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A prospective randomized controlled trial to evaluate effectiveness of registered dietitian led diabetes management on glycemic and diet control in a primary care setting in Taiwan

Short title: RD-led diabetes management in primary care

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Objective –This randomized controlled trial evaluated the effect of a registered dietitian (RD)-led management of diabetes on glycemic control and macronutrient intake in type 2 diabetic patients in primary care clinics in Taiwan and studied the association between changes in macronutrient intake and glycemic measures.

Research Design And Methods **–**We recruited 154 adult patients with type 2 diabetes and randomly assigned them to a routine care control group (n=79) or an RD-led intervention group (n=75) who received on-site diabetic self-management education every three months over 12 months.

Results **-** Over the one year period, neither the intervention group (n=75) nor the control group (n=79) had significant changes in HbA1c, while the intervention patients with poorly controlled baseline HbA1c(>7%) (n=56) had significantly greater improvements in HbA1c and fasting plasma glucose than the controls (n=60) (-0.7 *vs.* -0.2%, p=0.034; -13.4 *vs.* 16.9mg/dl, p=0.007) during the same period. We also found significant net intervention-control group differences in overall energy intake (-229.06+309.16 *vs.* 56.10+309.41kcal/day) and carbohydrate intake (-31.24+61.53 *vs.* 7.15+54.09 g/day) (p<0.001) in patients with poorly controlled HbA1c. Multivariable adjusted modeling revealed an independent association between changes in carbohydrate intake and HbA1c in the intervention group (n=56, beta=0.10; SE=0.033; p=0.004).

Conclusions- On-site RD-led management of diabetes can improve glycemic control in patients with poorly managed type 2 diabetes in primary care clinics in Taiwan. A reduction in carbohydrate intake may improve glycemic status.

The World Health Organization has predicted that the number of people with diabetes will increase from 135 million in 1995 to 300 million by 2025 (1) with the greatest increases in Asia (2). The annual incidence of diabetes is 0.5-1.0% in Taiwan. There are at least 100,000 new cases per year (3) and 11.5% of total medical costs covered by Taiwan's national insurance is spent on the treatment of diabetes and its complications (4).

The Diabetes Control and Complications Trial and U.K. Prospective Diabetes Study (UKPDS) reported that the use of multidisciplinary approaches aimed at making healthy changes in life-style can improve glycemic control and delay or reduce further complications, some by as much as 50 to 75% (5,6). Registered dietitians (RD) can contribute greatly to comprehensive care plan for diabetic patients, who as a result of dietary education, have been found to have improved anthropometric measures, glycemic control and use less prescribed medication (7,8). In addition, patients with chronic diseases, including DM, have been found to benefit from patient-centered approaches encouraging self-management of disease (9). Nevertheless, one study out of the United States reports that more than half of the diabetes patients did not receive diabetic-related knowledge and self-management skills at their primary clinics and were not referred to relevant educational programs (10). In Taiwan, where number of on-staff registered dietitians (RDs) is determined by number of beds in hospitals, primary care clinics are not required to have RDs on staff.

In this study, we hypothesized that patients receiving ongoing patient-centered consultation provided by a dietitian would more likely follow a diet designed to improve glycemic control than those not receiving such consultation. To find out, we first created a model through which physicians, dietitians, and nurses would cooperate to provide comprehensive individualized on-site patient care and RD-led self-management education. We then assessed the effect of this program on glycemic control and macronutrient intakes in seventy-five patients compared to seventy-nine type 2 diabetes receiving the routine care practiced in their primary care setting.

REARCH DESIGN AND METHODS

Subjects: To choose participating clinics, we visited the public health bureau of Kaohsiung, a city in southern Taiwan, to obtain clinics known for their care of diabetic patients. The investigators then visited clinics to find out their willingness to participate. Then, starting in May 2004, we recruited 154 diagnosed or newly diagnosed type 2 diabetes patients between 30 and 70 years old receiving treatment at five primary healthcare clinics. Type 2 diabetes was diagnosed by primary physicians based on criteria established by the American Diabetes Association (ADA) (11). Patients were excluded if they were pregnant or on dialysis or if they had received an amputation or had co-morbid blindness, systemic illnesses such as cancer or cardiovascular disease based on physician diagnosis of myocardial infarction or stroke on national insurance claim forms. If the subjects were eligible and willing to participate in this study, the primary physicians referred them to the RDs. The RDs explained the study to the participants and informed them that they would be randomly assigned to either a RD-led multi-discipline diabetes management group (n=75) or a usual care group (control group) (n=79). Once a participant signed an informed written consent, he or she was enrolled into the study. The name, age, and sex of the enrollees were entered into a computer which randomly assigned them in a 1:1 manner to control groups and intervention groups. The study protocol was approved by the IRBs of

National Health Research Institutes/Taiwan and Kaohsiung Medical University Hospital.

Intervention program: Patients in the control group received the routine care practiced at their primary care, which may have also included a summary of basic dietary principles by nurses. Patients in the intervention group in addition to receiving usual care, received ongoing instruction on the self-monitoring of glucose, medications, exercise, hygiene (foot care), and complication management (11) from 2 RDs who had received additional clinical training in the Department of Endocrinology and Metabolism and the Department of Nutrition at the participating medical center. The patients in the intervention group were also provided individualized nutrition counseling and dietary plans to reinforce the concepts of controlling portion sizes of foods every three months. During each visit, which lasted 30 to 60 minutes, the RDs assessed patients' understanding and practice of dietary plans, self-care skills, and reinforced important knowledge throughout the study period. The physicians would consult with the RDs based on medicines prescribed or patients' self-care related to adjustment of meal times and amount of food. The RDs were also provided a hospital-use mobile phone. The intervention patient could call the RDs if they needed dietary advice and the RDs called the patients to help solve problems that patients might have encountered when trying to follow the diet.

Nutrition Education Program: During each intervention patient visit, the RDs obtained daily nutrient intake by asking the patients to recall the foods consumed for the previous 24-hour period, a method of inquiry routinely used in clinical settings in Taiwan. Nutrient intake was analyzed by nutrient analysis software (Nutritionist Edition, Enhancement version 2002, Taichung, Taiwan). Each patient received dietary education recommended by the ADA (12). One goal was to avoid excessive energy intake and assure balanced nutrition by replacing high fat with low fat foods and consuming foods rich in fiber and micronutrients. A second goal was to introduce the concept of portion size of the six food groups to patients and emphasize the possible impact of portion size control, especially carbohydrate counting, on glycemic control. Food models resembling standard portion sizes for food groups were used to enhance the accuracy of diet-related information. Individualized diet plan was created to maintain intake of protein, fat and carbohydrate energy to around 15-20%, 25-30% and 50-60%, respectively, following the guidelines established by the ADA (12).

Measurement of clinical parameters: At baseline and at one year, both groups received anthropometric measurements, clinical laboratory measurements after an eight-to twelve-hour fast, and answered a RD-administered questionnaire regarding demographic characteristics and dietary habits. All clinical parameters were sent to a laboratory (Protech Pharmaservices Corporation, Taipei, Taiwan) certified by The College of American Pathology and US Commission on Office Laboratory Accreditation. HbA1c assays were performed using high-performance liquid chromatography (Variant II, Biorad, Hercules, CA, USA). Fasting plasma glucose, cholesterol, triglyceride, low-density lipoprotein cholesterol (LDL-Cholesterol), high-density lipoprotein cholesterol (HDL-Cholesterol), uric acid, creatinine, and high sensitivity c-reactive protein (hs CRP) were analyzed by enzymatic assay using an auto-analyzer (Hitachi 7060, Hitachi, Japan). Medical charts were reviewed to obtain information regarding patient use of medications.

Statistical Analysis: T test was used to analyze differences in continuous variables between two groups. The chi-squared test or

Fischer exact test (if n<5) was used to analyze distribution of categorical variables. Simple linear regression was used to examine the relations between changes of HbA1c and changes in macronutrient intake (g), and multiple linear regression was used to adjust for confounders. All statistics were performed on SPSS Version 11.5. A p<0.05 was considered significant.

RESULTS

Eighteen patients dropped out of the intervention group, and twenty-one out of the control group by the one year follow-up, leaving us with 154 subjects. There were no significant group differences in age, gender, disease duration and education in the 154 participants that remained (Table 1). We also found no significant difference in age, gender, disease duration and education between the intervention (n=56) and control (n=60) patients with poor baseline glycemic control (HbA1c >7%) (Table 2).

Clinical parameters. We found no significant improvement in HbA1c between the 75 intervention and 79 control patients regardless of baseline HbA1c (Table 1), though we did find a significant improvement fasting plasma glucose intervention group compared the controls (P=0.026) (Table 1). The 56 subjects in the intervention group with poor baseline glycemic control had a greater reduction in mean HbA1c (0.7%) than the 60 controls (0.2%) (p=0.034) as well as significantly greater improvements in fasting plasma glucose (-13.4+55.2 vs.16.9+63.6mg/dl, p=0.007) and systolic blood pressure (0.5+16.8 vs. 8.6+17.4 mmHg, p=0.012) (Table 2). There were no significant group differences in medication usage either at baseline or at follow-up in patients with poor baseline glycemic control (Table 2).

Dietary intake. In participants with HbA1c>7%, the intervention group had a mean decrease in energy intake of 229+309.16kcal/day, while the control had a mean increase of 56.10+309.41kcal/day (p<0.001). Over the 12-month period, there was a decrease in energy intake including overall reduction in absolute amounts (g) of carbohydrates, fat and protein in the intervention group. While the energy% values of carbohydrate, fat, and protein at the baseline and at one year intervention were similar for both groups, the intervention group had significantly greater net reductions in saturated fat than the control group (-0.98+3.40 vs. +0.60+2.93, p=0.01). Additionally, there was a significant reduction energy (Kcal/day) and fat (g/day) intake in those with HbA1c<7% than controls (data not shown).

Macronutrient intake and glycemic control. Our univariate analysis found a correlation between changes in HbA1c and baseline BMI, baseline HbA1c and changes in energy intake at per 100kcal/day (beta=0.200, SE=0.041, p<0.001) and carbohydrate intake at per 15g/day (beta=0.167, SE=0.029, p<0.001) in the intervention group with baseline HbA1c>7%. After adjusting for age, gender, duration of diabetes, baseline BMI and baseline HbA1c, we found an association between a 15g increase in carbohydrate (one carbohydrate counting) intake and a 0.1% increase in HbA1C (SE=0.033, p=0.004), but not in overall energy intake (beta=0.04, SE=0.04, p=0.310).

CONCLUSIONS

This study found that the RD-led diabetes management program in the primary care clinics significantly improved the glycemic control of type 2 diabetic patients with baseline HbA1c>7%. We found a strong and independent association between a reduction in carbohydrate intake and improvements in HbA1c (p<0.001). We observed a much greater reduction in HbA1c in our poorly controlled intervention group (0.7%) than in the control group (0.2%)

(p=0.034). Our intervention group also had a 13.4mg/dL reduction in mean fasting glucose plasma, while our control group had a 16.9mg/dL increase in that measure (p=0.007).

Recently, some large randomized controlled trials have also documented the effectiveness of life style or nutrition interventions on delaying the progression from impaired glucose tolerance to diabetes in high risk individuals (13,14). However, most of those studies were based on patient receiving care in academic or medical centers with more departments and greater capacity to provide individualized nutrition counseling than primary care clinics. Although there have been studies on the management of diabetes in primary care (15), none have studied the effect of the kind of RD-led management of diabetes on glycemic and diet controls that was proposed in this study.

The effects of diabetic self-management education focusing on dietary or lifestyle changes have been reported in some trials in primary care settings (16,17). The results of those studies showed the intervention groups to have greater reductions in HbA1c (-0.92% to-1.8%) than the control groups (-0.16% to-0.4%). One study out of France using the Staged Diabetes Management Program (18) in a primary care found that their intervention group had a 0.31% decrease in HbA1c, while their control group had a 0.56% increase, making an overall difference of 0.86%. The intervention group in this study had improvements comparable in magnitude to those reported by other trials (16-18) as well as to those reported by the UKPDS study, which reported 1% decrease in HbA1c for their invention group and 0.1% increase in their control group(6). Another study of a French population has also demonstrated that by introducing a diabetic management program, glycemic control can be improved without increasing the total health care cost (18).

In this study, we tried to identified how on-site nutrition counseling would affect not only glycemic control but also adherence with dietary recommendations and self-management of disease in primary care setting. Although this study found no differences in HbA1c when two groups were considered as a whole, it should be noted that in our study the patients in the intervention group with fair baseline HbA1c (<7%) had significantly greater reductions in fasting plasma glucose, intake of energy (Kcal/day) and fat (g/day), but not in overall change in HbA1c, compared to controls. This finding provides valuable information for future diabetic care.

Imparting knowledge about nutrition to patients is essential when teaching diabetes patients how to self-manage their diseases (11). Previous studies analyzing data by the India Health service Diabetes Care and Outcome Audit of 7490 medical charts found that patients receiving clinical nutrition education from an RD or an RD along with another staff member had greater improvements in HbA1c levels (-0.26% and -0.32%, respectively) than those receiving nutrition education from either a non-RD staff or no nutrition education (-0.19% and -0.10%, respectively)(19). Furthermore, one study entitled Improving Control with Activity and Nutrition Study, which randomized obese type 2 diabetes patients into a RD-led case management group and into a usual care group, reported that their RD-led case management group had greater reductions in weight, waist, HbA1c, and use of prescription medication than the controls (20). To our knowledge, the current study is the first in Taiwan to demonstrate that effective glycemic control can be achieved by interventions by RDs providing both diabetic self-management education and intensive dietary counseling in a primary care setting. After one year, energy intake had decreased by

229+309.16kcal/day in the intervention group but increased by 56.10+309.41kcal/day in the control group with HbA1c>7%. We also found concomitant reductions in the intake of absolute amounts of all three macronutrients in our intervention group. However, despite the significant reduction in total energy intake, we did not find significant reductions in body weight in the intervention group. The lack of a weight loss in the intervention group might be because most diabetes patients were prescribed the sulfonylurea which stimulate the storage of glycogen and lipogenesis. It has been well documented that the use of these drugs are often associated with weight gain (6)

Most randomized controlled trials evaluating the effectiveness of diabetes-self management or life-style education have reported improvements in clinical indices (5-6,16-18) but only very few have documented dietary changes (21,22). One study (21) employing lifestyle education in diabetic patients reported significant differences in reductions in total fat (% energy, p<0.001), saturated fat (% energy, p=0.001) and non-significant (p=0.13) decreases in the total energy intake between their intervention and control groups (-215kcal/day vs. -144kcal/day, respectively). Another randomized controlled trial (22), evaluating the effect of a weight reduction (including dietary counseling) and exercise program on diabetes management in older overweight patients, reported significant net differences in total energy intakes over three months (control: 210.9kcal/day, intervention: -200.4kcal/day, net difference: -411.3kcal/day). However, these studies did not examine simultaneous association between changes of dietary components and metabolic parameters. Our study showed that energy intake was decreased by 229+309.16kcal/day in the intervention subjects and increased by 56.10+309.41kcal/day in the controls with HbA1c>7% (p<0.001) after one year. Significant net differences were also observed between the absolute amounts (g per day) of carbohydrate/fat/protein consumption in the intervention group (-31.24/-7.74/-10.91) and the control group (7.15/3.84/2.94). After adjusting for confounders, independent associations were found between changes of carbohydrate intake and HbA1c, indicating that carbohydrates may be the most important among macronutrients in influencing changes of HbA1c. This finding is consistent with the findings that the amount of carbohydrates consumed is a strong predictor of glycemic response (23). Therefore, portion size or carbohydrate counting such as those suggested by the ADA may remain a key dietary strategy in achieving desirable glycemic control. RDs can play an important role in imparting this knowledge with diabetic patients and in helping them implement changes in diet.

There are some limitations in the current study. Twenty-four hour dietary recall is commonly used in routine clinical nutrition counseling to estimate the food intake of patients in Taiwan. Although 24-hour recall have been found to be confounded by recall bias (24), interviewing patients by trained dieticians who are able to retrieve more accurate dietary information may attenuate such errors. Besides, since both groups were likely to have recall bias, the rates of underreporting are probably comparable. Second, we did not analyze insulin sensitivity at baseline, and only began doing it after the one-year follow-up (data unpublished). Therefore, the present study did not report changes in insulin sensitivity after intervention was started.

In conclusion, we found that the RD-led diabetes management program aimed at increasing a diabetic patient's knowledge of how to self manage his or her illness to be an effective strategy for controlling glycemic status and improving dietary habits for poorly controlled type 2 diabetes. Changes in carbohydrate intake were independently associated with improvements in glycemic control, emphasizing the need for carbohydrate counting in nutrition education programs for diabetic patients.

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Table 1-Baseline characters and changes of clinical parameters in type 2 diabetic patients after receiving 12 month intervention or usual care (control). [†]

	Baseline			Changes from baseline to 12 month		
	Intervention (n=75)	**Control (n=79)**	**p**	**Intervention (n=75)**	**Control (n=79)**	**p**
Baseline characters						
Age	56.6±8.0	56.9±7.5	0.802	-	-	-
DM duration	4.8±4.4	4.8±4.5	0.996	-	-	-
Male (%)	29(38.7)	38(48.1)	0.238	-	-	-
Education						
< 6 year primary school	45(60.0)	59(74.7)	0.052	-	-	-
> 6 year primary school	30(40.0)	20(25.3)		-	-	-
Clinical measurements						
Height (cm)	159.1±8.3	161.1±8.2	0.141	-0.1±1.2	-0.1±1.0	0.872
Body mass index (kg/m2)	25.7±3.2	27.0±4.7	0.044	0.1±1.2	0.2±1.5	0.733
Systolic blood pressure (mmHg)	131.8±19.8	134.9±17.4	0.304	-0.7±15.8	6.0±18.9	0.019
Diastolic blood pressure (mmHg)	79.7±10.5	84.2±10.3	0.008	0.0±11.0	0.6±10.9	0.736
Glucose (mg/dl)	147.4±49.6	159.7±53.4	0.141	-6.8±50.1	12.7±56.9	0.026
HbA1c (%)	8.0±1.5	8.4±1.8	0.212	-0.5±1.1	-0.1±1.5	0.101
Triglyceride (mg/dl)	145.4±90.2	164.6±122.9	0.272	-3.8±69.2	-0.3±110.8	0.818
Total Cholesterol (mg/dl)	183.0±37.9	187.3±38.4	0.488	-5.1±39.3	0.3±43.7	0.424
HDL-cholesterol (mg/dl)	50.1±12.2	48.7±11.1	0.471	-0.1±11.2	-0.6±8.7	0.743
LDL-cholesterol (mg/dl)	117.8±33.4	118.5±32.5	0.898	-6.0±35.9	0.1±36.3	0.297
GPT (U/L)	35.3±26.5	40.1±35.9	0.350	2.9±44.6	-0.3±25.0	0.582
Creatinine (mg/dl)	0.8±0.3	0.8±0.2	0.631	0.0±0.4	0.0±0.2	0.765
Uric acid (mg/dl)	5.5±1.6	5.6±1.9	0.670	0.5±1.3	0.2±1.7	0.235
Hs CRP (mg/dl)	0.4±1.3	0.3±0.3	0.693	-0.1±1.5	-0.1±0.4	0.790

[†] Data are presented as mean + SD or n (%).T-test or χ^2 test was used to test differences between the intervention and control subjects at baseline. T test was also used to determine the changes in clinical parameters between the two groups after one year intervention. $p<0.05$ is considered significantly different.

Table2 –Baseline characters and changes of clinical parameters and medication in type 2 diabetic patients with baseline HbA1c > 7% after receiving 12 month intervention or usual care (control). †

	Baseline			Changes from baseline to 12 month		
	Intervention (n=56)	**Control (n=60)**	**p**	**Intervention (n=56)**	**Control (n=60)**	**p**
Baseline characters						
Age	55.8±8.2	57.4±7.5	0.286	-	-	-
DM duration	5.2±4.5	5.5±4.7	0.665	-	-	-
Male (%)	23/33(41.1)	31(51.7)	0.253	-	-	-
Education						
< 6 year primary school	34(60.7)	45(75.0)	0.099	-	-	-
> 6 year primary school	22(39.3)	15(25.0)		-	-	-
Medication use						
Glucose-lowering treatment						
Sulfonylurea	54(96.4)	57(95.0)	1.000	-	-	-
Bigrunide	45(80.4)	50(83.3)	0.677	-	-	-
Thiazolidinedione	7(12.5)	14(23.3)	0.130	-	-	-
Other oral hypoglycemia agent	0(0.0)	2(3.3)	0.496	-	-	-
Lipid-lowing treatment						
Gemfibozil	2(3.6)	0(0.0)	0.231	-	-	-
Statins	21(37.5)	13(21.7)	0.061	-	-	-
Fibrate	0(0.0)	1(1.7)	1.000	-	-	-
Antihypertensive treatment						
Diuretics	1(1.8)	2(3.3)	1.000	-	-	-
Beta-blocker	0(0.0)	2(3.3)	0.496	-	-	-
Alpha-blocker	1(1.8)	1(1.7)	1.000	-	-	-
Calcium-channel blocker	17(30.4)	20(33.3)	0.731	-	-	-
ACE inhibitor	7(12.5)	9(15.0)	0.696	-	-	-
ARB	4(7.1)	7(11.7)	0.531	-	-	-
Aspirins	4(7.1)	8(13.3)	0.365	-	-	-
Clinical measurements						
Height (cm)	159.3±8.2	161.2±8.4	0.206	-0.1±1.3	-0.2±1.0	0.769
Body mass index (kg/m^2)	25.7±3.2	26.8±4.2	0.093	0.2±1.3	0.2±1.3	0.953
Systolic blood pressure (mmHg)	132.4±20.9	134.3±18.9	0.627	0.5±16.8	8.6±17.4	0.012
Diastolic blood pressure (mmHg)	80.1±10.5	84.2±10.4	0.038	0.6±11.5	0.4±10.0	0.945
Glucose (mg/dl)	160.8±49.6	173.7±52.7	0.178	-13.4±55.2	16.9±63.6	0.007
HbA1c (%)	8.6±1.2	9.0±1.5	0.087	-0.7±1.1	-0.2±1.7	0.034
Triglyceride (mg/dl)	157.9±97.7	161.8±126.2	0.856	-9.7±67.9	3.6±111.8	0.445

Cholesterol (mg/dl)	183.8±38.1	191.5±39.4	0.290	-5.8±38.9	-0.3±44.7	0.485
HDL-cholesterol (mg/dl)	48.4±10.7	47.8±11.2	0.778	0.6±10.6	0.0±8.1	0.734
LDL-cholesterol (mg/dl)	119.5±32.0	123.5±32.3	0.500	-7.3±35.1	-1.9±37.2	0.430
GPT(U/L)	37.6±27.5	38.8±34.5	0.840	-2.8±18.1	0.0±22.9	0.468
Creatinine(mg/dl)	0.8±0.3	0.8±0.2	0.662	0.0±0.4	0.0±0.2	0.883
Uric acid(mg/dl)	5.5±1.6	5.6±2.1	0.819	0.5±1.3	0.3±1.8	0.451
Hs CRP (mg/dl)	0.5±1.5	0.3±0.3	0.540	-0.1±1.8	-0.1±0.3	0.908

[†] Data are presented as mean + SD or n (%). T-test or χ^2 test (Fisher test was used as n<5) was used to test differences between the intervention and control subjects at baseline. T test was also used to determine the changes in clinical parameters between the two groups after one year intervention. p<0.05 is considered significantly different.

Table 3 - Changes of nutrient intakes in type 2 diabetic patients with baseline HbA1c >7% after receiving 12 month intervention or usual care (control). [†]

Nutrient intakes	Baseline			Changes from baseline to 12 month		
	Intervention (n=56)	Control (n=54)	p	Intervention (n=56)	Control (n=54)	p
Energy (kcal/day)	1899.0±399.8	1877.5±405.3	0.778	-229.06±309.16	56.10±309.41	<0.001
Carbohydrates						
Energy %	54.4±7.9	54.4±8.5	0.999	-0.52±3.60	0.12±3.50	0.345
g /day	256.4±58.8	245.0±45.1	0.250	-31.24±61.53	7.15±54.09	0.001
Protein						
Energy %	14.9±2.8	14.8±3.5	0.786	-0.52±3.60	0.12±3.50	0.345
g /day	70.4±18.3	68.4±24.6	0.622	-10.91±18.85	2.94±18.60	<0.001
Fat						
Energy %	30.6±6.7	30.8±6.9	0.899	0.51±7.92	0.89±7.20	0.793
g /day	64.8±21.0	63.3±22.4	0.712	-7.74±18.36	3.84±19.99	0.002
Monounsaturates (%)	9.7±3.0	10.0±3.7	0.686	0.61±3.91	1.00±3.70	0.596
Polyunsaturates (%)	10.9±3.0	11.0±3.7	0.852	-0.05±4.47	-0.65±4.83	0.500
Saturates (%)	8.7±3.1	7.8±2.9	0.141	-0.98±3.40	0.60±2.93	0.010
Cholesterol (mg/day)	237.3±176.7	234.6±178.9	0.935	-3.59±200.15	14.97±223.45	0.647

[†] Data are presented as mean + SD. T-test was used to test differences between the intervention and control subjects at baseline. T test was also used to determine the changes in nutrient intakes between the two groups after one year intervention. $p<0.05$ is considered significantly different.

Table 4 - Univariate and multivariate regression analysis of factors associated with changes of HbA1c in Intervention subjects with baseline HbA1c > 7% after receiving 12 month intervention (n=56)

	Simple linear regression		**Multiple linear regression**	
	B (SE)	p	B (SE)	p
Age (years)	-0.031 (0.018)	0.096	-0.013 (0.12)	0.304
Gender	-0.252 (0.304)	0.411	-0.367 (0.205)	0.080
Duration of diabetes (years)	-0.016 (0.033)	0.641	0.027 (0.023)	0.232
Baseline BMI	0.104 (0.045)	0.026	0.042 (0.032)	0.200
Baseline HbA1c (%)	-0.606 (0.093)	< 0.001	-0.454 (0.084)	< 0.001
Change in energy intake (100 kcal/day)	0.200 (0.041)	< 0.001	0.045 (0.043)	0.303
Change in Carbohydrate intake (15 g/day)	0.167 (0.029)	< 0.001	0.100 (0.033)	0.004
Change in fat intake (15 g/day)	0.002 (0.124)	0.988	-	-
Change inprotein intake (15 g/day)	0.188 (0.118)	0.117	-	-