patients with Diabetes mellitus. A secondary objective was to investigate individual variations in effects and determine which biological and psychological patient characteristics predict a positive response to Qi-gong exercise.

RESEARCH DESIGN AND METHODS: Five patients with type 1 DM, 27 patients with type 2 DM and three subjects with other types of DM (secondary DM by hepatitis and pancreatitis) were treated with conventional diabetes therapy after an initial metabolic evaluation and biological and psychological testing. Subjects were divided into two treatment groups: the "First Treatment Group" consisting of 22 subjects and the "Second Treatment Group" consisting of 13 subjects. The "Second Treatment Group" was a delayed treatment group and regarded as a control group for the "First Treatment Group". Weekly Qi-gong sessions were held for each group for four months, and subjects were also requested to practice Qi-gong individually. HbA1c levels were measured before and after both treatment periods.

RESULTS: Compared to the control group, the treatment group demonstrated significant improvements ($p<0.01$) in HbA1c level. Psychological improvements were also demonstrated, including the Nurturing

Parent Personality Index on Ego-Gram, and the Fatigue Index and Total score on Mood Inventory. There were no significant changes in Caloric Intake, Caloric Consumption, body mass index (BMI), and lipid metabolism. There was no significant correlation between biological and psychological improvements. The improvement in HbA1c could be predicted using a combination of biological and psychological factors on multiple regression analysis, including pre-HbA1c, Age, BMI, the General Self-Efficacy Scale, and the Toronto Alexithymia Scale.

CONCLUSIONS: This study showed the biological and psychological benefits of Qi-gong exercise on diabetic patients. Additionally, the indications for the Qi-gong exercise on diabetic patients were identified by multiple regression analysis. Qi-gong exercise was found to be a useful adjunctive treatment for diabetes mellitus.

Introduction:

Diabetes mellitus (DM) is one of the most common chronic diseases in Japan and its prevalence is increasing (1). There are reported to be about 7 million type 2 diabetics, and 14 million patients with impaired glucose tolerance (IGT) in Japan (1). The disease is characterized by abnormalities in glucose metabolism. Poor glycemic control may result in severe complications including retinopathy, nephropathy, neuropathy, and cardiovascular and other life-threatening diseases (1).

DM is referred to as a "lifestyle diseases" or "hypokinetic diseases" because both dietary modifications and exercise regulations are important in its treatments (2). However, physical activity offers both benefits and risks for diabetics. When DM is poorly controlled, strenuous exercise can result in marked hyperglycemia and ketosis, and hypoglycemia may be promoted by abundant exogenous insulin or by endogenous insulin stimulated by oral hypoglycemic drugs (3). Therefore, exercise must be carefully planned (4).

Long-term, mildly aerobic exercises, such as slow paced walking, jogging, cycling, and swimming, are usually recommended for DM (2). Aerobic exercise is defined as a mild physical activity below the anaerobic threshold (AT) or lactate threshold (LT). Below this threshold enough oxygen is present that energy from adenosine triphosphate (ATP) is generated with maximum efficiency via oxidative respiration. A balance of the energy income and outgo is maintained during the exercise (5).

Patients with type 2 DM had two physiologic defects: abnormal insulin secretion and resistance to insulin action in target tissues such as muscle and liver. Insulin resistance is characterized as pre-receptor (abnormal insulin or insulin antibodies), receptor (decreased receptor number or diminished binding of insulin; insulin insensitivity), or post-receptor (abnormal signal transduction, especially failure to activate the receptor tyrosine kinase; poor insulin responsiveness), and may exist in combination (6). Lipid metabolism is closely related to this inslin resistance (7). Free fatty acid (FFA), tumor necrosis factor (TNF)-alpha, and other physiologically activate compounds from enlarged fatty cells induce insulin resistance at the receptor and post-receptor levels (7).

In the same way, using euglycemic clamp techniques, the existence of insulin resistance in type 1 DM has been demonstrated (8). This resistance correlates with maximal oxygen uptake and shows the influence of exercise, meaning that aerobic exercise may also be effective in type 1 DM (8).

Another remarkable study investigated the influence of catecholamine (epinephrine) on improvement in insulin sensitivity after long-term physical training (9). The study used a euglycemic insulin clamp technique and was performed in adrenodemedullated trained rats and control rats. Under conditions of physiological hyper-insulinemia, the glucose metabolism of adrenodemedullated trained rats was significantly higher than that of CT. These results suggest that epinephrine decreases insulin sensitivity after physical training. In other words, nonstrenous exercise may be more effective than normal exercise in improving insulin sensitivity (9).

In summary, current studies on exercise regulation of DM suggest that aerobic, nonstrenous exercise is most effective in controlling glycemic metabolism, and may be useful for both type 1 and type 2 DM.

Psychological and social stress have long been known to be risk-factors for poor control in both type 1 and type 2 DM. Both occurrence and exacerbation of the disease are frequently related to events in the broad psychosocial environment (10). The management of the disease process depends in part upon attention to these psychosocial factors occurring in the patient's life. To achieve effective treatment, the aid and assistance of mental health professionals is necessary (11).

Relaxation is one of the most important stress management techniques for reduction of psychosocial stress. It is defined as a set of integrated physiological changes elicited by focusing one's attention on a repetitive mental activity (12). The acute physiological changes associated with the relaxation response are shown in reductions in heart rate, blood pressure, and respiration rate (13). The mechanism of these responses is a decrease in sympathetic nerve activity and a increase in parasympathetic tone (14,15). Accordingly, the relaxation response is thought to have beneficial effects in patients with disorders associated with an exaggerated sympathetic or suppressed parasympathetic activity (16).

The close relationship between the autonomic nervous system and glycemic metabolism has been demonstrated (17-20). Acute administration of epinephrine inhibits both basal insulin and glucose-stimulated insulin release by an alpha-adrenergic mechanism (17). This immediate inhibitory effect on pancreas B-cell function contributes to the hyperglycemia observed during stress states. Even a low dose of epinephrine inhibits the acute insulin response to arginine over a wide range of glucose levels (18). More prolonged epinephrine infusion induced sustained hyperglycemia, resulting from a transient increase in hepatic glucose production and inhibition of metabolic clearance of glucose (19). Epinephrine is a dose-dependent amplifier of arginine-induced glucagon secretion that is also a cause of hyperglycemia (20). Moreover, epinephrine increases transiently plasma free fatty acid (FFA) (19), and catecholamines induce insulin resistance in target tissues by way of beta-adrenergic-receptors (21).

Owing to these studies, there are good theoretical reasons to expect stress management to be of value in clinical management of DM. Many centers in the US already include some form of stress management training as part of their routine education package for people with DM (22). The expected gains from stress management training have been summarized as follows: improved psychological well-being, improved blood glucose control and hence reduced risk of long-term complications, reduced insulin requirements, and a less frequent need to visit clinic (22).

Several case studies suggested that relaxation training may reduce the insulin requirement of patients with type 1 DM (23-26). Many uncontrolled studies also demonstrated the benefits of relaxation training in both type 1 and type 2 DM (27-29). However, the controlled studies that detailed effects of the relaxation techniques on glycemic control have produced inconsistent findings. But most of the studies have demonstrated benefits (30-34), while others have shown no effects (35-36).

We tried to use the Chinese traditional health-promotion exercise "Qi-gong" (pronounced chee-kung) for assisting DM treatments. Qi-gong is regarded as a useful self-management technique for several chronic illnesses and to promote physical and mental fitness (37). It consists of two aspects, controlled synchronized breathing with slow body movements as an aerobic exercise, and relaxation or meditation (37).

Several studies have evaluated the psycho-physiological states brought on by Qi-gong exercise. Mikuni, et al. (38,39) reported the following valuable investigations. To examine the effects of Qi-gong exercise, a treatment group was compared to a group of walkers performing an equivalent amount of exercise. As measured by oxygen requirements, the physical activity of Qi-gong exercise is equivalent to extremely slow paced walking at a speed of 0.8 to 1.0 km/hour on motor-driven treadmill with a 5 degrees slope; about 8.9 ± 1.58 ml/kg/min oxygen uptake or 2.1 to 3.1 METs. Pulse, blood pressure, peripheral circulation, lipid metabolism and blood levels of several stress-related hormones were measured. The results indicated greater improvements in lipid metabolism and stress reduction or relaxation from Qi-gong exercise compared to walking. Thus, Qi-gong is considered to be a relaxed aerobic exercise. For this reason, Qi-gong is suggested to be one of the most beneficial adjunctive treatments for DM.

There is only one study that investigated the effect of Qi-gong exercise on DM (40). Twenty DM patients (type 1 DM; n=2, type 2 DM; n=18, mean age=52.7 ± 7.3) attended daily Qi-gong group exercises for two or three months. Fasting and 30 minute blood glucose (BG) levels after a 75g oral glucose tolerance test (OGTT) decreased significantly post- compared to pre-treatment. Immunoreactive insulin (IRI) levels were not changed, but insulin release indexes (Δ IRI／Δ BG) increased significantly two hours after taking glucose as well as during fasting. Additionally, basal total cholesterol and triglyceride decreased significantly after treatment. It was suggested that the mechanism of the Qi-gong might be both improvement in pancreatic islets B cell function and promotion of glucose utilization in the target cells. However, as this was not a controlled study, the effects of Qi-gong exercise are still unclear.

The present investigation was designed as a controlled study, and two comparisons were made. Subjects were divided into two treatment groups, the "First Treatment Group" and the "Second Treatment Group (Delayed Treatment Group)". The treatment phase of the "First Treatment Group" was compared with the no-treatment phase of the "Second Treatment Group" that was waiting for the treatment. Next, the treatment phase of the "Second Treatment Group" was compared with its own previous no-treatment phase. During four-month long-term treatment periods, both biological and psychological measures were examined, and the correlation between these two aspects was assessed. A further distinctive feature of this study was the multiple regression analysis to indicate the psycho-physiological characteristics of diabetic patients for whom Qi-gong exercise is useful.

Research Design and Methods:

Subjects:

Subjects were recruited from an urban diabetes clinic in Kanagawa prefecture next to Tokyo. From January to February, 1996, 554 outpatients were selected who did not have any of the following exclusion criteria: age over 70 years, serious hearing loss, psychiatric illness (e.g. schizophrenia, depression, personality disorder), or major complications that would affect the performance of diabetic self-care activities (e.g. renal disease, neurological problem, retinopathy). Subjects were requested to complete questionnaires about their experience with and image of Qi-gong. Of the 554 eligible patients, 293 (53%) returned the questionnaires and 79 expressed a wish to attend the Qi-gong group sessions. Informed consent was obtained from all 79 patients. Subjects were informed that the aims of the study were investigation of the biological and psychological effects of Qi-gong on diabetes mellitus (DM). Fifty patients were selected at random, and divided into two equal groups of matched sex, age and the diagnostic type of DM. These two groups were designated the "First Treatment Group" and the "Second Treatment Group".

Three patients in the "First Treatment Group" and 12 patients in the "Second Treatment Group" who could not continue the four-month Qi-gong group sessions were excluded. Out of the total of 15 patients, 11 patients discontinued the group sessions for their business or family reasons. Two patients retired because of their hearing loss, and the remaining two retired because of the traffic accidents or eye-ground bleeding.

Finally, a total of 35 of patients (5 with type 1 DM, 27 with type 2 DM, and 3 with other form of DM such as secondary DM by hepatitis and pancreatitis) were analyzed in this study. The "First Treatment Group" consisted of 22 patients (7 men and 15 women, average age of 63.1±9.0), and the "Second Treatment Group" included 13 patients (5 men and 8 women, average age of 57.5±9.6). Patient characteristics are shown in Table 1. All patients had previously experienced group diabetic education.

Study protocol (Figure.1):

From March 3 to Jun 29, 1996, the "First Treatment Group" was requested to attend weekly Qi-gong group sessions (total of 17 sessions), practice by themselves, and keep a diary of their training time. During this period, the "Second Treatment Group" was not undergoing Qi-gong treatment and was considered a control group. From August 24 to December 21, 1996, the "Second Treatment Group" were requested to attend the Qi-gong group sessions (total of 17 sessions), practice by themselves daily and keep a diary in the same way as the "First Treatment Group".

Biological and psychological examinations were performed on both groups and a total of three times from February to March, July to August, and December, 1996 to January, 1997.

Conventional diabetes therapies such as pharmacological therapy (insulin or oral hypoglycemics), dietary modification and physical activity, were not modified during the study period.

Qi-gong Session:

In the weekly two hour Qi-gong group sessions, the following three techniques were taught by a Chinese Qi-gong doctor. The first was "Dynamic Qi-gong" which is an active breathing exercise with large and slow movement of the arms and legs in standing posture that looks like Tai-jii; Tai-Kyoku-Ken in Japanese. The dynamic Qi-gong used in this session is called "Tiao-yang-zang-fu-gong", which means the exercise to control and nourish one's internal organs. The second was "Static Qi-gong" called "Fang-song-gong". This is a relaxation technique used to put the whole body in a comfortable and natural state through step-by-step and rhythmical relaxation of all parts of the body coordinated by silent reading of the word "relax" in a seated or lying posture. And the third was "Self-massage and Acupressure Qi-gong" which involves massaging and pressing slowly and softly on points of the channel-collateral system in traditional Chinese medicine. In this session, the following pressure points were chosen for diabetes treatment using the principles of Chinese medicine: around the orbits, waist, lower leg and sole of the foot.

Assessments:

Level of glycemic control was assessed by glycosylated hemoglobin (HbA1c) assay. Values of HbA1c were determined according to the high performance liquid chromatography (HPLC) method. The range for normal, non-diabetic patients at the Hoken-Kagaku Laboratory is from 4.3% to 5.8%. Other biological measures were fasting blood glucose (FBS), C-peptide (CPR), total cholesterol (T-Cho), high-density lipoprotein cholesterol (HDL-Cho), the ratio of 'HDL-Cho／T-Cho', body mass index (BMI), caloric intake calculated by three-day diet records, and caloric consumption calculated by calorie-counter (Calorie-counter Select, Suzuken company).

Psychological measures included the following scales: the Maudsley Personality Inventory (41,42) which measures neurotic or extroverted personality, and the Tokyo University Egogram (43-45) which is a bar-chart analysis of an individual's functional ego states based on transactional analysis theory (46). The Cornell Medical Index-Health Questionnaire (47,48) which measures individual's psycho-physical symptoms, and the Toronto Alexithymia Scale (49,50) which measures the difficulty in identifying and describing their own emotions were also used. The General Self-Efficacy Scale (51) which measures self-confidence based on Bandura's social learning theory, and the Mood Inventory (52) which measures tensive, refreshing, fatigued, depressive, and anxious moods over a short time were also assessed. The following three additional items were assessed before the sessions to examine their expectation from the Qi-gong exercise. "Do you think that Qi-gong is useful for the treatment of various diseases?", "Do you think that Qi-gong is useful for the treatment for diabetes mellitus?", and "Do you expect an effect from this Qi-gong session?". Subjects responded to these items on a 5-point Likert scale ranging from "not at all" to "extremely".

Data Analysis:

Study 1: The effects of Qi-gong exercise.

(Ⅰ) Comparison of the criterion variables and baseline biological data between "First Treatment Group" and "Second Treatment Group" prior to treatment in order to confirm that there is no difference between the two groups.

A chi-square test or Fisher's exact test were performed to compare the following criterion variables between the two groups: gender, diagnosis (type 1, type 2, or others), and pharmacological treatment regimen (Insulin, Sulfonylurea, and α -glucosidase inhibiter). A two sample t-test or Wilcoxon rank sum test were performed to confirm the equality of the following pre-treatment biological data between the two groups: age, duration of illness, pre-HbA1c, body mass index (BMI), Caloric Intake, and Caloric Consumption. The FREQ, and TTEST or NPAR1WAY procedures of the Statistical Analysis System (SAS) (53) were used for these analyses.

Comparison of the criterion variables and baseline biological data between these "First and Second Treatment Group (n=35)" and the excluded subjects group (n=15) were also analyzed.

A chi-square test or Fisher's exact test were performed to compare the criterion variables (gender and diagnostic type) between the two groups. A two sample t-test or Wilcoxon rank sum test were performed to compare the baseline biological and psychological data between the two groups. The FREQ, and TTEST or NPAR1WAY procedures of the SAS were used for these analyses.

(Ⅱ) Comparison of the changes of pre- and post-HbA1c, between the "First Treatment Group" after Qi-gong treatment ('A' in Figure 1; n=22) and the "Second Treatment Group" during its no-treatment control period ('B' in Figure 1; n=13).

A two-way layout analysis of variance (Two-way ANOVA) was performed. The GLM procedure of the SAS was used for this analysis.

Next, the paired t-test analysis was performed to compare the pre- and post-HbA1c in each period. The univariate model (UNIVARIATE) procedure of the SAS was used for these analyses.

Finally, the covariance analysis, using pre-HbA1c as a covariate, was performed. The general linear model (GLM) procedure of the SAS was used for this analysis.

(Ⅲ) Comparison of the changes of pre- to post-HbA1c, between the no-treatment period ('B' in Figure.1) and the Qi-gong treatment period ('C' in Figure.1) in the same "Second Treatment Group" (n=13).

A one-way layout analysis of variance (One-way ANOVA) was performed. The GLM procedure of the SAS was used for this analysis.

Next, paired t-test analysis was performed to compare the pre- to post-HbA1c in each period. The univariate model (UNIVARIATE) procedure of the SAS was used for these analyses.

(Ⅳ) Comparison of the changes of other biological and psychological factors before and after treatment in the combined data of "First and Second Treatment Group" ('A' + 'C' in Figure.1) (n=35).

The paired t-test or Wilcoxon signed-ranks test was performed. The univariate models (UNIVARIATE) procedure of the SAS was used for these analyses.

(V) Correlation between the changes of HbA1c and the following items: psychological factors, the index of expectation in the session, and the average of self-training time in the combined data of "First and Second Treatment Group" ('A'+'B' in Figure.1) (n=35). The CORR procedure of the SAS was used for these analyses.

(VI) Comparison of the changes of pre- to post-HbA1c, between the subjects who continued the Qi-gong exercise (n=12) and the subjects who did not continue the exercise (n=10) in follow-up self-training period ('D' in Figure.1) in the "First Treatment Group".

The t-test analysis was performed to compare the pre- and post-HbA1c in each subjects. The univariate model (UNIVARIATE) procedure of the SAS was used for these analyses.

Study 2: Prediction of improvements in HbA1c using biological and psychological parameters measured before treatment in the combined data of the "First and Second Treatment Group" ('A'+'B' in Figure.1) (n=35).

Multiple regression analysis was conducted in order to evaluate the changes of pre- to post-HbA1c, using a combination of biological and psychological factors as predictor variables. The REG procedure of SAS was used for these analyses.

Results:

Study 1: The effects of Qi-gong exercise.

(I) Comparison of the criterion variables and baseline biological data between "First Treatment Group" and "Second Treatment Group" before treatment (Table 1).

There were no significant differences in any criterion variables including gender, age, duration of illness, diagnosis (type 1, type 2, or others), and pharmacological treatment regimen (Insulin, Sulfonylurea, and α - glucosidase inhibiter). The following pre-treatment biological data were also without significant differences: HbA1c, body mass index (BMI), caloric intake, and caloric consumption. The values of HbA1c before treatment ranged from 5.2 to 12.3% (Mean±SD; 8.1±1.6, n=35). Based on this analysis, the two groups "First and Second Treatment Group" were considered equivalent pre-treatment. Each patient's profile and biological data are shown in Table 2-1 and Table 2-2.

There were no significant differences in the following criterion variables and baseline bio-psychological data between the "First and Second Treatment Group (n=35)" and the excluded subjects group (n=15): gender, diagnostic type, age, HbA1c, the Tokyo University Egogram (TEG), the Cornell Medical Index-Health Questionnaire (CMI), the Maudsley Personality Inventory (MPI), the Toronto Alexithymia Scale (TAS), and the General Self-Efficacy Scale (GSES).

HbA1c results were shown in Table 3 and Figure 2. The average HbA1c level in the "First Treatment Group" changed as follows: 8.17 ± 1.71 in February-March before treatment, 7.42 ± 1.12 in July-August after treatment, and 7.47 ± 1.21 in December-January after the follow-up period. The average HbA1c level in the "Second Treatment Group" changes as follows: 8.09 ± 1.69 in February-March before the control period, 8.02 ± 1.47 in July-August before treatment, and 7.08 ± 1.01 in December-January after treatment.

(Ⅱ) Comparison of changes in HbA1c, between the Qi-gong session period of the "First Treatment Group" ('A' in Figure.1) and the control period of the "Second Treatment Group" ('B' in Figure.1).

By the two way layout 2 × 2 (group × time) analysis of variance (ANOVA), a significant interaction was ascertained ($F=4.85$, $p=0.0348 < 0.05$). Significant improvements in HbA1c levels before and after treatment in the "First Treatment Group" ('A'; n=22) was confirmed by paired t-test analysis ($p=0.0006 < 0.001$). In contrast, the HbA1c levels of the "Second Treatment Group" ('B'; n=13) during the control period did not change significantly by paired t-test analysis ($p=0.76$). The results of this t-test analysis are shown in Table 3. A covariance analysis, with pre-HbA1c as a covariate, was performed. There were significant improvements in HbA1c levels in the "First Treatment Group", compared to the control period of the "Second Treatment Group" ($p=0.0069 < 0.01$).

Restricting the analysis to subjects with type 2 DM, by the two way layout 2×2 (group×time) analysis of variance (ANOVA), a trend of interaction was confirmed ($F=3.95$, $p=0.0579 < 0.10$). Significant improvements in HbA1c levels of type2 DM before and after the treatment in the "First Treatment Group" ('A'; n=16) was determined by paired t-test analysis ($p=0.0014 < 0.005$). In contrast, the HbA1c levels of the "Second Treatment Group" ('B'; n=11) during the control period did not change by paired t-test analysis ($p=0.72$). The covariance analysis, using pre-HbA1c as a covariate, also showed significant improvements ($p=0.0152 < 0.05$).

(Ⅲ) Comparison of changes in HbA1c, between the control period ('B' in Figure 1) and the Qi-gong session period ('C' in Figure 1) within the "Second Treatment Group".

Using the one way layout (3-conditions) analysis of variance (ANOVA), a significant main effects of condition was ascertained ($F=10.76$, $p=0.0005 < 0.001$). No change was found during the control period ('B'; $p=0.76$), but significant improvements were ascertained during the Qi-gong session period in the "Second Treatment Group" by paired t-test analysis ('C'; $p=0.0003 < 0.0005$) (Table 3).

(Ⅳ) Comparison of changes in biological and psychological factors between pre- and post-treatment in the combined data of the "First and Second Treatment Group" ('A' + 'C' in Figure 1) (n=35).

The results of the biological data are shown in Table 4. Significant improvements in HbA1c levels were demonstrated in the 35 DM patients ($p=0.0001$) and the 27 type 2 DM patients ($p=0.0001$) by paired t-test analysis. The number of type 1 DM patients (n=5) and other types of DM (n=3) were too small to analyze. Significant improvements in fasting blood glucose

(FBS) were also demonstrated ($p=0.04$) by Wilcoxon signed-ranks test. No change was found in all other biological factors including C-peptide (CPR), total cholesterol (T-Cho), high-density lipoprotein cholesterol (HDL-Cho), the ratio of 'HDL-Cho／T-Cho', body mass index (BMI), caloric intake, or caloric consumption.

Psychological improvements were demonstrated, including the Nurturing Parent (NP) personality index on Ego-Gram ($p=0.002 < 0.005$), and the Fatigue (F) index ($p=0.03 < 0.05$) and total scores ($p=0.025 < 0.05$) on the Mood Inventory (MOOD). However, there were no significant changes in any other psychological tests, including the Maudsley Personality Inventory (MPI), "Critical Parent (CP), Adult (A), Free Child (FC), Adapted Child (AC)" personality index on the Tokyo University Egogram (TEG), the Cornell Medical Index-Health Questionnaire (CMI), the Toronto Alexithymia Scale (TAS), the General Self-Efficacy Scale (GSES), and "Tensive, Refreshing, Depressive, and Anxious mood index" on the Mood Inventory (MOOD). These results of the psychological data are shown in Table 5.

(V) Correlation between the changes in HbA1c and the following variables; the psychological factors, the index of expectation in the session, and the average self-training time in the combined data of the "First and Second Treatment Group" ('A' + 'C' in Figure 1; n=35) (Table 6) .

No significant correlation between the changes of HbA1c and the psychological factors, and the index of expectation in the session was identified. It therefore appeared that there was no association between improvement in HbA1c and improvement in psychological factors.

The average self-training time was 174.4±122.6 minutes a week. Figure 3 shows the plot of correlation between changes in HbA1c level and average self-training time. The data of two patients whose self-training time was over 500 min/week was considered to be outlying value, because the pre-HbA1c of these two patients were 5.3 and 6.3 respectively that were within the normal range. With the exclusion of these two data, there was no significant correlation between the changes of HbA1c and average self-training time.

(Ⅵ) Comparison of the changes of pre- to post-HbA1c, between the subjects who continued the Qi-gong exercise (n=12) and the subjects who discontinued the exercise (n=10) in follow-up self-training period ('D' in Figure.1) in the "First Treatment Group".

The average change of HbA1c level of the continuing subjects was 0.00±0.48%, and that of discontinuing subjects was 0.12±0.35%. There was no significant difference between these two groups.

Study 2: Prediction of improvements in HbA1c using biological and psychological parameters measured before treatment in the combined data of the "First and Second Treatment Group" ('A'+'B' in Figure.1) (n=35).

The multiple regression analysis was conducted in order to evaluate HbA1c improvement, with the combination of biological and psychological factors as predictor variables. All subjects in the "First and Second

Treatment Group"(n=35) were included for this analysis. The dependent variable was 'change in HbA1c = post-treatment HbA1c - pre-treatment HbA1c', and was calculated from the combined data of the "First and Second Treatment Group" before and after the Qi-gong sessions. ('A' + 'C' in Figure 1)

First, data of six biological parameters (age, duration of illness, pre-treatment HbA1c, body mass index, caloric intake, and caloric consumption) were entered in the stepwise multiple regression model as independent variables, using a criterion of 0.10 significance for inclusion and exclusion. On the results of this analysis, pre-treatment HbA1c demonstrated the highest value of R-squared (R*2=0.65, p=0.0001). The second highest value of R-squared was age (R*2=0.07, p=0.009), and the third was body mass index (BMI) (R*2=0.07, p=0.003) (Table 7).

Psychological variables were then added one by one in the multiple regression model, adjusted by the three biological dependent variables pre-treatment HbA1c, age, and body mass index (BMI). The results were shown in Table 8. The R-squared at a 0.10 significance level was obtained by all three factors of the General Self-Efficacy Scale (GSES) (Factor 1; R*2=0.03, p=0.08, Factor 2; R*2=0.07, p=0.005, Factor 3; R*2=0.04, p=0.03, Total Score; R*2=0.07, p=0.003), the Toronto Alexithymia Scale (TAS) (R*2=0.04, p=0.03), and the extroverted personality index of the Maudsley Personality Inventory (MPI) (R*2=0.03, p=0.06).

Finally, the following three biological variables and four psychological variables were selected to put into the multiple regression analysis with stepwise forward selection method, using a criterion of 0.10 significance for inclusion and exclusion, in order to obtain the maximum value of R-squared: pre-treatment HbA1c, age, and BMI, the first factor of the GSES (indicating a lower level of anxiety about making mistake), the second factor of the GSES (indicating a higher level of aggressiveness of action), the third factor of the GSES (indicating a higher level of social locus of ability), the TAS, and the extroverted personality index of the MPI. Since the total score of the GSES had a high correlation with each three factors of the GSES, we did not enter it into this model. This analysis was conducted to determine which combination of predictor variables best predicted the change in HbA1c after Qi-gong treatment.

Selection of variables resulted in a combination of five variables that were most relevant or concurrent to the change of HbA1c: pre-treatment HbA1c (R*2=0.58, p=0.0001), age (R*2=0.06, p=0.003), and BMI (R*2=0.06, p=0.06) as biological variables, and the second factor of the GSES (R*2=0.08, p=0.01), and the TAS (R*=0.03, p=0.06) as the psychological variables. The total variance explained by these five variables was 0.808 (R*2=0.808, F=24.36, p=0.0001). The prediction equation was '(change of HbA1c)= 0.650 - (0.364*pre-HbA1c) - (0.154*GSES-f2) + (0.023*Age) - (0.022*BMI) + (0.016*TAS)'. Table 9 shows these results.

Discussion:

Study 1:

[Biological Effects]

The significant improvements in HbA1c in this study indicate the value of Qi-gong exercise as an adjunctive treatment for DM. There was no change in daily average caloric intake, caloric consumption or dose of anti-diabetic medications. It is reasonable to conclude that the decline of HbA1c levels was caused by the weekly group and daily individual Qi-gong training.

The lack of correlation between improvement in HbA1c and psychological data indicates that the glycemic control might not be caused by any improvement in psychological state. Patients who could improve the glycemic control using Qi-gong appear to be distinct from those who experience psychological improvement.

The absence of correlation between improvement in HbA1c and any expectations of benefit from Qi-gong suggests that the improvement in glycemic control should not be regarded as a placebo effect (54).

There was no significant correlation between self-training time and improvement in HbA1c. The long self-training time may not necessarily show how skillfully those patients mastered Qi-gong exercise. It is the limitation of this study that there was no parameter to judge the ability level of Qi-gong exercise.

In the follow-up self-training period, there was no new change in HbA1c level in the group that continuing Qi-gong self-training. Additionally, there was no clear differences between the continuing group and discontinuing group. Because there were no Qi-gong group sessions in this period, it is difficult to judge how correctly they trained the Qi-gong exercise by themselves. This result may suggest the importance of group sessions. Group sessions may play a role of social and technical support or keep the motivation to continue the Qi-gong exercise. In any evident, it can be presumed that the larger sample size and the longer duration of follow-up period will produce a difference between those continuing and discontinuing groups.

Measured by oxygen requirements, Mikuni, et al. (38,39) reported that the physical activity of Qi-gong exercise is about 8.90±1.58 ml/kg/min oxygen uptake or 2.1 to 3.1 METs. This activity equivalent to slow paced walking at a speed of about 3.3km/hour or 55m/min. The kind of Qi-gong exercise in Mikuni's research was called "Swai-show-gong", and the Qi-gong exercise in this present study was called "Tiao-yang-zang-fu-gong". As the physical activity of these two kinds of Qi-gong is different, the aspect as aerobic exercise of the present Qi-gong exercise is not clear. The mechanism of the effectiveness of Qi-gong exercise for DM is still unclear.

[Psychological Effects]

The significant improvement in Mood Inventory (52), especially in the sense of fatigue, suggests that Qi-gong has an aspect of psychological relaxation.

According to previous studies using electroencepharography (EEG), Qi-gong creates an unusual state of excitation that is neither wakefulness nor sleep. In contrast to the ordinary resting state with eyes closed, alpha activity occurred predominantly in the anterior regions, and the peak frequency of the alpha rhythm was slower during Qi-gong exercise (55,56). It is also reported that Qi-gong causes an enhancement of brainstem-auditory-evoked response with a concomitant depression of cortical responses (57). Psychological relaxation induced by Qi-gong exercise may be caused by these changes in brain function.

In the recent controlled studies that described the effects of relaxation training for DM, Surwit & Feinglos (31) showed that the relaxation-induced improvement in glucose tolerance was associated with decreased plasema cortisol, Lane JD, et al. (33) and Aikens JE, et al. (34) demonstrated that the relaxation training was mostly effective in subgroup of stress-responsive patients. Since the aspect of physiological relaxation of Qi-gong exercise was identified (38,39), it is reasonable to expect the benefit of Qi-gong exercise for DM. In our study, one of the reasons of the improvements in glycemic control was suggested to be this relaxation response. But there was no correlation betweeen improvement in HbA1c and MOOD Inventory; the psychological effects. Although the aspect of psychological relaxation of Qi-gong was indicated in this study, the aspect of physiological relaxation was not identified. This is one of the limitations of this study to evaluate the mechanism of effectiveness of the Qi-gong exercise for Diabetic patients.

It is difficult to determine the significance of an increase in the Nurturing Parent (NP) personality index on the Tokyo University Ego-Gram (TEG) after Qi-gong exercise. The Ego-Gram is a bar-chart analysis of an individual's functional ego-state based on the transactional analysis theory (46). This is a theory of human personality, relationships, and communication developed by Eric Berne (58). Ego-sate is defined as a consistent pattern of feeling and experience directly related to a corresponding pattern of behavior (59). This model recognizes the following five distinct ego-states: Critical Parent (CP), Nurturing Parent (NP), Adults (A), Free Child (FC), and Adapted Child (AC). Each state has its own way of feeling and behaving. The character of CP is a symbol of fatherhood and is a behavior copied from a parent's controlling, criticizing and telling their child what to do. On the other hand, the character of NP is a symbol of motherhood and is a behavior copied from a parent's looking after their child. A higher NP indicates more sympathy, compassion, thoughtfulness, protection, and acceptance.

Previous studies have reported a reasonable correlation between certain sub-scales of TEG, Cornell Medical Index (CMI) (47,48), Profile of Mood States (POMS) (60,61), and Self-rating Depression Scale (SDS) (62). The neurotic subgroup assessed by CMI had higher CP and AC, but lower NP scores compared to the normal subgroup. NP on the TEG correlated negatively with the score of M-R in CMI: psychological symptoms such as maladjustment, depression, anxiety, irritability, aggression, and tension. NP also correlated negatively with scores for depression, fatigue, and confusion, but correlated positively with vitality on the POMS. Moreover, NP showed a negative correlation with the depression score on the SDS (45,63,64). A significant increase in FC and an increasing trend in NP have been described with psychotherapy in neurotic patients (65). From these observations, the meaning of an increased NP may be a certain improvement in psychological health.

In view of traditional Chinese philosophy and religion, the strengthening of the NP character is interesting. Development of a feeling of sympathy and compassion toward the surroundings and indeed the whole universe is one of the most important purposes of the Qi-gong philosophy: Taoism. In order to obtain a long life and good fortune, it is said that a man must realize the close connection between the universe and himself as a human being: the macro-cosmos and the micro-cosmos. This realization may lead to feelings of gratitude for all life and the nature that supports us.

It was concluded that Qi-gong exercise has the effect of promoting psychological wellbeing.

Although this conclusion may be true, the present study cannot completely rule out the possibility that the psychological benefits of Qi-gong exercise may include some placebo effect. Desharnais, et al. (66) demonstrated the placebo effect of aerobic exercise. A controlled study was conducted with 48 healthy young adults engaged in a supervised 10-week aerobic exercise program. One-half of the subjects were led to believe that their program was specifically designed to improve psychological well-being, whereas no such intervention was made with the other half. The results showed similar significant increases in fitness levels in both groups, but self-esteem as an indicator of psychological well-being was significantly improved over time in the experimental group but not in the control group. These findings provide evidence to support the notion that the placebo effect is a powerful psychological mechanism in itself. Because the Qi-gong instructor in our study described the possibility of the benefits of Qi-gong exercise, the psychological improvement we found may include some placebo effects.

Study 2:

Using the three biological variables: pre-treatment HbA1c (58% variance), age (6% variance), and body mass index (6% variance), and the two psychological variables: Self-Efficacy (8% variance) and Alexithymia (3% variance), the improvement in HbA1c through Qi-gong exercise was highly predictable in this study (total 81% variance).

Johnson (67) pointed out the importance of identifying individual differences in bio-psycho-social characteristics of DM patients in order to find more effective combinations of therapies. Some studies have described the predictability of DM control by multivariate analysis of bio-psycho-social variables (68-73).

[pre-HbA1c and DM control]

The strongest predictor was pre-treatment HbA1c, that is, the degree of diabetic control before Qi-gong exercise. The poorer the glycemic control was, the greater the benefit of Qi-gong exercise. Many studies have described pre-treatment HbA1c as an important variable for predicting HbA1c on follow-up (74-76).

Dunn, et al. (74) examined the impact of a formal diabetes education program on diabetes-specific knowledge and attitude, and also examined the relationship between patients' personalities and metabolic control of the disease over a 15-months period. Three-hundred and nine patients, with a mean age of 49±15 years, were enrolled in the study. Stepwise regression analysis was used to predict improvement in HbA1c. A further 8% variance was explained by male gender, a negative shift in attitude towards diabetes education, more recent diagnosis and increased knowledge. Pre-treatment HbA1c was the strongest predictor and had 60% variance. Larger improvements in HbA1c occurred in patients who had poorer control at entry in the educational program.

Kavanagh, et al. (75) aimed to predict adherence to diabetic treatment regimens and sustained diabetic control. Sixty-three adult outpatients were requested to complete a questionnaire on diabetic history, current treatment, diabetic control, compliance, and Self-efficacy about compliance with treatment. A stepwise multiple regression analysis to predict HbA1c levels after treatment used pre-treatment measures of diabetic control (pre-HbA1c; 23% variance), treatment type (19% variance), and Self-efficacy (9% variance), which together predicted about 50% of the variance. Niemcryk, et al. (76) demonstrated similar results. Pre-treatment HbA1c, gender, and anxiety significantly predicted the post-treatment HbA1c level (total 80% variance). Our study supports the above conclusions.

It is possible that at least some of this prediction could be accounted for by the regression to the mean. The theory of this regression meany is one of the phenomenon in epidemiology (77-79). It means the tendency for individuals with very high or very low scores on one measurement of a variable to have scores closer to the center of the distribution when measured a second time.

[Age and DM control]

Our results showed that greater benefits from Qi-gong exercise may be obtained by younger patients. This may be because the younger body has more flexible regulation of homeostasis in the endocrine and autonomic nervous systems. Some studies have demonstrated "age" to be a major predictor on multiple regression analysis. Glasgow, et al. (69) reported that both specific social learning factors (knowledge, Self-Efficacy, self-motivation, problem solving and refusal skills, and environmental support), and the basic patients profile (treatment type, duration of illness, gender, and age) were the most important variables for predicting the post-treatment HbA1c level. Rapley (80) also reported that metabolic control of DM patients was predicted by hardiness (the capacity to resist psychosocial stress), diabetes type, gender, and age. Our results support these findings.

[Body Mass Index and DM control]

Since the p-values of body mass index in the results of multiple regression analysis shown in Table 9 are over 0.05, the limitations of the discussion about this valuable must be noted. Even so, the present study showed that greater benefits of Qi-gong exercise may be achieved by patients who are rather obese. This result suggested to support our hypothesis that Qi-gong exercise is useful for diabetes mellitus because it causes aerobic exercise and relaxation.

Both lipid consumption and improvement in insulin sensitivity and responsiveness are attained only by aerobic exercise, not by anaerobic exercise (81). Regarding lipid metabolism during the Qi-gong exercise, there was no change in body mass index (BMI), weight, total cholesterol, HDL-cholesterol, or the ratio of 'HDL-Cho ／ T-Cho' during treatment. Although obesity is the most common cause of the insulin resistance, glycemic metabolism was controlled without any change in BMI and lipid metabolism in our study. These results support the recent finding (82) that improvement in insulin resistance caused by exercise does not always relate to changes in body weight. Long-term mild aerobic exercise, which did not influence BMI, appears to improve insulin action in both glycemic and lipid metabolism and to increase the metabolic clearance of insulin (82).

Compared with the slow-paced walking on motorized treadmill test with the same oxygen requirement, Qi-gong exercise significantly decreased pulse rate and systolic and diastolic blood pressure 30 minutes after the Qi-gong exercise (38). Peripheral blood circulation measured by doppler ultrasound was also significantly improved (38). Although there was no difference in the reduction of blood cortisol level, the blood level of epinephrine, norepinephrine and growth hormone significantly decreased 30 minutes after Qi-gong exercise (39). These findings demonstrate the physiological relaxation caused by Qi-gong exercise. Another remarkable finding is the report that Qi-gong exercise is superior to other aerobic exercise in lipid and carbohydrate metabolism. The total blood cholesterol, lactic acid, and the ratio of lactic acid and pyruvic acid (L／P) significantly decreased 30 minutes after Qi-gong exercise compared to walking (38,39).

Thus, Qi-gong is especially suitable for diabetes patients with obesity.

[Self-Efficacy and DM control]

The present study indicates that the higher Self-efficacy, especially the factor of "Positiveness in behavior", resulted in better DM control from Qi-gong exercise.

In the present study, the General Self-Efficacy Scale (GSES) (51) was used. There are few scales (83) in Japan that evaluate the Self-efficacy, however, the GSES has been most widely used. High reliability in adults and strong discriminant validity between normal and clinical subjects such as patients with depression have also been identified (84,85). The GSES include three factors including "Anxiety concerning failure; Factor 1", "Positiveness in behavior; Factor 2", and "Social locus of ability; Factor 3".

Initially, the concept of "Self-efficacy" grew out of the social learning theory developed by Bandura (86). This theory postulates a system of reciprocal determinism, a dynamic balance between environment, behavior, and specific modifiable personal variables that include cognition and emotional state. The initiation and regulation of transactions in an environment are governed by judgment of one's own expectations; "Self-efficacy". Self-judged efficacy also determines how much effort people will expend and how long they will persist in the face of obstacles or aversive experiences. The stronger the perceived Self-efficacy is, the more vigorous and persistent the efforts are. Since efficacy expectations are not accompaniments but determinants of behavior, changes in behavior result from changes in Self-efficacy. Behavior-modification programs succeed according to the extent to which people alter their Self-efficacy (87,88).

The theory of "Self-efficacy" has been widely applied to various areas, such as training programs to develop social skills (89), reduce cigarette-smoking (90,91), increase condom use to prevent the spread of HIV (92), weight control (93), and rehabilitation of low back pain (94). Thus, it has been demonstrated that Self-efficacy has important theoretical and practical applications for health promotion and disease prevention (95,96).

It is reasonable to postulate that Self-efficacy may play an important role in diabetic control. Kim, et al. (97) reported that the group of type 2 DM patients who had the high motivation toward a psycho-educational program showed high Self-efficacy especially in the "Positiveness in behavior" scale, and showed a significant decrease in HbA1c. Kavanagh, et al. (75) reported that Self-efficacy was one of the most important variables in predicting adherence to diabetic treatment regimens and sustained diabetic control. Our study supports these results.

[Alexithymia and DM control]

Since the p-values of Alexithymia in the results of multiple regression analysis shown in Table 9 are over 0.05, the limitations of the discussion about this valuable must be noted. Even so, the present study may indicate that lower Alexithymia causes better DM control from Qi-gong exercise.

The Toronto Alexithymia Scale (TAS) (49,50) was used to measure Alexithymia. Of the various techniques used to measure Alexithymia, the TAS has been most widely used (98,99). Multiple studies on its validity and reliability have shown that TAS has internal consistency, high test-retest reliability, construct validity, and criterion validity (100-102).

Initially, the term "Alexithymia" was a psychoanalytically-derived concept. Alexithymia patients have difficulty in identifying and describing feelings, their cognitive style is concrete and reality-based, and they have impoverished inner emotional and fantasy lives (103,104). These characteristics were originally found in persons with classical psychosomatic disorders such as ulcerative colitis, peptic ulcer, and rheumatoid arthritis (105). However, recent studies have shown high rates of Alexithymia among patients with post-traumatic stress disorder (106-108), eating disorders (109), substance use disorders (110), silent myocardial ischemia (111), coronary artery spasm (112), chronic pain (113-115), and hemodialysis (116-119).

Diabetes has long been identified as a disease that may include psychological disturbance. From the viewpoint of the concept of Alexithymia, among uncontrolled DM patients the lack of awareness of their own psycho-somatic symptoms has been pointed out in historical clinical reports. It is said that the restraint of emotional expression in diabetes makes it more difficult to regulate glucose level (120).

Abramson, et al. (121) examined the hypothesis that diabetes would be more Alexithymic than controls. Thirty type 1 DM patients, with a mean age 32.9, were recruited through newspapers, and 49 similarity aged normal subjects were recruited as a control group. The number of emotional words in six imaginative (Thematic Apperception Test; TAT) stories produced by subjects viewing six pictures was used as the measure of Alexithymia, with a result of fewer emotional words reflecting Alexithymic characteristics. The percentage of glycosylated hemoglobin (HbA1c) was measured to check metabolic control. DM patients were found to be significantly more Alexithymic than controls. Furthermore, fewer emotional words, corresponding to greater Alexithymia, were associated with poorer glycemic control. The reseachers suggest that Alexithymic characteristics may interfere with a DM patients' ability to manage their illness. Our results support these speculations.

In the philosophy of Qi-gong, the invisible energy floating inside the body and mind, called "Qi", is the key paradigm, and "Gong" refers to the level of accomplishment in some area of endeavor (57). In other words, "Qi-gong" is the way to develop an inner sense of one's body and mind through practicing control of posture, breathing, and mind state. Since Alexithymic patients are poor at imaging and being aware of their feeling, they may require greater effort to master Qi-gong exercise. This may also be the reason for our finding that the patients who have a tendency for Alexithymia had difficulty achieving the benefits of Qi-gong exercise.

The psychotherapeutic approach to patients with Alexithymia should include treatment to increasing emotional awareness. The psychotherapeutic processes of fantasizing, dreaming, play, verbal communication, and sharing of feelings with others are recommended to treat the patients. Behavioral medicine techniques, such as relaxation training, autogenic training, and biofeedback are also recommended. These techniques focus directly on one's bodily sensations, and they increase both patients' awareness of the relationship of their sensations to environmental events and their capacity to self-regulate various physiological functions (122). Therefore, Qi-gong can be hypothesized to improve Alexithymia. However, we found no change in the Alexithymia scale between pre- and post treatment. A longer duration of treatment may be required to test this hypothesis.

[Limitation of the present study]

Since the present study was the first preliminary investigation to evaluate the effect of Qi-gong exercise for Diabetes Mellitus using the controlled study design in the world, there were many unanswered questions remained.

As the physical activity and the physiological relaxation response of the Qi-gong treatment were not identified in this study, it cannot be determined which aspect of treatment (Dynamic Qi-gong, Static Qi-gong, Self Acupressure) was the active component. The character of Dynamic Qi-gong and Acupressure is mostly that of an aerobic exercise while Static Qi-gong is mostly relaxing or meditative. It may be difficult to divide the effects of the Qi-gong exercise into only the two aspects; aerobic exercise and relaxation. The mechanism of Qi-gong exercise remains to be elucidated.

The results of our study #2 were very similar to those found by Dunn (74), Kavanagh (75), and Niemcryk (76). They were identical in that initial glycemic control (pre-treatment HbA1c) and various psycho-social variables including Self-efficacy were found to be predictive of diabetic control on follow-up. In addition, Kavanagh & Niemcryk did not adapt any special treatment program, while Dunn adapted educational program. Considering this point, our prediction may not be specific to Qi-gong exercise. If the patients' conditions were initially poor glycemic controlled, young age, and obesity with higher Self-efficacy or lower Alexithymia, it is possible that they could achieve good control on follow-up without Qi-gong exercise. Other physical exercises such as aerobic dance, psychotherapy, behavioral therapy, group education, etc., and exercises diabetic patients adapt especially for themselves could be useful to achieve such benefits.

In the future, the effectiveness of Qi-gong exercise for Diabetes Mellitus should be demonstrated to be reproducible. The following points can be improved by future studies: increasing sample size of both type 1 DM and type 2 DM patients, increasing duration of treatment, adding measurements of insulin resistance by way of the euglycemic clamp technique, measuring levels of catecholamines and cortisol or other stress-related hormones, measuring the physical activity by way of oxygen requirements or pulse rate, and adding the parameter to judge the ability of Qi-gong exercise and the parameter to evaluate the changes in life style.

Equally important, it would be useful to reconfirm what variables predict benefit from Qi-gong. To evaluate the specificity of benefit from Qi-gong exercise, it would be useful to make a comparable control group that performs other exercise, such as slow-paced walking, relaxation training, or Acupressure.

Conclusions:

The benefits of a Chinese traditional health care technique, Qi-gong exercise, on diabetes mellitus were identified in this study as follows: the physical effect was demonstrated by a significant improvement in HbA1c level, and the psychological effect was demonstrated by significant improvement in Nurturing Parent on Ego-Gram, and the Fatigue Index and Total scores on Mood Inventory.

The following were found to predict benefit from Qi-gong exercise using multiple regression analysis:

1. Higher pre-treatment HbA1c.
2. Younger age.
3. Trend of obesity.
4. Stronger Self-Efficacy.
5. Weaker Alexithymia.

In conclusion, the usefulness of Qi-gong exercise on diabetes mellitus as an adjunctive treatment was demonstrated by this study.

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Table 1. Sample Characteristics

	First Treatment Group		Second Treatment Group			Total	
	n	Mean ±SD	n	Mean ±SD		n	Mean ±SD
Demographic Variables							
Gender Men	7		5			12	
Women	15		8			23	
Total	22		13			35	
Age		63.1 ±9.0		57.5 ±9.6	n.s.		61.0 ±9.5
Duration of illness		9.1 ±5.3		11.4 ±7.1	n.s.		9.9 ±6.1
Diagnostic Types							
Type 1	4		1			5	
Type 2	16		11			27	
Others	2		1			3	
Treatment Regimen							
Insulin	10		6			16	
Sulfonylurea	11		8			19	
α-Glucosidase Inhibitor	14		8			22	
Examination Before Treatment							
pre-HbA1c (%)		8.2 ±1.7		8.0 ±1.5	n.s.		8.1 ±1.6
Body Mass Index (BMI)		25.7 ±6.9		24.7 ±6.8	n.s.		25.3 ±6.8
Caloric Intake (kcal)		1576.3 ±311.9		1557.7 ±255.8	n.s.		1568.9 ±287.0
Caloric Consumption (kcal)		1989.1 ±251.3		1994.5 ±217.8	n.s.		1991.2 ±235.7

n: number of subjects n.s.: no significant difference

Table 2-1. Patient's Profile and Biological Data

Patient ID	Treat. Group	Sex	Age	Duration of Illness	Diagnostic type	Treatment Regimen			HbA1c(%)			HbA1c Change	Fasting Blood Glucose		C-peptide	
						Insulin	Sulfonylurea	¿ Glu.Inhibit.	Mar.-Apr.	Jul.-Aug	Dec.-Jan.	in Treatment Period	Before Treat.	After Treat.	Before Treat.	After Treat.
1001	1	F	68	17	Type 2	0	1	1	7.8	7.7	7.5	−0.1	168	251	2	4.6
1002	1	F	68	1	Type 1	1	0	0	9.7	9.2	9.4	−0.5	150		0.7	
1003	1	F	60	11	Type 1	1	0	1	8.6	8.0	7.7	−0.6	245	213	0.2	0.2
1005	1	M	67	18	Type 2	0	1	0	6.5	6.7	6.7	0.2	109	136	1.5	3.3
1006	1	M	70	8	Type 2	0	1	1	8.4	8.3	8.3	−0.1	153	137	1.7	1.3
1007	1	F	45	3	Type 2	0	1	0	6.6	5.7	5.6	−0.9		126		1.7
1008	1	M	71	8	Type 2	1	0	0	8.0	7.3	8.0	−0.7	153	91	0.8	0.2
1009	1	F	64	18	Type 2	1	1	0	9.5	8.4	8.8	−1.1	194		1.1	1.2
1011	1	F	54	3	Type 1	1	0	1	7.7	7.4	7.4	−0.3	269	62	0.2	0.2
1012	1	M	41	3	Type 1	1	0	0	10.4	7.7	7.0	−2.7	214	218	0.7	0.8
1013	1	M	57	3	Type 2	1	0	1	7.7	7.1	7.5	−0.6	113	101	1	0.7
1014	1	M	62	9	Type 2	0	0	1	8.4	7.3	7.5	−1.1	119	145	1.8	1.3
1015	1	F	54	18	Type 2	0	1	1	12.3	9.6	10.1	−2.7	286	194	3.7	2.2
1016	1	F	76	9	Type 2	0	1	1	8.1	7.0	7.0	−1.1	170	142	1.2	1.5
1017	1	F	69	9	Type 2	1	1	1	11.5	9.1	8.9	−2.4	267	208	2.8	2.5
1018	1	F	67	6	Type 2	0	0	1	7.9	6.9	6.2	−1.0	150	128	3.9	2.3
1019	1	F	65	7	Type 2	0	1	1	5.9	5.7	6.4	−0.2	105	163	3.1	3.2
1020	1	M	53	9	Others	0	1	1	8.0	8.2	7.9	0.2	119	139	0.8	1.2
1021	1	F	66	5	Type 2	1	0	0	7.4	6.5	6.1	−0.9	151	148	1.4	1
1022	1	F	72	14	Type 2	1	0	0	7.8	7.5	8.3	−0.3	138	110		0.3
1023	1	F	67	7	Others	0	0	1	5.3	5.4	5.3	0.1	107	111	1.1	1
1024	1	F	71	13	Type 2	0	1	1	6.3	6.5	6.8	0.2	118	138	1.3	1.1
2001	2	F	65	12	Type 2	0	1	0	5.2	5.2	5.2	0.0	102	97	0.7	2.7
2002	2	F	59	18	Type 2	1	0	1	8.4	8.8	7.7	−1.1	99	78	0.2	0.2
2003	2	M	69	12	Type 2	0	1	0	6.2	6.9	6.7	−0.2	205	133	5.6	1.4
2005	2	M	42	2	Others	1	0	0	7.7	7.7	6.5	−1.2	146	77	0.2	0.2
2007	2	M	62	21	Type 2	1	0	0	11.1	10.2	8.5	−1.7	261	43	1	0.2
2008	2	F	56	7	Type 2	1	1	1	9.3	7.3	7.4	0.1	224	186	1.3	0.9
2010	2	M	52	5	Type 2	0	1	1	8.5	8.0	6.9	−1.1	169	167	0.7	1
2011	2	M	40	3	Type 2	0	1	1	8.5	7.4	5.9	−1.5	160	122	2.9	2
2012	2	F	60	19	Type 2	0	1	1	9.8	9.7	8.5	−1.2	266	274	1.5	2
2017	2	F	59	2	Type 2	0	1	0	6.0	6.1	6.1	0.0	115	124	1.9	1.4
2018	2	F	61	19	Type 2	1	0	1	8.5	9.2	7.7	−1.5	178	180	0.8	0.7
2023	2	F	73	10	Type 2	0	0	1	6.6	8.1	6.9	−1.2	143	163	2.4	1.8
2024	2	F	50	18	Type 1	1	1	1	9.4	9.6	8.0	−1.6	229		1.2	

Table 2-2. Patient's Profile and Biological Data

Patient ID	Treat. Group	HDL-Cholesterol		Total-Cholesterol		Body Mass Index		Caloric Intake(kcal)		Caloric Consumption(kcal)		Self-Training Time(min/week)
		Before Treat.	After Treat.	Before Treat.	After Treat.	Before Treat.	After Treat.	Before Treat.	After Treat.	Before Treat.	After Treat.	
1001	1	35	37	259	231	28.2	26.0	1331	1381	2146	2184	409
1002	1	51	56	148	52	21.7	19.9			1563	1851	191
1003	1	63	53	203	174	31.3	27.0	1242	1202	1908	1774	248
1005	1	63	75	200	203	13.5	13.3	1833	1517	1775	1956	148
1006	1	58	48	179	174	21.8	19.4	1728	1632	2420	2547	110
1007	1	55	48	190	178	25.5	20.9	1581	1624	1747	1866	102
1008	1	61	68	166	151	23.2	23.2	1941	1740	1934	1868	189
1009	1	69	61	216	213	35.4	32.4	1760	1779	1871	1824	267
1011	1	70	67	236	240	26.0	23.4	941	1056	2231	2227	132
1012	1	54	65	159	181	17.8	18.0	1728	1916	1915	2161	85
1013	1	52	46	215	231	26.2	23.2		1672	2612	2568	79
1014	1	35	34	201	176	17.7	15.7	1867		2104	2110	115
1015	1	56	61	225	254	35.6	31.4	2029	1738	1842	1963	77
1016	1	92	94	201	231	26.0	23.5	1244	1325	2016	1988	117
1017	1	63	56	178	180	32.3	35.4	1676	1163	2197	2068	152
1018	1	98	87	259	245	39.9	33.6	1259	1363	2119	2162	294
1019	1	54	66	159	179	29.6	29.1	1720	1379	2146	2073	282
1020	1	56	65	139	141	17.8	15.8	1971	1739		1976	56
1021	1	30	43	179	162	26.6	25.5	1416	1541	1849	1806	148
1022	1	52	54	267	193	25.5	24.0	1403	1424	1925	2026	189
1023	1	72	67	205	193	15.4	14.6	1749	1746	1662	1799	552
1024	1	49	53	231	251	29.3	28.3	1106	1072	1788	1787	519
2001	2	68	60	214	203	22.1	24.5	1637	1717	1761	1916	192
2002	2	43	47	222	271	30.7	32.8	1221	1248	2200	2072	251
2003	2	50	54	203	230	14.5	21.5	1832		1844	1860	66
2005	2	50	55	171	186	15.4	19.2	2005	1827	1984	2041	44
2007	2	65	65	170	171	18.2	22.4	1637		1940	2097	155
2008	2	75	81	199	273	25.1	28.5	1173	1533	1968	1894	177
2010	2	65	57	222	203	16.0	18.2	1741		1942	1871	103
2011	2	30	25	239	216	31.4	32.3	1579	1235	2377	2579	48
2012	2	39	41	223	256	28.3	31.0	1388	1248	2310	2374	75
2017	2	41	40	252	225	32.9	36.4	1160	1020	1885	1743	154
2018	2	52	20	259	224	28.5	30.8	1643	1576	2172	2175	221
2023	2	87	83	215	186	32.8	31.3	1602	1404	1940	1899	133
2024	2	64	96	275	272	24.7	26.0	1632		1606		23

Table 3. Results of Paired-t test Analysis of Changes in Glycosylated Hemoglobin (HbA1c;%)

Treatment Group	Mar.-Apr. Mean ± SD	Jul.-Aug. Mean ± SD	Dec.-Jan. Mean ± SD
First	8.17 ±1.71	7.42 ±1.12	7.47 ±1.21
	[A] $p<.001$ (Mar.-Apr. vs. Jul.-Aug.)		
Second	8.09 ±1.69	8.02 ±1.47	7.08 ±1.01
	[B] n.s. (Mar.-Apr. vs. Jul.-Aug.)	[C] $p<.0005$ (Jul.-Aug. vs. Dec.-Jan.)	

Table 4. Results of Biological Data Before and After The Qi-Gong Treatment

Variable		n	Before Mean	Before SD	After Mean	After SD	Changes Mean	Changes SD		
HbA1c (%)	Total	35	8.1	1.6	7.3	1.1	−0.8	0.8	T	*****
	Type 1	5	9.2	1.1	8.1	0.7	−1.1	1.0		
	Type 2	27	8.0	1.6	7.2	1.1	−0.8	0.8	T	*****
	Others	3	7.0	1.5	6.7	1.4	−0.3	0.8		
FBS (mg/dl)		31	168.5	58.1	144.5	53.5	−24.0	62.8	W	*
CPR (ng/ml)		31	1.60	1.24	1.43	1.05	−0.17	1.15	W	
T-Cho (mg/dl)		35	208.0	35.2	204.3	44.3	−3.7	31.9	T	
HDL-Cho (mg/dl)		35	57.6	15.9	57.9	17.5	0.3	10.4	W	
HDL-Cho／T-Cho		35	0.28	0.09	0.31	0.16	0.02	0.13	W	
Body Mass Index		35	25.3	6.8	25.1	6.2	−0.2	3.0	T	
Caloric Intake (kcal)		28	1574.9	277.2	1571.3	346.3	−3.6	267.2	W	
Caloric Consumption (kcal)		28	1942.7	434.1	1599.7	859.1	−343.0	826.3	W	

†:p<0.1 *:p<0.05 **:p<0.01 ***:p<0.005 ****:p<0.001 *****:p<0.0005

T: paired t-test; W: Wilcoxon signed-ranks test

FBS: fasting blood glucose; CPR: C-peptide; T-Cho: total cholesterol; HDL-Cho: high-density lipoprotein cholesterol

Table 5. Results of Psychological Data Before and After The Qi-Gong Treatment

Variable	n	Before		After		Changes			
		Mean	SD	Mean	SD	Mean	SD		
TEG Critical Parent (%)	35	49.2	10.8	48.1	9.6	−1.1	5.2	T	
TEG Nurturing Parent (%)	35	52.5	9.0	55.7	9.3	3.2	6.3	W	***
TEG Adult (%)	35	52.1	9.5	53.8	9.5	1.7	5.1	T	†
TEG Free Child (%)	35	48.8	9.1	49.9	9.6	1.1	6.2	W	
TEG Adapted Child (%)	35	44.1	9.0	42.1	8.9	−2.0	6.5	T	†
CMI CIJ	35	4.7	4.6	4.3	3.6	−0.5	2.1	W	
CMI M-R	35	5.5	6.5	5.3	5.5	−0.2	3.7	W	
MPI Extroverted Scale	35	29.4	9.8	29.6	9.9	0.2	5.0	T	
MPI Neurotic Scale	35	13.0	10.1	12.5	9.1	−0.5	5.1	T	
MPI Lie Scale	35	19.7	5.9	19.7	5.6	0.0	3.9	W	
MOOD Tension	35	12.0	3.6	10.9	3.3	−1.1	3.7	T	†
MOOD Refreshment	35	18.7	4.4	17.3	4.7	−1.4	5.3	T	
MOOD Fatigue	35	12.3	3.4	10.8	3.2	−1.5	3.9	T	*
MOOD Depression	35	10.7	3.2	9.8	2.9	−0.8	3.4	W	
MOOD Anxiety	35	12.0	4.0	10.5	3.2	−1.5	4.2	W	†
MOOD Total	35	65.6	13.6	59.3	14.4	−6.2	15.7	T	*
Toronto Alexithymia Scale	35	67.2	8.7	66.3	9.1	−0.9	8.0	T	
GSES Factor-1	35	4.8	2.0	5.0	2.0	0.2	1.4	T	
GSES Factor-2	35	3.2	1.2	3.1	1.6	−0.1	1.3	W	
GSES Factor-3	35	1.5	1.1	1.5	1.1	0.0	0.7	W	
GSES Total	35	9.5	3.1	9.6	3.5	0.1	1.8	W	

†:p<0.1 *:p<0.05 **:p<0.01 ***:p<0.005 ****:p<0.001 *****:p<0.0005

T: paired t-test; W: Wilcoxon signed-ranks test
TEG: Tokyo University Egogram; MOOD: Mood Inventory; MPI: Maudsley Personality Inventory
CMI: Cornell Medical Index-Health Questionnaire; CIJ: score of physical symptoms; M-R: score of psychological symptoms
GSES: General Self-Efficacy Scale; Factor-1: Anxiety concerning failure; Factor-2: positiveness in behavior; Factor-3: social locus of ability

Table 6. Correlation between Change in HbA1c Level and Following Items: Psychological Variables, Expectations, and Self-training Time.

	Correlation Ratio
TEG Nurturing Parent	−0.119
MOOD Fatigue	−0.136
MOOD Total	−0.165
Expectation 1†	−0.042
Expectation 2‡	−0.098
Expectation 3§	−0.208
Expectation 1+2+3	−0.196
Self-training Time (hour)	0.277

† "Do you think that Qi-gong is useful for the treatment of various diseases?"
‡ "Do you think that Qi-gong is useful for the treatment for diabetes mellitus?"
§ "Do you expect an effect from this Qi-gong session?"

Table 7. Results of Stepwise Multiple Regression Analysis Predicting the Change Level of HbA1c from Biological Parameters before Treatment

Predictor Variables	Step	R-square	
pre-HbA1c	1	0.6531	*****
Age	2	0.0732	**
Body Mass Index	3	0.0738	***
Caloric Intake	4	0.0246	†
Duration of Illness	5	0.0216	†
Total		0.8462	*****

†:p<0.1 *:p<0.05 **:p<0.01 ***:p<0.005 ****:p<0.001 *****:p<0.0005

Table 8. R-squared between HbA1c and Psychological Independent Variables, Adjusted by Three Biological Independent Variables‡

	R-square	
TEG Critical Parent	0.0002	
TEG Nurturing Parent	0.0092	
TEG Adult	0.0002	
TEG Free Child	0.0016	
TEG Adupted Child	0.0007	
CMI CIJ	0.0138	
CMI M-R	0.0016	
MPI Extroverted Scale	0.0331	†
MPI Neurotic Scale	0.0008	
MPI Lie Scale	0.0043	
MOOD Tension	0.0051	
MOOD Refreshment	0.0063	
MOOD Fatigue	0.0008	
MOOD Depression	0.0045	
MOOD Anxiety	0.0152	
MOOD Total	0.0108	
TAS	0.0415	*
GSES Factor-1	0.0273	†
GSES Factor-2	0.0654	***
GSES Factor-3	0.0427	*
GSES Total	0.0749	***

†:p<0.1 *:p<0.05 **:p<0.01 ***:p<0.005

‡pre-treatment HbA1c, age, Body Mass Index

TEG: Tokyo University Egogram

CMI: Cornell Medical Index-Health Questionnaire

CIJ: score of physical symptoms; M-R: score of psychological symptoms

MPI: Maudsley Personality Inventory

MOOD: Mood Inventory; TAS: Toronto Alexithymia Scale

GSES: General Self-Efficacy Scale; Factor-1: Anxiety concerning failure

Factor-2: positiveness in behavior; Factor-3: social locus of ability

Table 9. Results of Stepwise Multiple Regression Analysis Predicting the Change Level of HbA1c from Bio-psychological Parameters before Treatment

Predictor Variables	Step	Partial Regression Coefficient	R-square	
pre-HbA1c	1	−0.364	0.5847	*****
GSES Factor-2*	2	−0.154	0.0767	*
Age	3	0.023	0.0634	***
Body Mass Index	4	−0.022	0.0578	†
TAS†	5	0.016	0.0251	†
Total			0.8077	*****

†:p<0.1 *:p<0.05 **:p<0.01 ***:p<0.005 ****:p<0.001 *****:p<0.0005

* General Self Eficacy Scale Factor-2; Positiveness in Behavior

† Toronto Alexithymia Scale

Standardized prediction equation:

[HbA1c-Change] = 0.650 − 0.364[preHbA1c] − 0.154[GSESf2] + 0.023[Age] − 0.022[BM I] + 0.016[TAS]

Figure Legends:

Figure 1.

The Schedule of Qi-gong session and data collection. The "First Treatment Group" attended the weekly Qi-gong session from March to July, and it was named 'A'. The "Second Treatment Group" was waiting the session during this period as a control group, and it was named 'B'. From August to December, the "Second Treatment Group" attended the weekly Qi-gong session, and it was named 'C'. The data of biological and psychological examinations were collected three times; during one month before March, during July to August, and during one month after December.

Figure 2.

The graph shows the change of HbA1c. The data of the "First Treatment Group" is on the left side, and the data of the "Second Treatment Group" is on the right side. The data of each patients are shown as the light solid line. The mean levels of HbA1c are shown as the solid squares, and standard deviations are shown as the solid diamonds. The thick solid lines between solid squares shows the mean change of HbA1c level during Qi-gong sessions, and thick broken lines between solid squares shows the change during control term or follow up term.

Figure 3.

The solid square shows the plot of changes in HbA1c level and self-training time of 35 patient's data. The two data that their self-training time were over 500 min/week were regarded as outlying value.

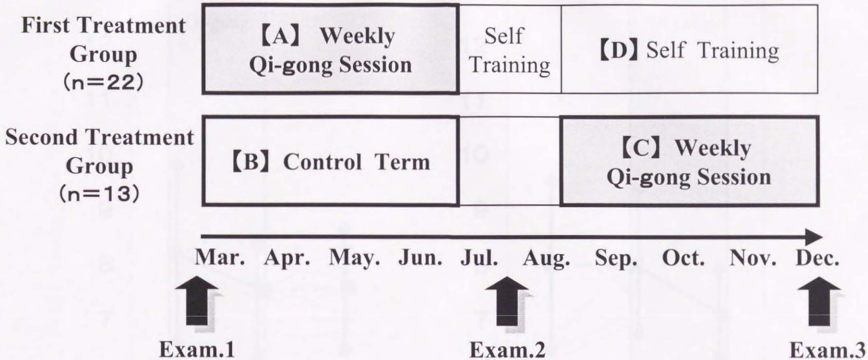


Figure 1. Study Protocol

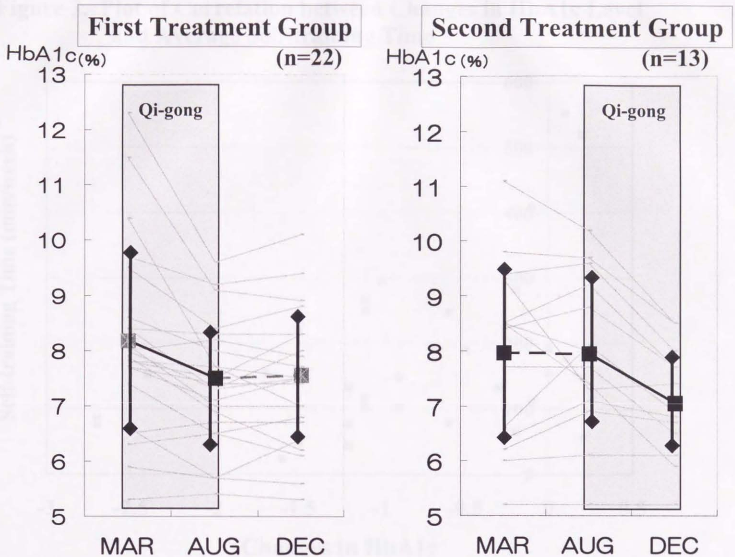
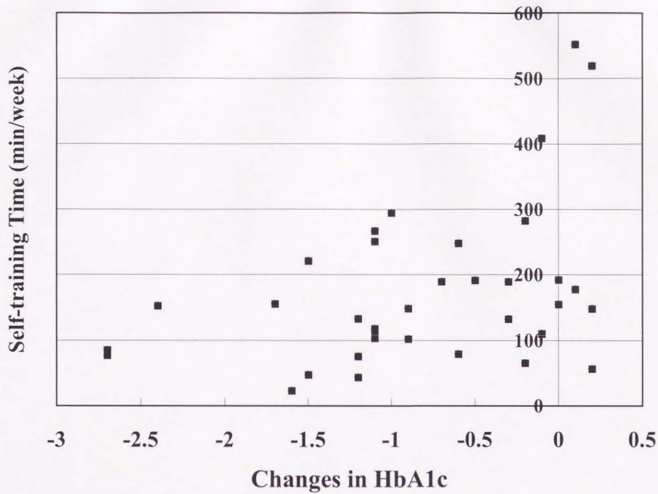


Figure 2：Change of HbA1c

Figure 3. Plot of Correlation between Changes in HbA1c Level and Average Self-training Time



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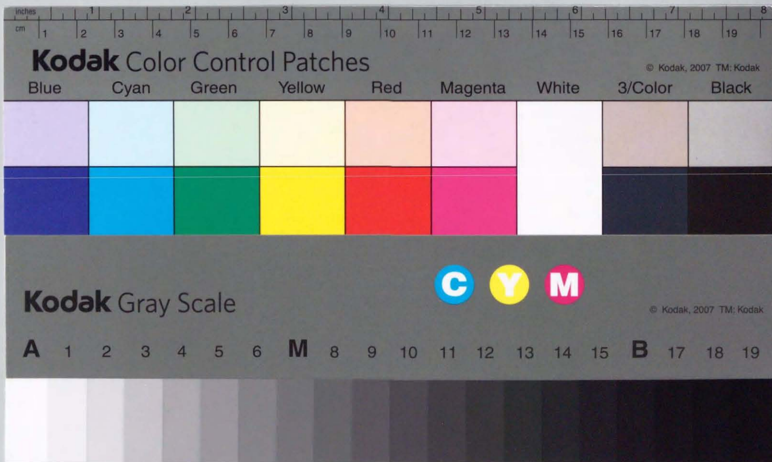
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